Table 17.1A. GRADE evidence profile on HIV self-testing offered as an additional approach to deliver HIV testing services

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Question: Should HIV self-testing (HIVST) be offered as an additional approach to delivering HIV testing services (HTS)?

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	HIV self-testing	Standard of care	Relative (95% CI)	Absolute		
Uptake of HIV testing (follow-up at up to 6 months) (assessed with: meta-analysis using number randomised as denominators)												
3[1]	randomised trials	serious[2]	no serious inconsistency[3]	no serious indirectness[4]	no serious imprecision	none	777/987 (78.7%)	363/993 (36.6%)	RR 2.12 (1.51 to 2.98)	409 more per 1000 (from 186 more to 724 more)	⊕⊕⊕O MODERATE	CRITICAL
Uptake of HIV testing in male partners of women in antenatal care (follow-up at 3 months) (assessed with: meta-analysis using number of women randomised as denominator)												
2[5]	randomised trials	serious[6]	no serious inconsistency[7]	no serious indirectness	no serious imprecision	none	584/772 (75.6%)	254/778 (32.6%)	RR 2.33 (1.31 to 4.14)	434 more per 1000 (from 101 more to 1000 more)	⊕⊕⊕O MODERATE	CRITICAL
Uptake of HIV testing among men who have sex with men (follow-up at 6 months)												
1[8]	randomised trials	serious[9]	no serious inconsistency[10]	no serious indirectness	no serious imprecision	none[11]	193/215 (89.8%)	109/215 (50.7%)	RR 1.77 (1.54 to 2.04)	390 more per 1000 (from 274 more to 527 more)	⊕⊕⊕O MODERATE	CRITICAL
Uptake of HIV testing among 18 -25 years (follow-up at 6 months)												
1[8]	randomised trials	serious[9]	no serious inconsistency[10]	no serious indirectness	no serious imprecision	reporting bias[12]	67/72 (93.1%)	40/77 (51.9%)	RR 1.79 (1.43 to 2.24)	410 more per 1000 (from 223 more to 644 more)	⊕⊕OO LOW	CRITICAL
Uptake of HIV testing among age 26+ (follow-up at 6 months)												
1[8]	randomised trials	serious[9]	no serious inconsistency[10]	no serious indirectness	no serious imprecision	reporting bias[12]	126/143 (88.1%)	69/138 (50%)	RR 1.76 (1.48 to 2.1)	380 more per 1000 (from 240 more to 550 more)	⊕⊕OO LOW	CRITICAL
Uptake of HIV testing among most recent testers: > 4 tests in past 3 years (follow-up at 6 months)												
1[8]	randomised trials	serious[9]	no serious inconsistency[10]	no serious indirectness	no serious imprecision	reporting bias[12]	23/24 (95.8%)	22/30 (73.3%)	RR 1.31 (1.04 to 1.65)	227 more per 1000 (from 29 more to 477 more)	⊕⊕OO LOW	CRITICAL
Uptake of HIV testing among recent testers: 1 - 3 tests in past 3 years (follow-up at 6 months)												
1[8]	randomised trials	serious[9]	no serious inconsistency[10]	no serious indirectness	no serious imprecision	reporting bias[12]	113/121 (93.4%)	61/114 (53.5%)	RR 1.75 (1.46 to 2.08)	401 more per 1000 (from 246 more to 578 more)	⊕⊕OO LOW	CRITICAL
Uptake of HIV testing among non-recent testers: 0 tests in past 3 years (follow-up at 6 months)												
1[8]	randomised trials	serious[9]	no serious inconsistency[10]	no serious indirectness	no serious imprecision	reporting bias[12]	57/70 (81.4%)	26/71 (36.6%)	RR 2.22 (1.61 to 3.08)	447 more per 1000 (from 223 more to 762 more)	⊕⊕OO LOW	CRITICAL

HIV positivity (assessed with: confirmed HIV-positive diagnosis following HIV testing)												
2[13]	randomised trials	serious[14]	no serious inconsistency	no serious indirectness	very serious[15]	none	12/413 (2.9%)	6/417 (1.4%)	RR 2.02 (0.76 to 5.32)	15 more per 1000 (from 3 fewer to 62 more)	⨁◯◯◯ VERY LOW	CRITICAL
Frequency of HIV testing (range from 12 - 15 months) (Better indicated by higher values)												
2[16]	randomised trials	serious[9]	no serious inconsistency	no serious indirectness	serious[17]	none	275	263	-	MD 2.13 higher (1.59 to 2.66 higher)[18]	⨁◯◯◯ LOW	IMPORTANT
Frequency of HIV testing Risk Ratios (range from 12 - 15 months) (Better indicated by higher values)												
2[16]	randomised trials	serious[9]	no serious inconsistency	no serious indirectness	serious[17]	none	275	263	-	Rate Ratio 1.88 higher (1.17 to 3.01 higher)	⨁◯◯◯ LOW	IMPORTANT
Frequency of HIV testing among recent testers (tested =< 2 years) (follow-up 12 - 15 months; Better indicated by higher values)												
1[19]	randomised trials	serious[9]	no serious inconsistency[11]	no serious indirectness	no serious imprecision[20]	reporting bias[12]	147	140	-	Rate Ratio 2.23 higher (1.93 to 2.58 higher)	⨁◯◯◯ LOW	IMPORTANT
Frequency of HIV testing among non-recent testers (tested > 2 years) (follow-up 12 - 15 months; Better indicated by higher values)												
1[19]	randomised trials	serious[9]	no serious inconsistency[11]	no serious indirectness	serious	reporting bias[12]	30	24	-	Rate Ratio 5.54 higher (3.15 to 9.74 higher)	⨁◯◯◯ VERY LOW	IMPORTANT
STI diagnosis												
1[21]	randomised trials	serious[22]	no serious inconsistency[10]	no serious indirectness	serious[23]	reporting bias[24]	5/116 (4.3%)	12/114 (10.5%)	RR 0.41 (0.15 to 1.13)	62 fewer per 1000 (from 89 fewer to 14 more)	⨁◯◯◯ VERY LOW	IMPORTANT
Condomless sex (follow-up 6 months; assessed with non-concordant condomless anal intercourse)												
1[8]	randomised trials	serious[25]	no serious inconsistency	no serious indirectness	serious[26]	reporting bias[24]	53/215 (24.7%)	37/215 (17.2%)	RR 1.43 (0.98 to 2.08)	74 more per 1000 (from 3 fewer to 186 more)	⨁◯◯◯ VERY LOW	IMPORTANT
Condomless sex (follow-up 9 months; assessed with non-concordant condomless anal intercourse)												
1[21]	randomised trials	serious[25]	no serious inconsistency[10]	no serious indirectness	serious[27]	reporting bias[24]	21/116 (18.1%)	22/114 (19.3%)	RR 0.94 (0.55 to 1.61)	12 fewer per 1000 (from 87 fewer to 118 more)	⨁◯◯◯ VERY LOW	IMPORTANT
Condomless sex (follow-up 15 months; assessed with non-concordant condomless anal intercourse)												
1[21]	randomised trials	serious[25]	no serious inconsistency[10]	no serious indirectness	serious[27]	reporting bias[24]	28/116 (24.1%)	24/114 (21.1%)	RR 1.15 (0.71 to 1.85)	32 more per 1000 (from 61 fewer to 179 more)	⨁◯◯◯ VERY LOW	IMPORTANT
Adverse events												
1[28]	randomised trials	serious[25]	no serious inconsistency[10]	no serious indirectness	very serious[27]	reporting bias[24]	1/297 (0.34%)	1/303 (0.33%)	RR 1.02 (0.06 to 16.24)[29]	0 more per 1000 (from 3 fewer to 50 more)	⨁◯◯◯ VERY LOW	IMPORTANT

[1] Masters et al., 2017: Male partners of women attending antenatal and postpartum care in Kenya; Gichangi et al., 2016: Male partners of women attending antenatal care in Kenya; and Wang et al., 2016: Men who have sex with men in Hong King SAR of the People's Republic of China.

[2] Risk of Bias: We down-graded once. The outcome of HIV testing was based on self-report in two trials and the risk of detection bias cannot be excluded. In Wang 2016 self-report of testing was validated against clinical records.

Performance bias may be operational across trials as neither providers nor participants were blinded.

[3] Inconsistency: We did not downgrade for inconsistency despite a high statistical heterogeneity (Heterogeneity: $Tau^2 = 0.08$; $Chi^2 = 32.88$, df = 2 ($P < 0.00001$); $I^2 = 94\%$). This heterogeneity was driven by the Gichangi trial which we were unable to explain. However the effects were beneficial across all trials and hence we did not downgrade.

[4] Indirectness: We did not down-grade for indirectness but note that two trials (Gichangi and Masters) were conducted as couples testing trials (female participants were given HIVST kits to give to or self-test with their male partners) and Wang which randomized men who have sex with men presenting with no HIV testing in the previous 6 months to HIVST or control.

[5] Masters et al., 2017: Male partners of women attending antenatal and postpartum care in Kenya; Gichangi et al., 2016: Male partners of women attending antenatal care in Kenya.

[6] Risk of Bias: We down-graded once. The outcome of HIV testing was based on self-report in two trials and the risk of detection bias cannot be excluded. Performance bias may be operational across trials as neither providers nor participants were blinded.

[7] Inconsistency: We did not downgrade for inconsistency despite a high statistical heterogeneity ($Chi^2 = 28.16$, df = 1 ($P < 0.00001$); $I^2 = 96\%$ This heterogeneity was driven by the Gichangi trial which we were not able to explain. However the effects were beneficial across all trials and hence we did not downgrade.

[8] Wang et al., 2016: Men who have sex with men in Hong King SAR of the People's Republic of China.

[9] Risk of bias: We down-graded once for risk of bias. The outcome of HIV testing was validated but performance bias cannot be excluded as neither the participants nor the providers could be blinded.

[10] Inconsistency cannot be appraised in a single study.

[11] These results are from a single trial only and generalizability to other settings among men who have sex with men may be limited. However, the beneficial effects are supported by trials in women attending antenatal and postpartum care services (Gichangi and Masters).

[12] These results are from a sub-group of a single trial and should be viewed with caution.

[13] Katz et al., 2015: Men who have sex with men in the United States; Masters et al., 2017: Male partners of women attending antenatal care in Kenya.

[14] Risk of bias: We down-graded once. The HIV diagnosis would be validated but the risk of performance bias cannot be excluded given that providers and participants could not be blinded in either study.

[15] Imprecision: The event rate is very low and the confidence interval is very wide.

[16] Jamil et al., 2015: Men who have sex with men in Australia; and Katz et al., 2015: Men who have sex with men in the United States.

[17] Imprecision: Down-graded once as the confidence interval is wide.

[18] Standard deviations were calculated from the 95% confidence interval provided.

[19] Jamil et al., 2015: Men who have sex with men in Australia.

[20] Imprecision: The confidence interval is not wide, but the results are from a sub-group and should be viewed with caution.

[21] Katz et al., 2015: Men who have sex with men in the United States.

[22] Risk of bias: We downgraded once. The STI diagnosis would be validated but the risk of performance bias cannot be excluded given that providers and participants could not be blinded.

[23] Imprecision: We down-graded once. The event rate is very low in both groups. The estimate crosses both the line of no effect and appreciable benefit.

[24] These results are from a single trial only.

[25] Risk of Bias: We down-graded once. The outcome was by self-report and performance bias could not be excluded due to a lack of blinding.

[26] Imprecision: We down-graded once. The event rate is very low in both groups and the confidence interval is wide.

[27] Imprecision: We down-graded once. The event rate is very low in both groups.

[28] Masters et al., 2017: Women attending antenatal and postpartum care in Kenya.

[29] The adverse event in the HIVST arm was not actually related to HIVST per se. A participant in the intervention arm reported experiencing verbal/physical abuse from her husband because she agreed to participate in the study without consulting him. She left the home for a period of about three weeks, after which she returned home. When a Research Assistant communicated with the participant at a two-month follow-up, the participant reported that all was well between her and her husband. One participant from the control arm also reported (IPV. Neither participant experienced IPV in the 12 months prior to the intervention. (Additional data provided by authors via email.)