

A Review of HIV Home Self-Testing Issues and Implications from a Global Perspective

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BACKGROUND

Introduction: Recent developments with HIV Home-Self-Testing (HST) may influence wider adoption around the world. In particular, in 2012 the Food & Drug Administration (FDA) approved the OraQuick In-Home HIV Test. Such support from the U.S. Government for HIV self-screening has implications for larger HIV testing and counseling (HTC) approaches, globally. In addition, the World Health Organization has published a review of HIV self-testing among health workers, describing the strategy's advantages and disadvantages. Advocates suggest HIV HSTs could be a tool for expanding access for key populations; claiming that individuals at risk for HIV who would not go to a clinic or other sites for HTC, may be interested in self-screening. However, concerns about abuse, accuracy, interpretability, and safety remain.

Objectives: This review aims to provide a synthesis of available literature on HIV HSTs and to characterize the findings of such research studies. Key areas of focus include: HST acceptability, accuracy, and implementation. This information will be used to generate empirical evidence to inform policy/programmatic approaches to HIV HST and identify research gaps.

METHODS

Inclusion & Exclusion Criteria: Articles, abstracts, and gray literature using keyword searches "HIV" AND ("Home test" OR "Self test"), "Self-Testing", and "HIV Home-self-testing" across Google Scholar, Academic Elite, Medline, the USAID Development Experience Clearinghouse (DEC) were included; as well as Blood Products Advisory Committee (BPAC) and FDA documents regarding the approval of the OraQuick In-Home HIV-Test documents, e.g. Orasure Technologies documents, and FDA Summary of Safety & Effectiveness. Bibliographies of articles identified were also reviewed for relevant articles. All identified articles were reviewed in full-text. Home-based collection studies, systematic reviews, editorials, commentaries, and opinion-based articles were all excluded. Studies were required to use primary data and involve one or more of the following topics: acceptability, accuracy, interpretability, population characteristics, and/or research gaps.

Data Collection & Coding: For both qualitative and quantitative studies, study characteristics were described with special attention to study type, study population, and geographic focus. Acceptability studies were further analyzed and divided into areas of key focus using an abstraction tool. Degrees of acceptability were characterized as: high, medium, low, and low-medium.

- **High acceptability:** $\geq 72\%$ of study population
- **Medium acceptability:** 31-71%
- **Low acceptability:** $\leq 30\%$
- **Low-Medium acceptability:** 20-37%

Studies were also analyzed by gender and population. Study populations were described based on the following definitions: exclusively or primarily (defined as $\geq 59\%$ of the sample) male, female, and/or health worker (HW), as well as ($\geq 49\%$) Men who have sex with men (MSM).

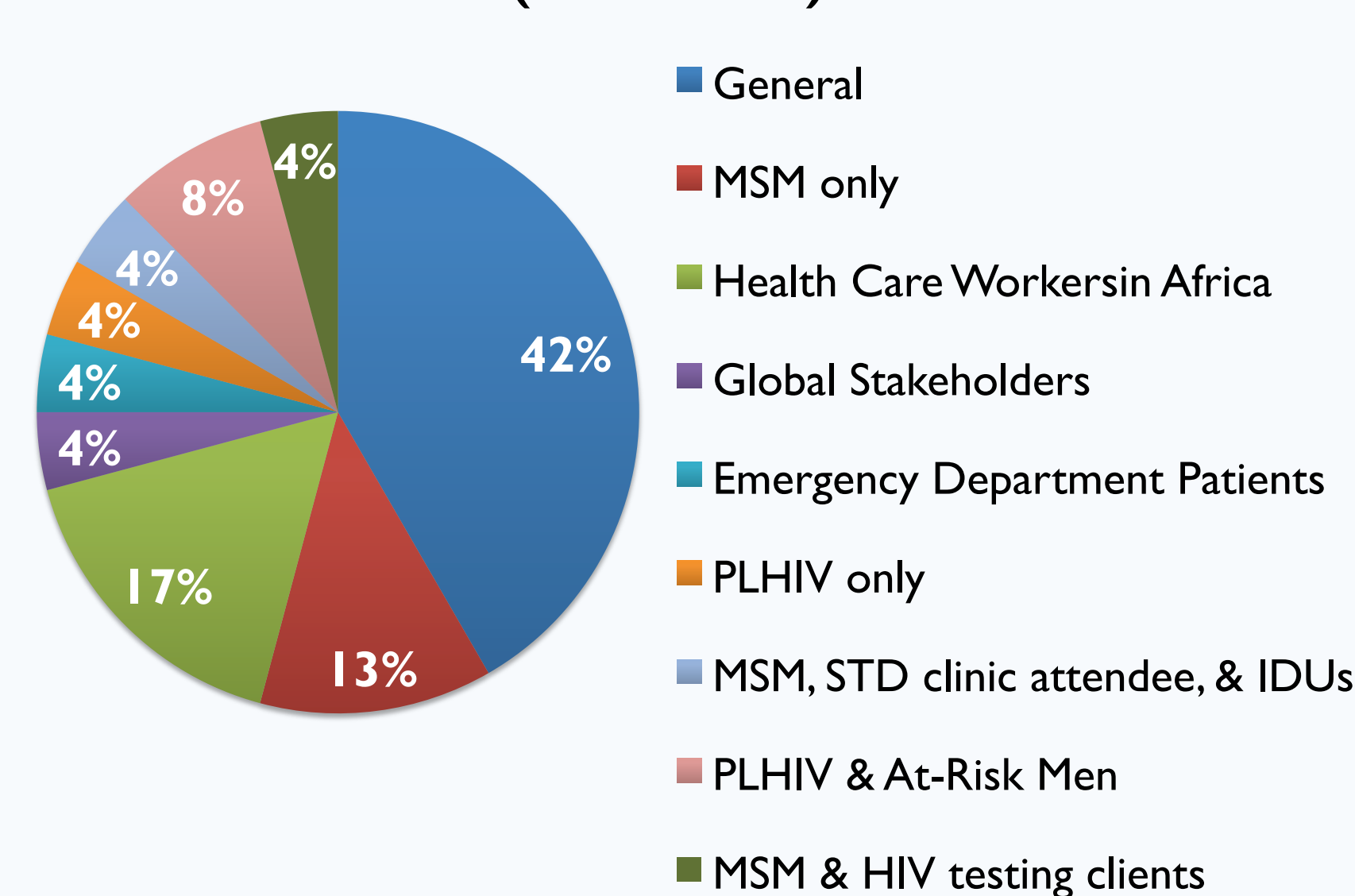
RESULTS

Study Characteristics

Summary

- **24 publications included:** 1 rapid field assessment, 1 clinical trial, 1 labeling study, 1 situational analysis, 12 cross-sectional studies, 6 pilot studies, 1 acceptability/feasibility study, and 1 feasibility study.
- **3/24 studies reported low education and/or low literacy** among $\geq 40\%$ of the study population.
- 19/24 studies reported on acceptability
- 11/24 reported on interpretability & usability
- 7/24 reported on inaccurate results
- 6/24 reported on partner-testing
- 7/24 studies reported on costs users were willing to pay for an HST.

Populations Reflected in Studies (% of studies)



Geographic Focus of Studies



Study Locations: USA (9), Europe (5), Africa (7), & Southeast Asia (3); of which 3/24 were multi-country studies.

Accuracy & Interpretability

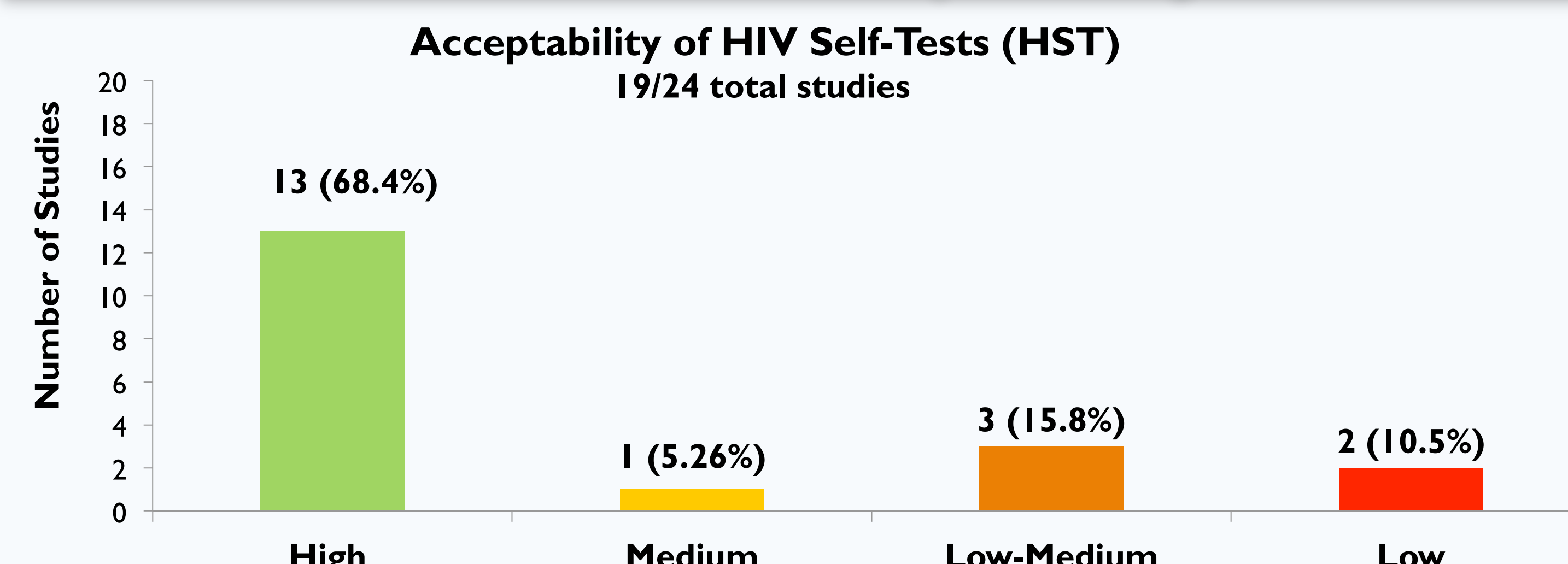
- **14/24 studies involved participants conducting an HIV self-test.**
- **7/14 studies recorded false and inaccurate results.** 5/7 still had high acceptability and 2/7 did not report on acceptability.
 - 6/7 reported invalid test results. All reported at least 1 operational error, 5/7 report at least 1 false result. Additionally, 5/7 of these studies reported high acceptability among users.
- **11/14 reported on HST usability.**
 - 4/11 had 5-12% of participants reported difficulty using an HST. In all 11 studies, $\geq 72\%$ reported that HSTs were easy to use.
 - 8/11 reported high acceptability, 1 reported medium acceptability, and 2 did not report on acceptability.
- **11/14 reported on HST interpretability.**
 - 9/11 reported difficulty interpreting results and/or reading instructions. 8/9 show 0.4 - 9% interpretation errors. 2/11 had no difficulties to report and 9/9 reported that the majority of users found results and/or instructions easy to interpret.
 - 8/11 reported high acceptability, 1 reported medium acceptability, and 2 did not report on acceptability.

Implementation

- **7/14 studies were supervised by counselors/ HWs.** All 7 supervised studies had high acceptability. 2/14 unsupervised studies had high acceptability. 3/14 studies did not have reports on acceptability. 2/14 studies that were unsupervised reported low to low-medium acceptability.
- **13/24 studies reported the type of HIV HST used.** 11/13 were oral-fluid tests, 5/13 were whole-blood tests, 2/13 used both oral-fluid and whole-blood tests. 4 studies compared oral-fluid HSTs to whole-blood HSTs. All 4 of these reported that participants preferred oral-fluid HSTs.
- **9/13 reported high acceptability:** 7/9 were oral-fluid tests, 1/9 used both oral-fluid and whole-blood tests, and 3/9 used whole-blood tests.
- **11/24 reported on whether participants thought counseling was necessary** when using HIV HSTs. 10/11 report that participants think counseling is necessary.
- **6/24 studies reported on internet or telephone hotlines for counseling.** 5/6 report on phone counseling and 1/6 report on internet counseling.
 - 5/5 reported that phone counseling hotlines were underutilized or unacceptable.
 - 2/6 reported that no adverse events or counseling calls were taken, and all calls were regarding test use and/or interpretation.
 - 2/6 reported that although counseling is suggested, phone-counseling is unacceptable. 1/6 reports that only face-to-face counseling is acceptable.
 - 1/6 reported that 68% preferred internet-based counseling over staff counseling.

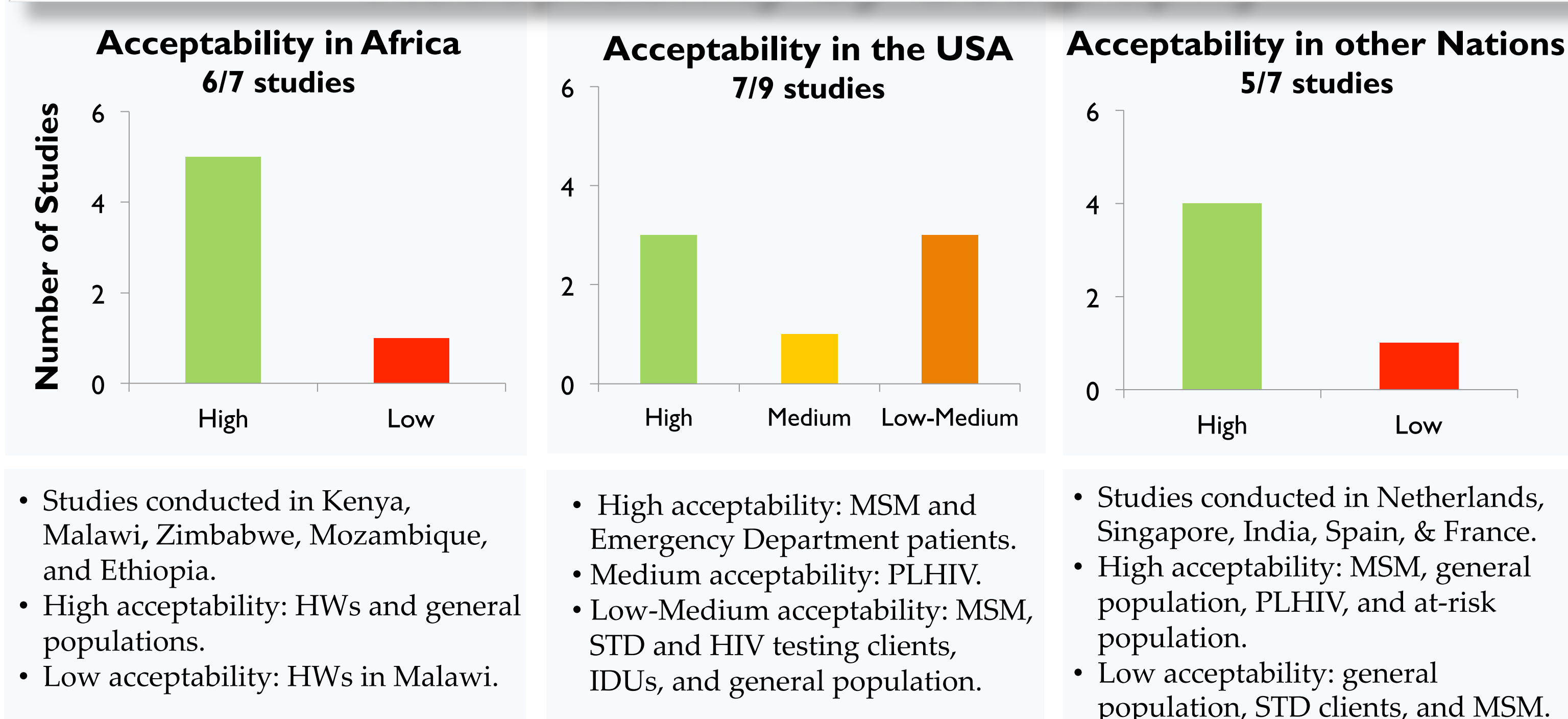
RESULTS

Overall Acceptability



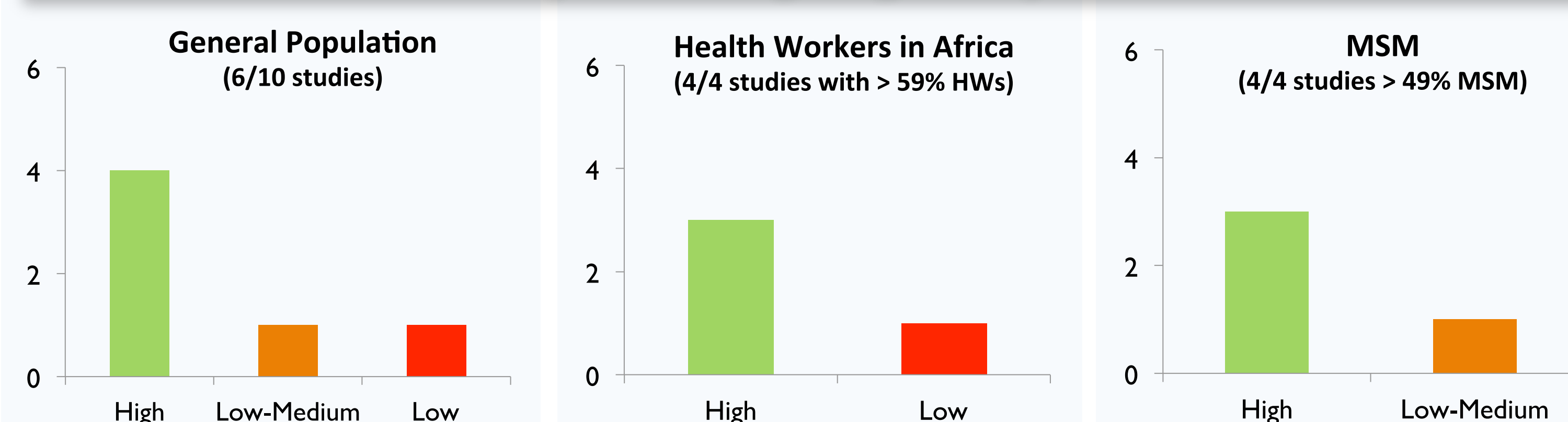
- **19/24 studies measured acceptability.** 5/24 studies did not measure acceptability, but reported accuracy, interpretation, partner testing, information on gaps and characteristics of HST users, and other points of interest.
 - **5/19 studies have unclear and/or multiple acceptability measures.** 3 of these studies reported between 20-37% acceptability (low-medium), and 2 studies reported low acceptability.
 - **3 Low-Medium Acceptability studies:** 1 study among those with high income (37%), 1 study among those never tested for HIV (30%), and 1 study among 20% who did use an HST, but 37% who would "probably" use an HST.
 - **2 Low Acceptability studies:** 11% of Malawi HWs reported having used an HST. And 0.8% of people in Amsterdam (among general population, MSM, and STD clinic attendees) reported having used an HST.
- **6/19 studies measuring acceptability reported that some participants had previously used an HIV HST.** 4/6 had high acceptability and 2/6 had low acceptability.
- **6 studies reported whether participants recommend HSTs to others.** 5/6 studies also reported high acceptability. 1/6 with medium acceptability reported that only 14% of users would recommend HSTs.

Acceptability by Geography



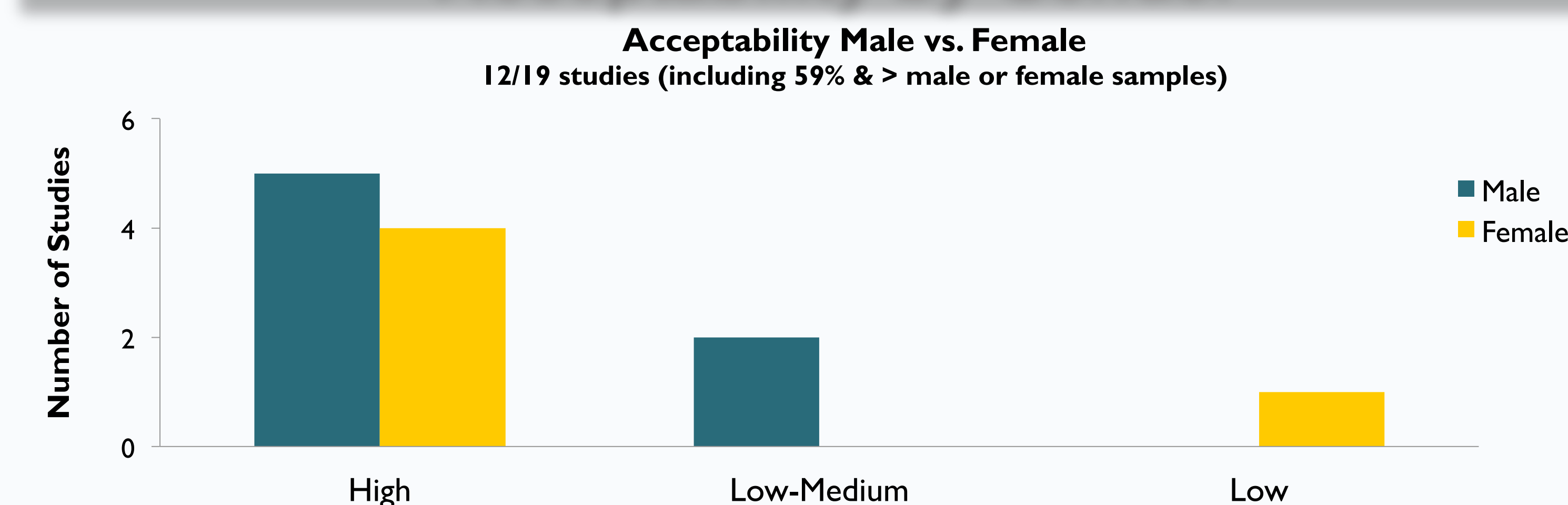
- **Acceptability in Africa (6/7 studies):** High (5), Low (1).
 - Studies conducted in Kenya, Malawi, Zimbabwe, Mozambique, and Ethiopia.
 - High acceptability: HWs and general populations.
 - Low acceptability: HWs in Malawi.
- **Acceptability in the USA (7/9 studies):** High (3), Medium (1), Low-Medium (3).
 - High acceptability: MSM and Emergency Department patients.
 - Medium acceptability: PLHIV.
 - Low-Medium acceptability: MSM, STD and HIV testing clients, IDUs, and general population.
- **Acceptability in other Nations (5/7 studies):** High (4), Low (1).
 - Studies conducted in Netherlands, Singapore, India, Spain, & France.
 - High acceptability: MSM, general population, PLHIV, and at-risk population.
 - Low acceptability: general population, STD clients, and MSM.

Acceptability by Population



- **General Population (6/10 studies):** High (4), Low-Medium (1), Low (1).
 - Studies in Malawi, Spain, India, U.S., Singapore, and Netherlands.
 - High acceptability: 3/4 pilot studies, 1/4 cross-sectional surveys.
 - Low-Medium acceptability: users prefer standard rapid-testing, but 37% would consider using an HST.
 - Low acceptability: General population study which also includes STD clinic clients and MSM (n=5105), acceptability ranges 0.8% - 2.1%.
- **Health Workers in Africa (4/4 studies with >59% HWs):** High (3), Low (1).
 - High acceptability: Range is from 73-89% acceptability; 2/3 studies took place exclusively in Kenya, and 1 multi-country study in Zimbabwe, Kenya, Mozambique, Malawi, and Ethiopia. All report urgency and interest in self-testing.
 - Low acceptability: 11% acceptability in Malawi. Reports fear of self-testing.
- **MSM (4/4 studies >49% MSM):** High (3), Low-Medium (1).
 - Studies in U.S. and France.
 - 3/4 studies report $\leq 10\%$ with low literacy/education.
 - High acceptability: 2/3 used oral-fluid tests, 2/3 in the U.S.
 - Low-Medium acceptability: among MSM and HIV testing clients. 37% of those with high incomes found HSTs acceptable.

Acceptability by Gender



- Studies took place in the U.S., Kenya, Malawi, Zimbabwe, Ethiopia, France, and Singapore.
- No study was among only women. 3/5 studies among $\geq 59\%$ women took place in Africa and among HWs. 1/5 was among U.S. Emergency Department patients.
- 4/5 studies among women reported high acceptability. Low acceptability occurred in 1 study among HWs in Malawi.
- 3/7 studies took place among only men (and all among MSM). High acceptability was found among MSM, PLHIV, & At-risk men (5/7). Low-Medium acceptability was found among MSM, STD clinics & HIV testing clients, & IDUs (2/7).

Acceptability of Partner-Testing / Screening

- **6/24 studies reported some acceptability of partner testing/screening.** 5/6 also reported high acceptability.
- **3/6 took place in Africa; of which 2/3 took place among HWs.**
 - 64% of HWs in Kenya gave a HIV HST to a sex-partner, and 54% discussed test results with their sex-partner.
 - A multi-country study among HWs in Africa reported, in Zimbabwe, that men were open to self-testing with a partner, but women were not.
 - In Malawi, men and women in the general population were interested in HIV HSTs, but men preferred to test alone first.
- **3/6 were among MSM and men; of which 2/3 were in the U.S., and 1/3 was a Western European multi-country study.**
 - 83% of MSM reported they would use a HIV HST as a couple for screening sex-partners.
 - 1 study among MSM reported that during their research, couple's testing occurred at least once, even though this was not apart of their study design.
 - 23% of HST users (58% male & 36% MSM) used an HST with someone else, but not necessarily a sex-partner.

RESULTS

Acceptable Costs

What people were willing to pay for a HIV HST (\$USD)



Country	Number of Studies	Willingness to Pay Range (\$USD)
Kenya	1	\$0.50 - \$0.80
India	1	\$0.80 - \$1.25
Singapore	2	\$7-\$15
USA	3	\$15-\$50

DISCUSSION

- **Despite a range of reported inaccuracies and difficulties with interpreting and using HSTs, overall acceptability was high.** 6/7 studies reported inaccurate results, 4/11 reported difficult usability, and 9/11 reported difficult interpretability. However, most studies still reported high acceptability (5/7 and 8/11). For instance, 1 study reported 90% acceptability, 85% operational errors, and 56% invalid results.
- **8/11 studies reported both high levels of usability and high acceptability.** And 5/9 studies reported both high levels of interpretability and high acceptability. For example, 1 study reported that although it was easier for participants to interpret whole-blood HSTs results, users preferred oral-fluid HSTs which they found easier to perform.
- **High acceptability mostly appeared among MSM (generally in the U.S.), female HWs in Africa, general populations, PLHIV, and at-risk men.**
- **Acceptability of HIV HST differs by regions and population.** Studies in Africa showed high acceptability; in the U.S. there was mixed acceptability.
- **Oral-fluid HIV HSTs appeared to be highly acceptable.** 7/9 studies using only an oral-fluid HST reported high acceptability. 2/9 reported high acceptability for only whole-blood HSTs. Despite some high acceptability of whole-blood HSTs, when compared head-to-head with oral-fluid HSTs, users preferred oral-fluid tests (4/4).
- **Of the studies included, none of the studies which reported low to low-medium acceptability featured participants using HIV HSTs.** In contrast, 10/14 studies with high or medium acceptability involved participants using an actual HIV HST. It is conceivable that the usage of an HST could have influenced acceptability; likewise participants recruited for studies involving actual usage may generally be more open to HSTs than those recruited for other study types.
- **Partner-testing was a topic of interest among MSM and HWs.** 6 studies document the use and/or interest in HSTs among couples, mostly among MSM and HWs. Currently the FDA does not approve the use of the OraQuick In-Home HIV test for screening sex partners. According to Ventuneac et al.'s (2009) mathematical model, partner-testing / sex-partner screening may have a public health benefit for high risk populations in high-prevalence areas.
- **The majority of users reported that they need counseling (10/11).** However, studies which utilized telephone counseling hotlines reported low call-volume, no counseling questions, and no adverse events. Instead, calls dealt with interpretation and procedural questions. Additionally, there was 1 study which reported high levels of acceptability of an internet-based counseling system in India.
- **Cost may have an impact on who and how people use HIV HSTs.** People in the developing world were only willing to pay $< \$2$ USD.
- **Research gaps:**
 - How are results and instructions interpreted by populations?
 - Will HST users link to HIV care with a positive screening test? And what is the likelihood that users will seek confirmatory testing after HST results?
 - Are there psycho-social impacts on HST users? If so, what are they and how can they be best addressed and managed?
- Research is needed to understand acceptability among: MSM in the developing world, women (non-HWs), HWs throughout Africa, IDUs, and key populations.
- Questions remain regarding the accuracy of HST kits in the hands of untrained users, especially among low-literacy and low-education populations.
- There is a need for more information on non-oral-fluid HSTs and their acceptability.
- It is critical to examine multiple modes of counseling which could improve utilization of counseling services by HIV HST users.
- **Limitations:** There is limited research on HIV HSTs and self-screening. There has been only one clinical trial by the FDA, and no randomized control trials to date. All others are primarily observational/descriptive and pilot studies on acceptability. Methodological differences, as well as varying sample sizes, made it difficult to compare studies. This review is not a comprehensive analysis of all aspects of HIV HST use and self-screening.

CONCLUSIONS

- In the U.S., there were equal proportions of studies with low-medium acceptability and high acceptability.
- In Africa, studies found high proportions of acceptability, with only 1 study with low acceptability.
- Studies suggest that HIV HSTs are highly acceptable: specifically among MSM, female HWs in Africa, PLHIV, and at-risk men. Many of the studies reporting high acceptability used oral-fluid tests.
- Oral-fluid HSTs appear to be consistently preferred to whole-blood HSTs by self-screener.
- Studies in which users did not receive or directly perform an HIV HST all report low or low-medium acceptability.
- In the included studies, users provided a wide range of potential prices which they were willing to pay for an HST.
- Despite expressed need for counseling, phone-hotline counseling services are generally underutilized.
- There is limited literature on HIV HSTs. In particular, there is limited information on psycho-social impacts, adverse effects, accuracy issues, usability, and interpretability.
- Key gaps need to be addressed by further research around implementation, accuracy, outcomes, and impact. Additional robust research is needed to inform whether and how HIV self-testing ought to be rolled out on a global scale.