

Table S1. EXPLORE and VAX 004 Questions Used for the MSM Condom Effectiveness Analysis

Explore		VAX 004	
Question #	Question wording	Question #	Question wording
D2	“How many of your male partners were HIV-positive?”	1	“In the last 6 months or since your last visit, how many male partners have you had?”
		1a	“Of these male sex partners, how many do you know were HIV-positive?”
D7	“How many times did you have anal sex with this / these partner(s) when his / their penis was in your rectum? This would be with or without a condom and whether or not he / they ejaculated.”	3	“How many times did you have anal sex with this / these partners when his / their penis was in your rectum? This would be with or without a condom and whether or not he / they ejaculated.”
D7a	“How many of these times did your partner(s) use a male condom or did you use an anal condom (Reality® condom)?”	3a	“How many of these times were with a condom? Do not include episodes in which a condom broke or slipped off, or if a condom wasn’t used for the entire episode.”
D7a1	“How many of these times did a condom slip off, tear, break, or otherwise fail?”.		
D8	“How many times did you have anal sex with your HIV-positive partner(s) when your penis was in his / their rectum? This would be with or without a condom and whether or not you ejaculated.”	4	“How many times did you have anal sex with this / these partners when your penis was in his / their rectum? This would be with or without a condom and whether or not you ejaculated.”
D8a	“How many of these times did you use a male condom or did your partner(s) use an anal condom (Reality® condom)?”	4a	“How many of these times were with a condom? Do not include episodes in which a condom broke or slipped off, or if a condom wasn’t used for the entire episode.”
D8a1	“How many of these times did a condom slip off, tear, break, or otherwise fail?”.		

Table S2. The univariate estimated effectiveness and corresponding 95% confidence interval (CI) using an interval censored time to event model for EXPLORE, VAX 004, and the combined EXPLORE and VAX 004 analyses (combined analysis includes study in the model).

Analysis	EXPLORE		VAX 004		Combined EXPLORE and VAX 004*	
	Effectiveness (95% CI)	P-value	Effectiveness (95% CI)	P-value	Effectiveness (95% CI)	P-value
Receptive						
Always versus Never	86.6 (73.0, 93.4)	<0.0001	63.4 (44.7, 75.8)	<0.0001	72.2 (60.7, 80.4)	<0.0001
Always versus Sometimes	81.8 (62.4, 91.2)	<0.0001	65.6 (46.7, 77.8)	<0.0001	70.5 (57.5, 79.5)	<0.0001
Sometimes versus Never	26.6 (-29.9, 58.5)	0.29	-6.2 (-67.2, 32.5)	0.79	5.9 (-34.4, 34.1)	0.74
Insertive						
Always versus Never	77.5 (51.1, 89.6)	0.0002	54.7 (30.8, 70.3)	0.0002	61.7 (44.7, 73.5)	<0.0001
Always versus Sometimes	78.7 (53.7, 90.2)	<0.0001	57.7 (33.3, 73.2)	0.0002	64.7 (48.1, 75.9)	<0.0001
Sometimes versus Never	-5.8 (-91.1, 41.5)	0.85	-7.2 (-66.0, 30.7)	0.75	-8.3 (-53.9, 23.8)	0.66
Receptive + Insertive						
Always versus Never	85.8 (71.0, 93.1)	<0.0001	59.4 (38.9, 73.0)	<0.0001	69.7 (57.1, 78.6)	<0.0001
Always versus Sometimes	80.8 (60.9, 90.6)	<0.0001	62.9 (45.6, 74.7)	<0.0001	68.3 (55.7, 77.3)	<0.0001
Sometimes versus Never	26.2 (-22.1, 55.4)	0.24	-9.5 (-60.1, 25.1)	0.64	4.4 (-29.4, 29.4)	0.77

Figure S1. VAX 004 cohort participants analyzed using study data for receptive, insertive, and combined anal intercourse

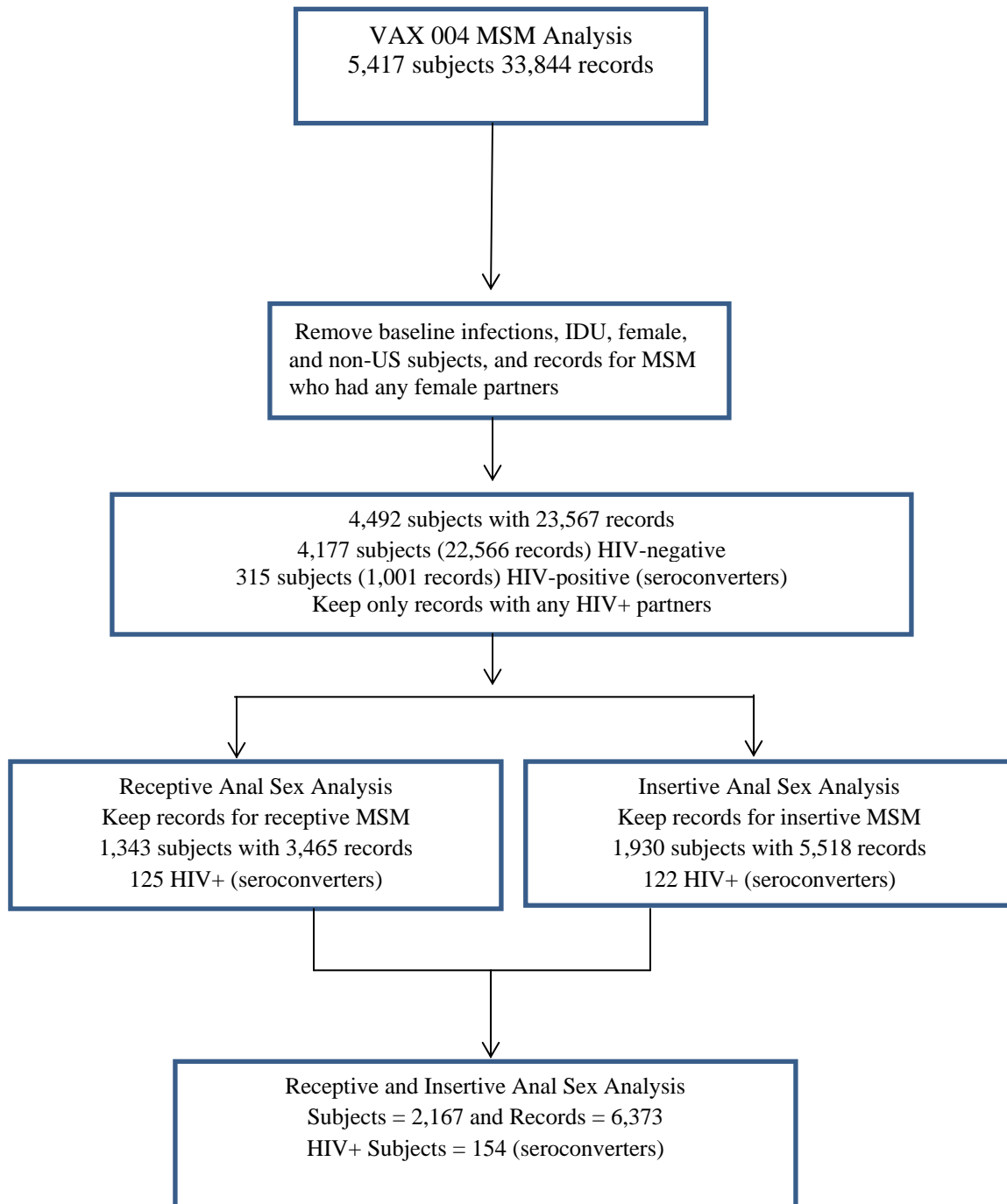


Figure S2. EXPLORE cohort participants analyzed using study data for receptive, insertive, and combined anal intercourse

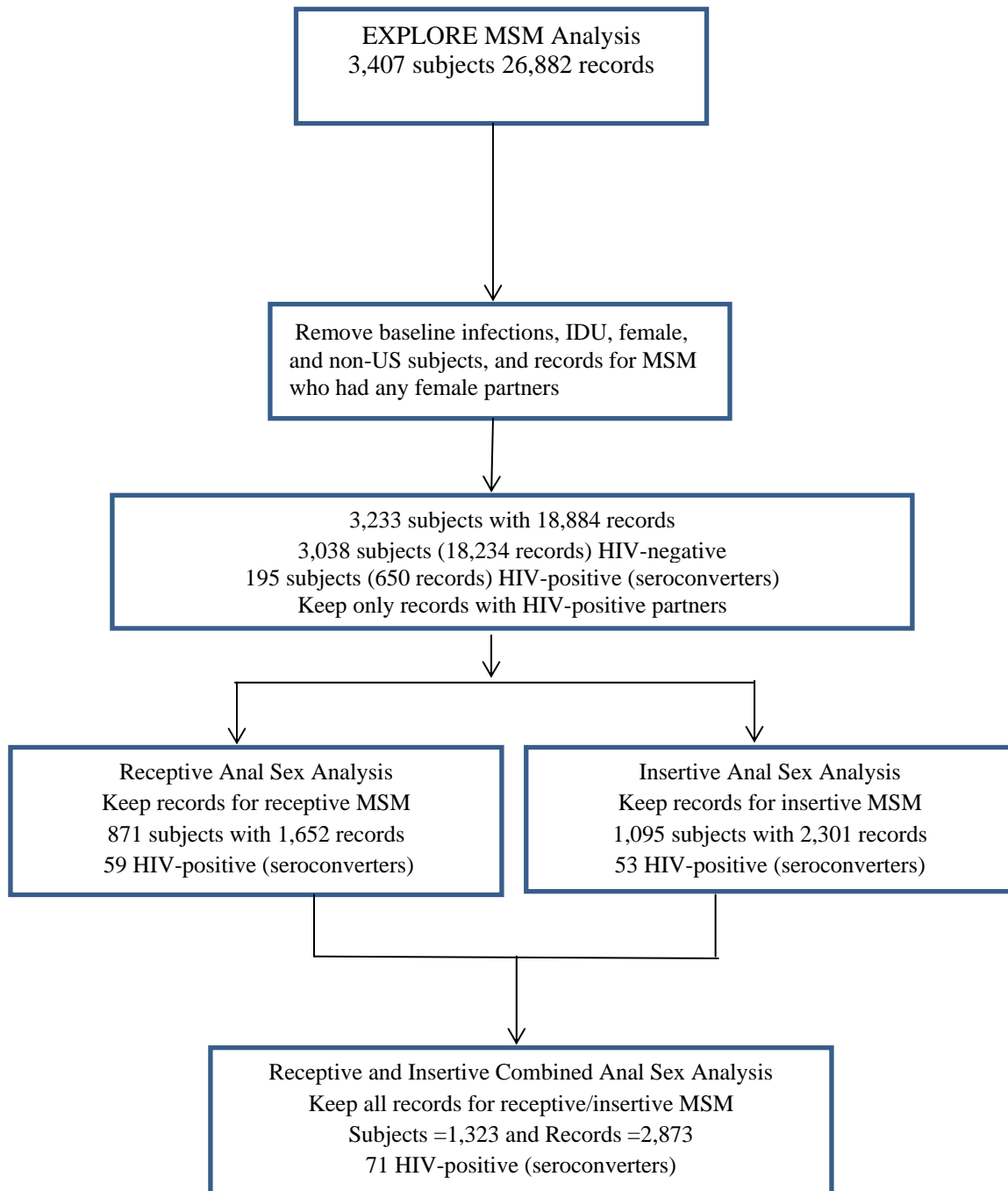


Figure S3. Combined EXPLORE and VAX 004 cohort participants analyzed using study data for receptive, insertive, and combined anal intercourse

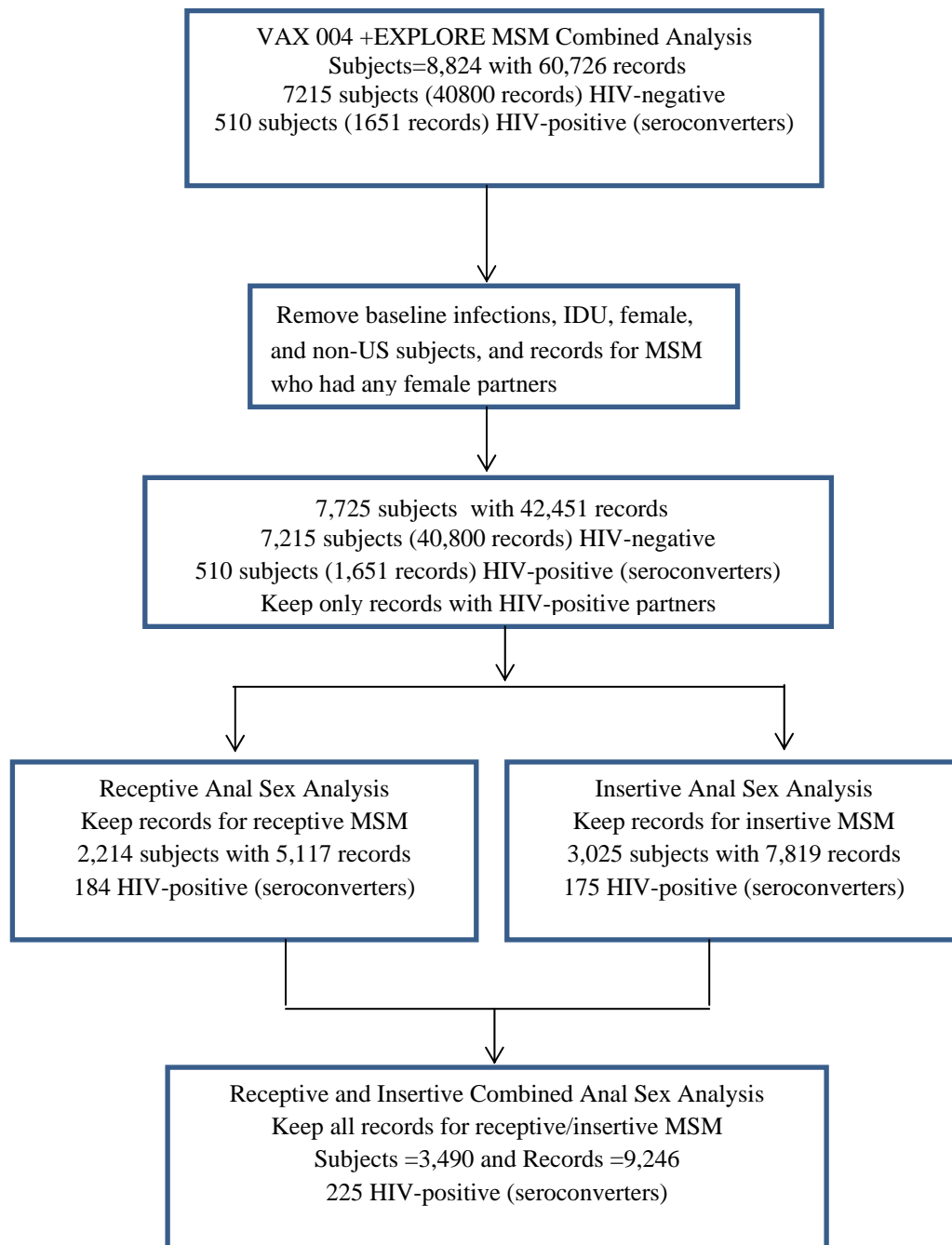


Table S3. The probability of HIV seroconversion per sex act by HIV partner status and condom risk group for the EXPLORE and VAX 004

Subjects having Sex with HIV-positive Partners					
Condom Risk Group	HIV+ ¹	HIV- ²	Sex events ³ Receptive and Insertive	Risk per sex act ⁴	95% Confidence Interval
EXPLORE					
Never	30	593	8638	0.0035	0.0024, 0.0050
Sometimes	31	805	20646	0.0015	0.0011, 0.0021
Always	10	1404	13777	0.00073	0.00039, 0.0013
Total	71	2802	43061	0.0016	0.0013, 0.0021
VAX 004					
Never	47	1355	25754	0.0018	0.0014, 0.0024
Sometimes	62	1630	55769	0.0011	0.00087, 0.0014
Always	45	3234	44717	0.0010	0.00075, 0.0013
Total	154	6219	126240	0.0012	0.0010, 0.0014
Subjects having Sex with HIV-negative Partners					
EXPLORE					
Never	6	1730	68103	0.000088	0.000040, 0.00020
Sometimes	15	1979	61066	0.00025	0.00015, 0.00041
Always	12	1840	21485	0.00056	0.00032, 0.00098
Total	33	5549	150654	0.00022	0.00016, 0.00031
VAX 004					
Never	11	2211	79387	0.00014	0.000077, 0.00025
Sometimes	31	1858	55430	0.00056	0.00039, 0.00080
Always	22	2668	38107	0.00058	0.00038, 0.00088

SUPPLEMENTAL DIGITAL CONTENT

Total	64	6737	172924	0.00037	0.00029, 0.00047
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Subjects having Sex with HIV-Unknown Status Partners

EXPLORE

Never	3	281	3508	0.00086	0.00028, 0.0026
Sometimes	17	1009	1678	0.0010	0.00063, 0.0016
Always	5	1163	8066	0.00062	0.00025, 0.0015
Total	25	2453	28342	0.00088	0.00060, 0.0013

VAX 004

Never	4	637	7758	0.00052	0.00019, 0.0014
Sometimes	24	1132	20455	0.0012	0.00079, 0.0017
Always	9	1689	13189	0.00068	0.00036, 0.0013
Total	37	3458	41402	0.00089	0.00065, 0.0012

¹ HIV+ is the number of subjects that seroconverted during an interval.

² HIV- is the total number of subjects per interval per condom use group that did not seroconvert during an interval.

³ Sex events is the total number of sex acts for all subjects for the entire study period.

⁴ Risk /sex act is the probability of HIV seroconversion per sex event.

Table S4. The per sex act estimated effectiveness by level of reported condom use and 95% confidence interval (CI) for the EXPLORE, VAX 004, and combined analyses.

Analysis	EXPLORE		VAX 004		Combined EXPLORE / VAX 004	
	Effectiveness (95% CI)	P-value	Effectiveness (95% CI)	P-value	Effectiveness (95% CI)	P-value
Receptive Anal Sex						
Always versus Never Condom use	86.8 (73.4, 93.5)	<0.0001	46.2 (18.8, 64.3)	0.0032	62.6 (47.2, 73.6)	<0.0001
Insertive Anal Sex						
Always versus Never Condom use	58.9 (10.7, 81.1)	0.025	34.3 (-0.2, 56.9)	0.051	41.6 (15.7, 59.5)	0.0041
Receptive and Insertive Anal Sex						
Always versus Never Condom use	79.1 (57.3, 89.8)	<0.0001	44.9 (17.0, 63.3)	0.0043	58.0 (40.7, 70.3)	<0.0001

Figure S4. Condom use percentage for subjects having HIV-negative partners by interval for EXPLORE and VAX 004.

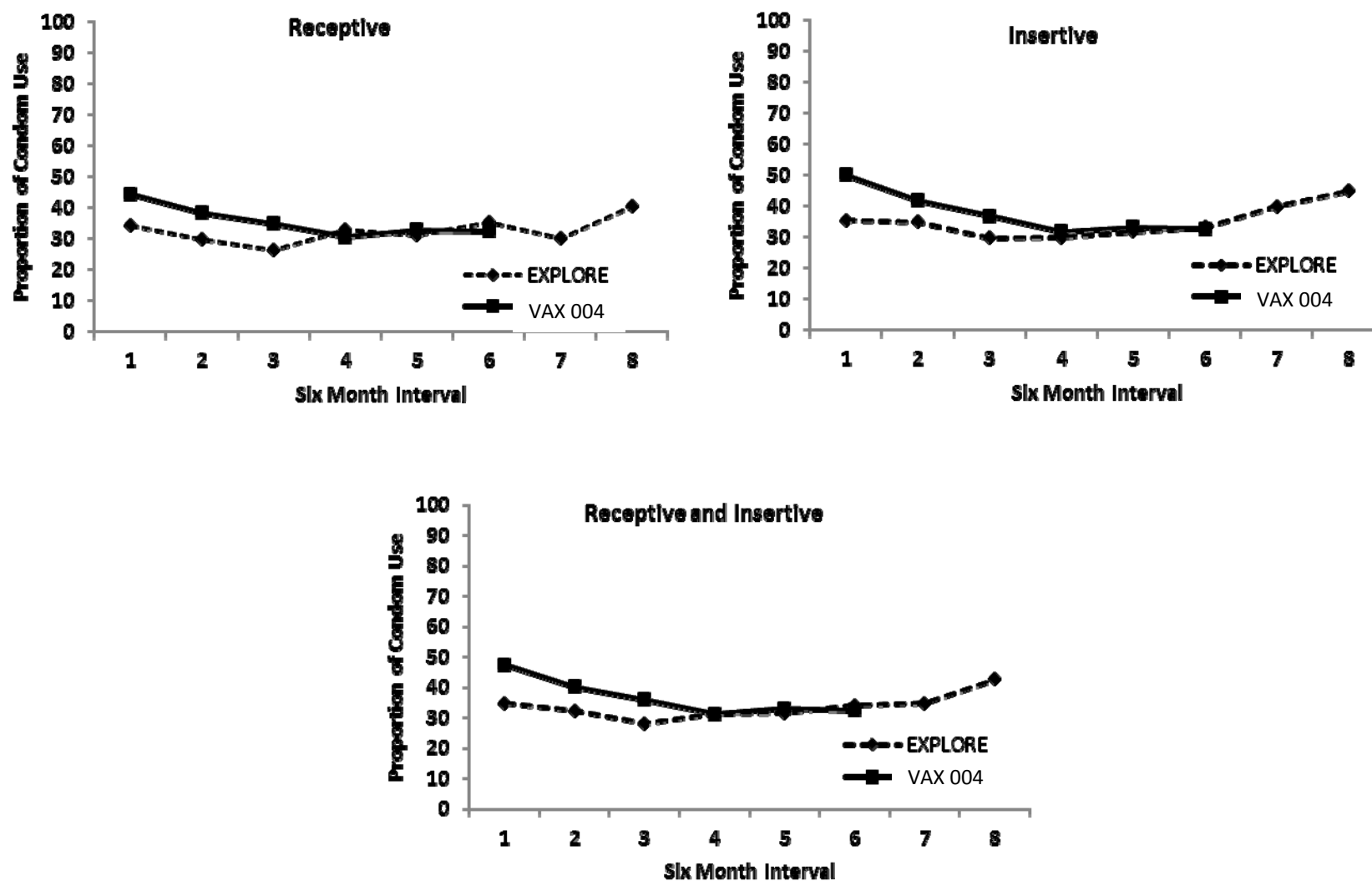


Figure S5. Condom use percentage for subjects having HIV-unknown status partners by interval for EXPLORE and VAX 004

