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Continued high levels of condomless sex in serodifferent couples when the positive partner is on antiretroviral therapy: the PARTNER study

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for the PARTNER Study Group

Background

- It is consistently reported that a proportion of people with diagnosed HIV do not always use a condom when having sexual intercourse with partners of negative or unknown HIV status
- There are likely to be many reasons for this, and these reasons may have changed over time
- Increasingly, one reason for not using condoms may be due to being on ART with the viral load < 50 copies/mL

Background

- The results from the HPTN 052 trial increased the focus on potential use of ART for prevention of HIV transmission
- However, condom use also effectively prevents HIV transmission and studies in heterosexual serodifferent couples with viral suppression have so far only reported follow-up data for 330 couple-years when condoms were not being used
- Data are even more limited for anal sex in men who have sex with men

Design and Methods

- The PARTNER study (Partners of people on ART: a New Evaluation of the Risks) is an NIHR funded, observational multi-centre study, taking place in 75 European sites from 2010 to 2014 (Phase 1) and 2014-2017 (Phase 2)

Design and Methods

- PARTNER recruits serodifferent partnerships (+ve partner on ART) who had condomless (CL) penetrative sex in the past 4 weeks in order to study:
 - (i) the risk of HIV transmission to partners, in partnerships that do not use condoms consistently and the HIV positive partner is on therapy with a viral load < 50 copies/mL
 - (ii) why some partnerships do not use condoms, the proportion who begin to adopt consistent condom use, and factors associated with this
- Study procedures: 4-6 monthly self completed confidential risk behaviour questionnaire and collection of clinical data including HIV results

Comparison of results generated by HPTN 052, and projected for PARTNER phase 1 and 2

	HPTN 052	PARTNER Phase 1 (by March 2014)	PARTNER Phase 2 (by March 2017)
Number serodiscordant couples	1763	App 1350	App. 1780
Number MSM couples	37	App. 500	App .950
Condom-less sex	96% reported regular condom use	Only couples reporting condomless sex included in final analyses	Only couples reporting condomless anal sex included in final analyses
PYFU eligible	1145 *	1753*	3124*
PYFU of condomless sex	Estimated <200 PYFU	1753*	3124*
MSM/Anal sex	2%	48%	100%
PYFU couples who have anal sex	< 50	879	2250
upper 95% confidence limit for risk of transmission – overall	1/54 couple years**	1/474 couple years **	1/847 couple years**
upper 95% confidence limit for risk of transmission – anal sex	Unknown	1/238 couple years anal sex**	1/610 couple years anal sex**
upper 95% confidence limit for risk of transmission – receptive anal sex with ejaculation	Unknown	1/76 couple years **	1/196 couple years **

* Eligibility criteria: HIV negative reporting condom-less sex; HIV+ VL<200

** These numbers will be lower if one or more linked transmissions are observed



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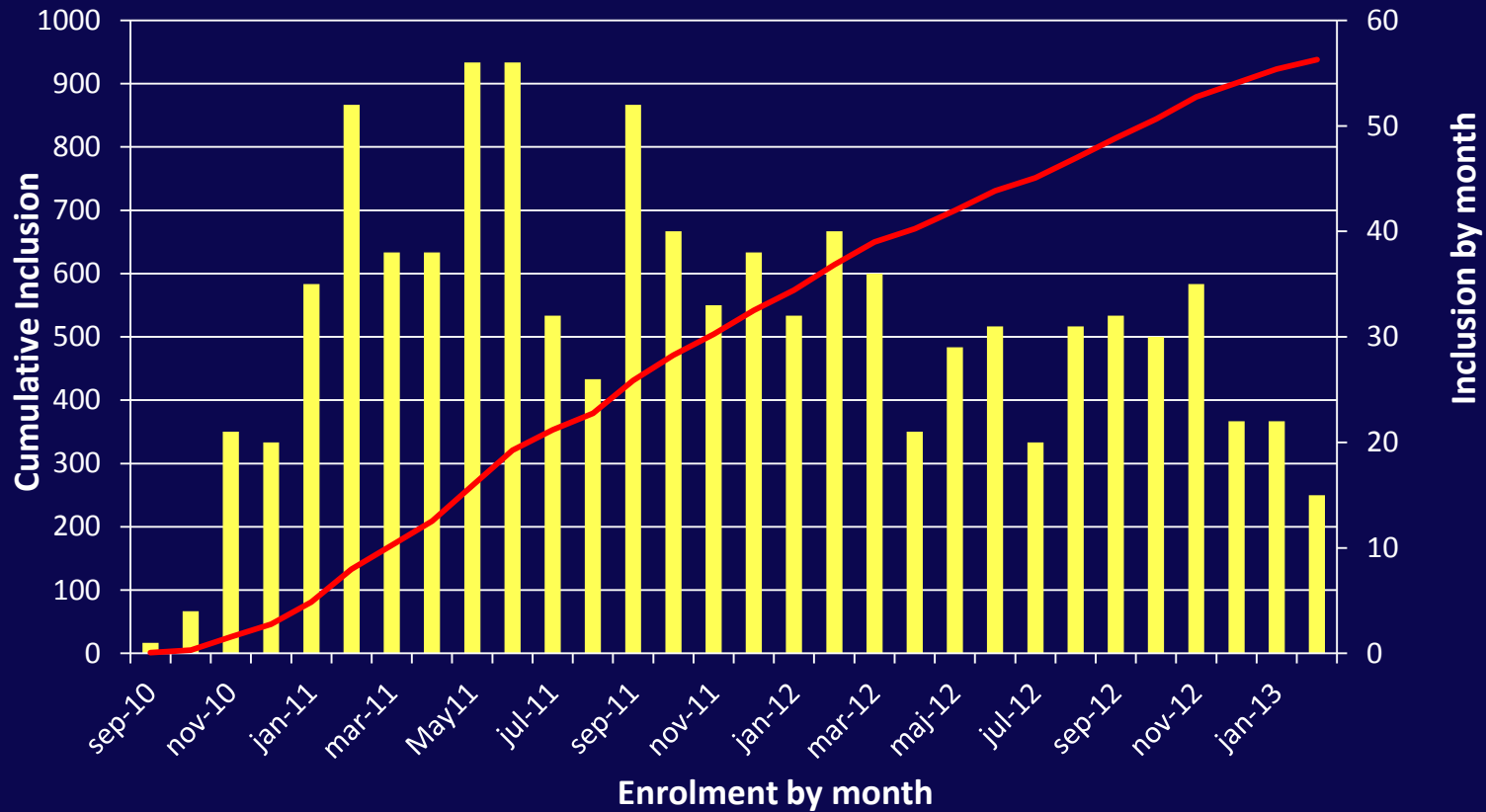
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Design and Methods

- Informed consent for the PARTNER study included information on the need for consistent condom use. The informed consent for HIV –ve partner includes explicit reference to the fact that their partner has HIV and there is a transmission risk, particularly with condomless sex
- Consent also obtained to provide a blood sample in the event of a transmission for delinked anonymous phylogenetic analysis
- We report here baseline and longitudinal data in frequency and characteristics of condomless sex and reasons for not using condoms in the context of study counselling on condom use and after the HPTN 052 study

Results: Enrolment by month from Sep 2010 to Mar 2013



- 958 couples (601 HS and 357 MSM) recruited by 03/04/2013 - 1179 PYFU



Socio-demographic data and risk behaviours

	Heterosexual couples (n=601)				MSM couples (n=357)	
	M HIV +ve (n=296)	F HIV +ve (n=305)	M HIV -ve (n=305)	F HIV -ve (n=296)	HIV +ve (n=357)	HIV -ve (n=357)
Age, median years (IQR)*	45 (39-49)	43 (34-45)	44 (32-54)	43 (34-46)	42 (35-46)	40 (32-46)
Ethnicity (%)*						
White	83%	61%	82%	82%	91%	88%
Black	8%	25%	15%	6%	1%	2%
Other	8%	14%	3%	12%	8%	11%
University Education*	19%	29%	34%	27%	44%	29%
Years CL sex partner, median (IQR)*	3.3 (0.8, 11.0)	3.0 (0.8,8.0)	3.0 (0.6, 7.4)	3.4 (0.8, 10.5)	1.7 (0.5, 4.1)	1.5 (0.5,3.6)
Use PEP past 4/12, HIV-ve (%)*	-	-	2.2%	2.8%	-	4.9%
IVDU past 4/12 (%)	2.0%	1.4%	0.7%	1.1%	3%	1.8%
Diagnosed with STI past 4/12 (%)*	3.3%	4.6%	1.8%	4%	12.9%	10.2%

*P<0.001



HIV acquisition route, adherence and VL knowledge

	HIV+ heterosexual M (n=296)	HIV+ heterosexual W (n=305)	HIV+ MSM (n=357)	p-value
HIV Acquisition route				
Heterosexual Sex	37.2%	69.7%	0%	<0.001
Homosexual Sex	7.1%	0.4%	96.6%	
IVDU	30.8%	5.4%	0%	
Other	24.9%	24.5%	3.4%	
Years on ART, median (IQR)	9.7 (4.1-14.9)	7.5 (3.4-13.5)	5.6 (2.0-11.7)	<0.001
Self-reported adherence >=90%	92.2%	93.5%	95.6%	0.228
Missed ART for >4 cons days	5.5%	5.3%	3.1%	0.284
Informed partner if missed ART	50.6%	46.6%	38.9%	0.003
Thought had undetectable VL	84.5%	86.7%	91.8%	0.021
Undetectable VL (<50 copies)	92.6%	94.8%	93.5%	0.876
CD4 count >350 mm³	83.1%	87.9%	88.7%	0.084

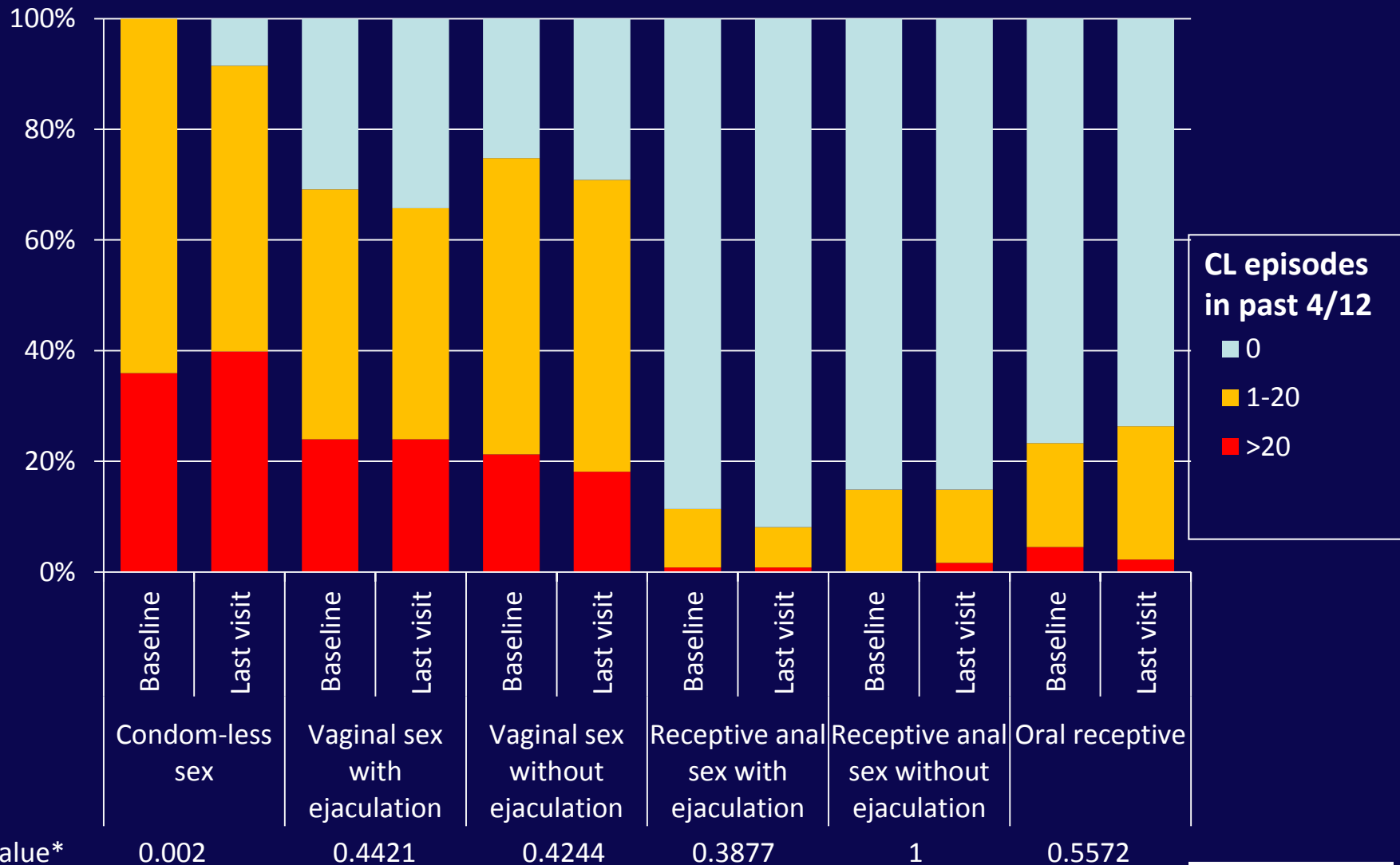
Episodes of condomless penetrative sex within the couples over previous 4 month period at baseline

		Heterosexual couples (n=601)								MSM couples (n=357)			
		HIV+				HIV-				HIV+		HIV-	
		M		W		M		W					
		n	%	n	%	n	%	n	%	n	%	n	%
Condom-less (CL) sex episodes in past 4/12	None	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	1	17	6.4%	23	8.2%	19	6.7%	18	6.7%	22	6.8%	18	5.6%
	2-10	91	34.1%	102	36.4%	102	35.9%	100	37.0%	99	30.7%	101	31.2%
	10-20	66	24.7%	54	19.3%	58	20.4%	59	21.9%	63	19.5%	54	16.7%
	21-40	36	13.5%	43	15.4%	48	16.9%	35	13.0%	68	21.1%	75	23.1%
	>40	56	21.0%	58	20.7%	57	20.1%	58	21.5%	70	21.7%	76	23.5%

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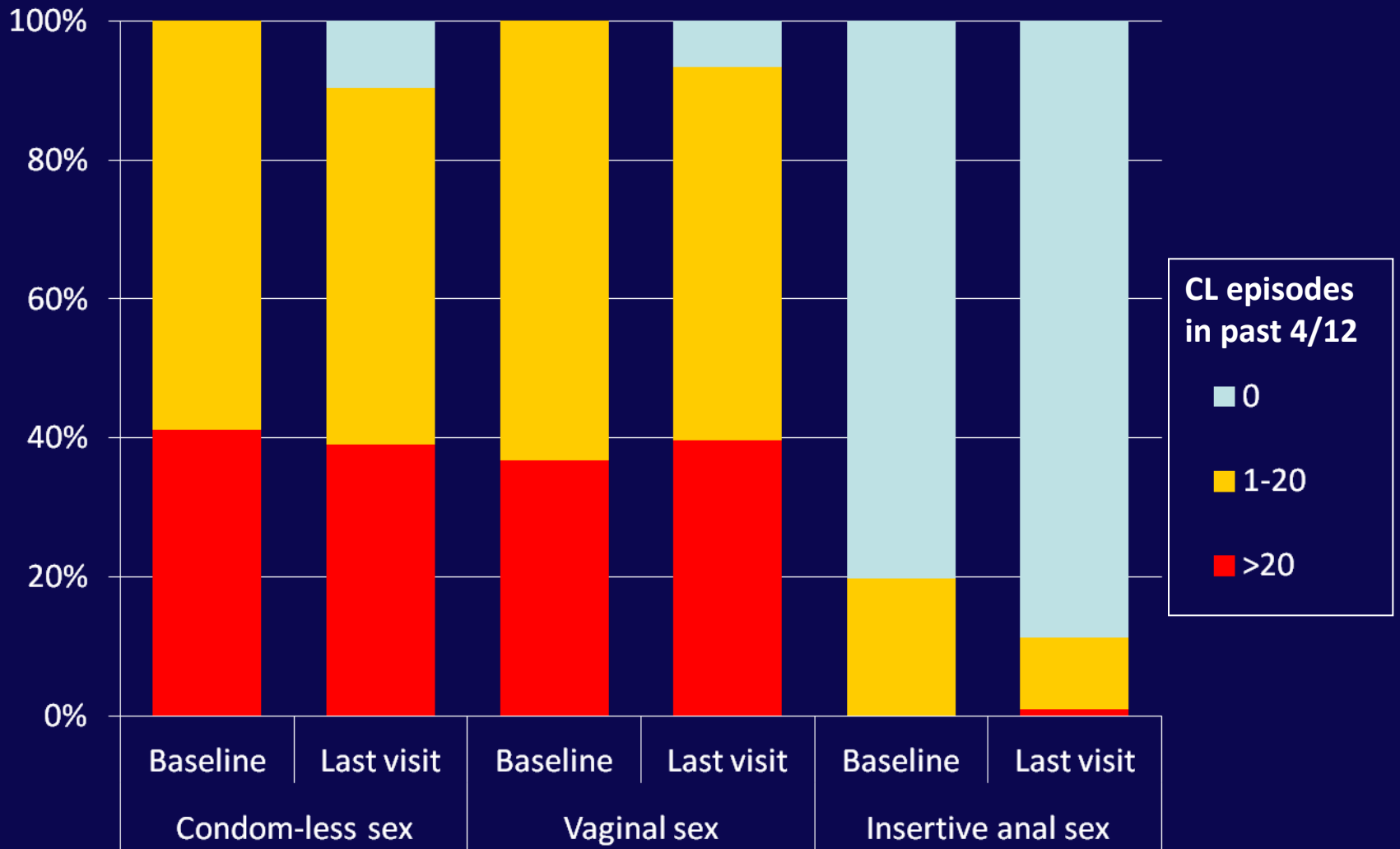
		Heterosexual couples (n=601)								MSM couples (n=357)			
		HIV+				HIV-				HIV+		HIV-	
		M		W		M		W					
		n	%	n	%	n	%	n	%	n	%	n	%
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Sexual behaviour and condom use at baseline and latest follow up: heterosexual couples (M+/W-)



*Mc Nemar's test

Sexual behaviour and condom use at baseline and latest follow up: heterosexual couples (W+/M-)



P-value*

0.001

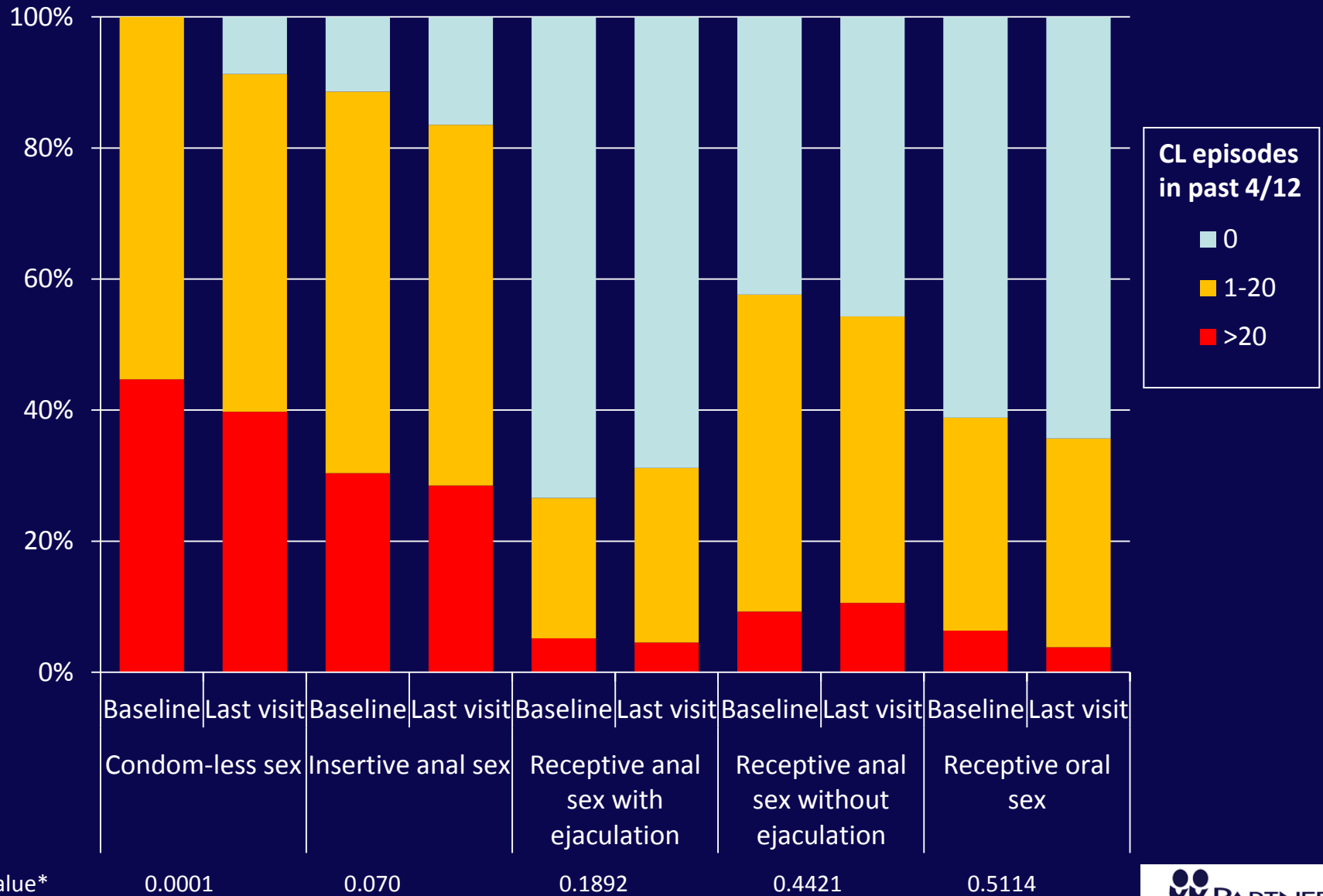
0.004

0.069

*Mc Nemar's test



Sexual risk behaviour and condom use at baseline and latest follow up: MSM



P-value*

0.0001

0.070

0.1892

0.4421

0.5114

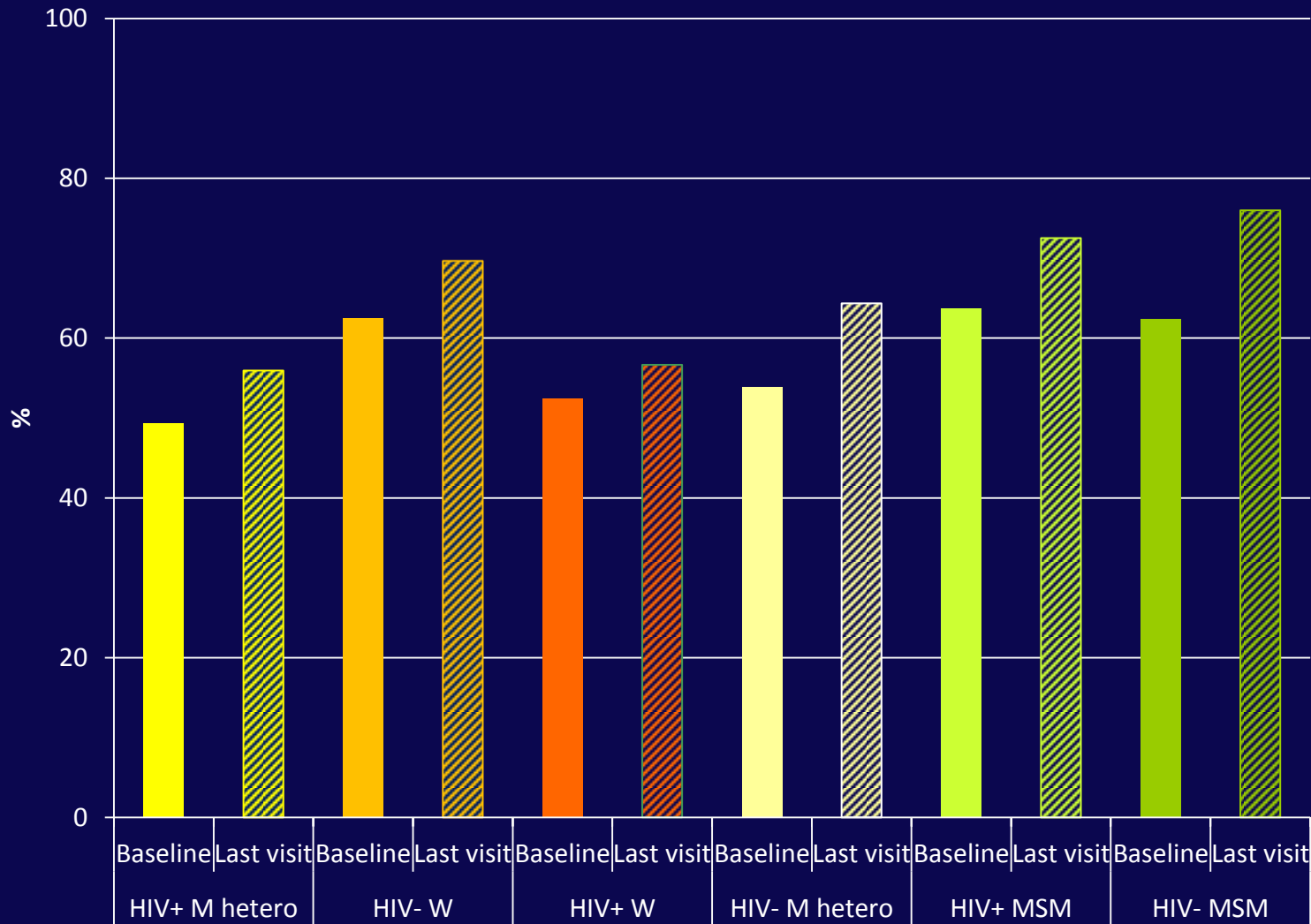
*Mc Nemar's test



Reasons given for not using condoms at baseline

		The risk of HIV transmission is low	Sex more enjoyable without a condom	Currently trying for a pregnancy	Difficulty maintaining an erection	Partner did not want to use a condom
HS	M HIV+	49%	43%	18%	17%	10%
	W HIV-	62%	44%	11%	-	6%
	W HIV+	52%	36%	25%	-	32%
	M HIV-	54%	44%	22%	13%	3%
MSM	HIV+	64%	62%	-	19%	30%
	HIV-	62%	56%	-	19%	6%

Reported reason for not using a condom was 'the risk of HIV transmission is very low' at baseline and follow up



P-value

0.16

0.22

0.36

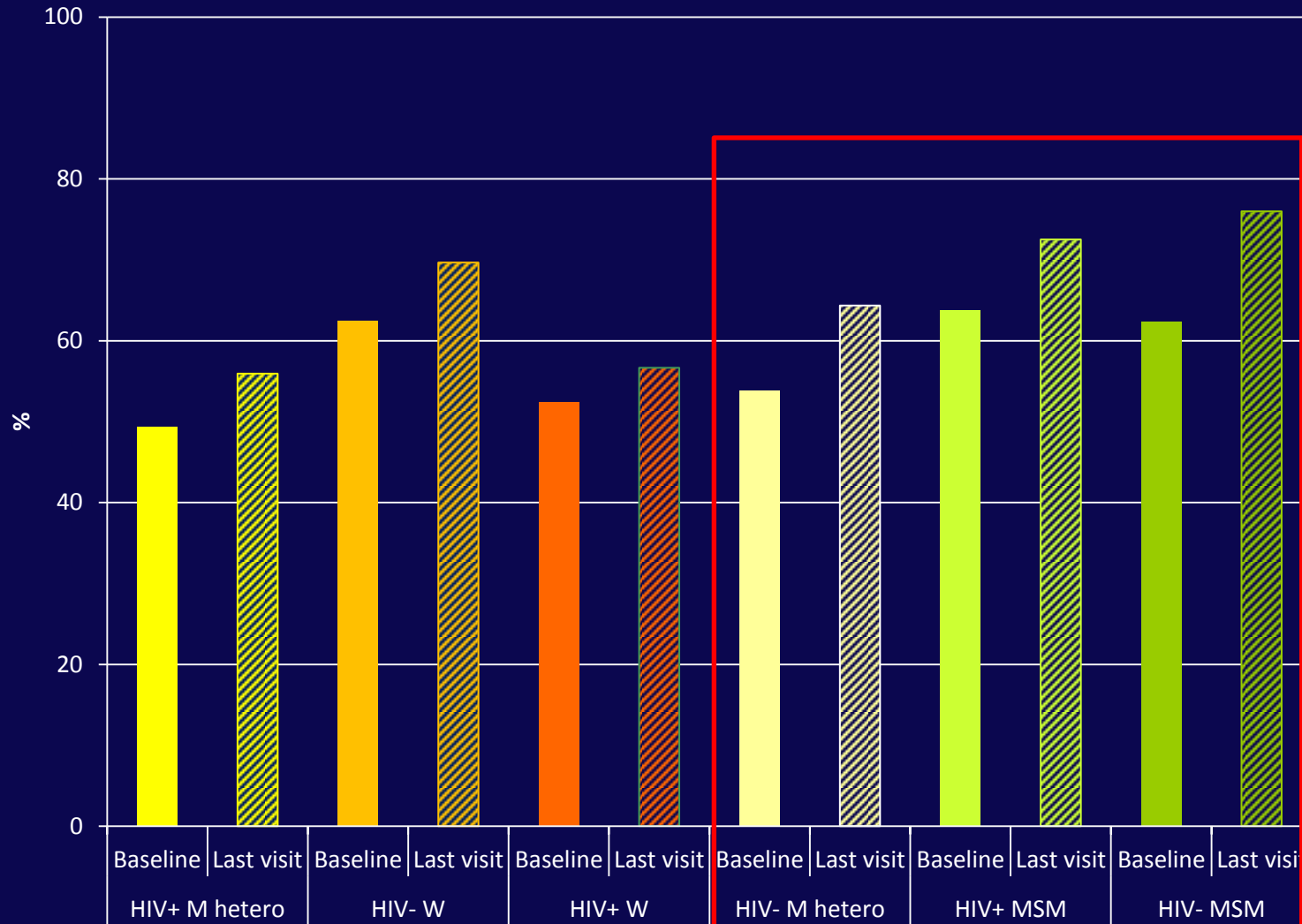
0.02

0.02

0.0002



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P-value

0.16

0.22

0.36

0.02

0.02

0.0002



Conclusions

- There was minimal change in sexual behaviours during follow up despite in-study counselling in couples with a history of condom-less sex
- In MSM we found the HIV positive partner was more likely to be anal receptive and, if insertive avoided ejaculation
- A significant proportion of heterosexual HIV positive men had anal sex with ejaculation with their HIV negative female partners

Conclusions

- In all groups the commonest reason not to use condoms, at both baseline and during follow up, is due to a belief that they are unnecessary as the risk of HIV transmission is low
- Results from the HPTN 052 trial and publicity about the potential role of ART in prevention, are likely to increase this belief
- Accurately defining the actual risks for condomless sex, both anal and vaginal, with the use of ART will be critical to defining the safety or risk of these choices

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PARTNER UK clinic teams

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The views expressed in this presentation are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.



The logo of the British HIV Association (BHIVA) is a circular emblem with a complex, geometric pattern of dots and lines, resembling a molecular structure or a network. It is positioned behind the text.

British HIV Association
BHIVA

A light blue map of the United Kingdom is visible in the background. A red circular marker is placed on the map, indicating the location of Manchester in the north-west of England.

**19th Annual Conference of the
British HIV Association (BHIVA)**

16–19 April 2013

Manchester Central Convention Complex