



PARTNER Study

Investigator meeting
Glasgow 12th November 2012

Agenda

- Welcome: Andrew Phillips
- Status of PARTNER: Andrew Phillips
 - Recruitment
 - Follow up visit/retention rates
- Nurses panel/ Tina Bruun
 - Discussion on Recruitment
 - Follow up
 - Retention rates
- Latest data from PARTNER /Pietro Vernazza



Welcome Andrew Phillips

Executive Committee

- Andrew Phillips, University College London (UCL)
- Jens Lundgren, University of Copenhagen and Rigshospitalet, Copenhagen, Denmark
- Alison Rodger, UCL
- Simon Collins, HIV i-Base, London
- Pietro Vernazza, Switzerland
- Vicente Estrada, Spain
- Jan Van Lunzen, Germany
- Giulio Maria Corbelli, EATG, Italy
- Tina Bruun, Copenhagen HIV Programme (CHIP)

National Coordinators

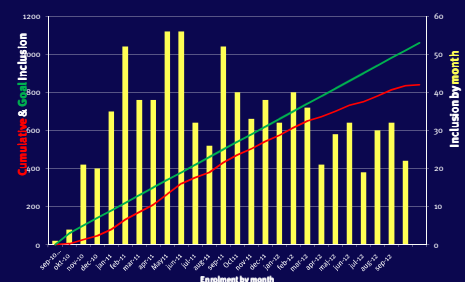
Amin Rieger,
Nathan Clumeck,
Lars Mathiesen,
Matti Ristola,
Christian Pradier,
Jan Van Lunzen,
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Antonella d'Arminio Monforte,
Francisco Antunes,
Vicente Estrada,
Katarina Westling,
Pietro Vernazza,
JM Prins,
Alison Rodger,

Austria
Belgium
Denmark
Finland
France
Germany
Ireland
Italy
Portugal
Spain
Sweden
Switzerland
The Netherlands
UK



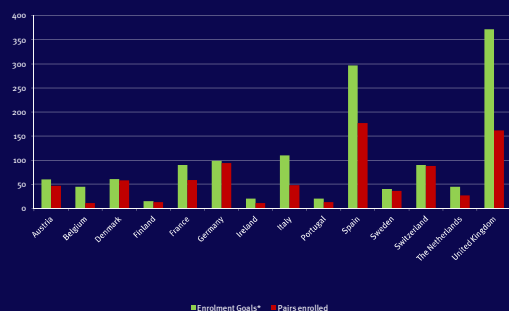
Recruitment update Andrew Phillips

Enrolment by month from Sep. 2010-November 2012



Enrolment by country

Enrolment 2012



Global overview

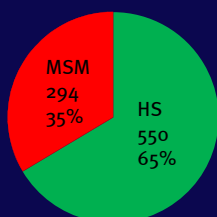
Update on enrolled partnership as of 08 November 2012

Country	No. of pairs enrolled				
	Open sites*	In last 3 weeks	Total	Projected total	% of projected enrolled
Austria	4	0	47	60	78
Belgium	3	1	11	45	24
Denmark	4	0	58	67	95
Finland	1	0	13	75	87
France	4	2	59	90	66
Germany	8	2	94	99	95
Ireland	1	0	11	20	55
Italy	5	1	48	110	43
Portugal	1	0	13	20	60
Spain	12	2	177	285	62
Sweden	2	1	36	40	90
Switzerland	5	1	88	90	98
Netherlands	3	0	27	45	60
UK	21	4	162	357	45
Total	73	14	844	1349	63%



Couples enrolled and MSM/Hetero

Total enrolment:



Eligible PYFU

	Heterosexual couples		Homosexual couples (n=272)	Total
	Men HIV+ (n=255)	Women HIV+ (n=256)		
Potential PYs [§]	260.0	265.2	268.4	793.7
Total PYs*	146.8	158.7	148.6	454.1
PY eligible (primary)	108.5	130.3	121.3	360.1
Number of unprotected sex acts (I)~	4308.5	5787.5	5795.5	15891.5
PYs eligible (II)	124.5	138.8	129.9	393.2
PYs eligible (III)	46.6	63.1	66.3	176.0
PYs eligible (IV)	0.3	0.0	0.4	1.3
PYs eligible (V)	108.7	128.2	120.1	357.1
PYs eligible (VI)	127.7	144.7	130.9	403.3
PYs eligible (VII)	128.6	144.7	131.4	404.7

- (i) the rate of infection in partners per unprotected sex act where index patient has viral load < 50 c/mL as opp
(ii) the rate of infection if we replace 50 copies/mL by 200 copies/mL in the above definition and
(iii) the rate of transmission if we insist that the next viral load value in the HIV positive partner after the end of
(iv) the rate of transmission if we consider periods to be eligible if only oral sex is reported,
(v) the rate of transmission if we ignore viral load measures made on the HIV positive partner which are within
(vi) the rate of infection if we replace 50 copies/mL by 500 copies/mL in the above definition and
(vii) the rate of infection if we replace 50 copies/mL by 1000 copies/mL in the above definition and



Reasons for Person-years (PYs) of follow up not being eligible in primary analysis

	Heterosexual couples				Homosexual couples		Total
	Men HIV+ (n=255)		Women HIV+ (n=256)		(n=272)		
PY not eligible for primary analysis**	38.3		28.4		27.3		94.1
	n	%	n	%	n	%	
Because HIV status at the B unknown	0.0	0%	0.6	2%	0.0	0%	0.6
Because HIV status at the E unknown	2.5	7%	4.1	15%	4.3	16%	11.0
Because data on unprotected sex missing at the B and at the E	3.5	9%	1.6	6%	3.7	13%	8.8
Because data on unprotected sex negative	3.7	10%	3.8	14%	6.0	22%	13.5
Because no VL measurement available in the last year preceding each day	4.6	12%	1.4	5%	3.5	13%	9.4
Because most recent VL is detectable (>50 copies)	26.8	70%	18.7	66%	13.4	49%	58.9

Feedback on recruitment and follow-up rates
Tina Bruun

Feedback on recruitment and follow-up rates

Recruitment

- More difficult than expected to reach the enrolment goals
- About 3% of the HIV positive patients are eligible and willing to enrol in Partner
- Refocus on PARTNER in the clinic and contact couples that initially showed some interest
- Focus on MSM couples as a new approach



Percentage of ptt. in care and retention rate

Global overview - follow-up within past 6 months (HIV-negatives)

	Pairs active in study	Activity reported past 6 months				Average % of clinic population recruited
		Visits reported	HIV tests reported	Questionnaires submitted	Average retention rate*	
Austria	44	46	44	47	83,8	80,8
Belgium	8	11	11	8	62,5	45,5
Denmark	51	55	54	55	80,0	67,4
Finland	11	9	4	10	27,3	23,1
France	54	47	46	48	59,4	55,9
Germany	79	69	63	78	62,7	55,5
Ireland	10	10	10	12	100,0	90,9
Italy	46	38	38	51	70,3	67,7
Portugal	13	13	13	16	100,0	100,0
Spain	157	126	125	134	66,1	58,8
Sweden	33	26	24	25	52,0	47,7
Switzerland	78	71	71	74	79,3	69,3
The Netherlands	25	27	27	31	89,7	86,4
United Kingdom	142	139	136	138	76,9	69,4
Hovertotal	751	687	666	727	72,1	65,6



Missed visits 1-5

	Pairs active in	# Missed visits	Feedback on missed visits*				
			1	2	3	4	5
Austria	44	23	6	0	0	0	33
Belgium	8	2	3	0	0	0	2
Denmark	51	23	27	1	0	0	8
Finland	11	10	2	0	0	0	1
France	54	42	28	0	2	0	64
Germany	79	35	30	0	0	0	67
Ireland	10	6	2	0	0	0	6
Italy	46	45	16	0	1	2	23
Portugal	13	4	0	0	0	0	0
Spain	157	149	42	6	4	4	77
Sweden	33	36	16	0	0	0	27
Switzerland	78	32	26	1	0	0	26
The Netherlands	25	130	1	0	0	0	4
United Kingdom	141	80	34	2	8	8	45
Hovertotal	750	617	233	10	15	14	383

1. In contact with person, confident visit will be arranged
 2. In contact with person, have not refused to do visit but not confident of getting them to come in
 3. Cannot contact the person - still trying
 4. Cannot contact the person - have given up trying
 5. Awaiting site response



Nurses Panel

- Nicky Perry - UK
- Bente Baadegaard - Denmark
- Maarit Maliniemi - Sweden



Latest data from PARTNER Pietro Vernazza

Continued High Levels of Condomless Sex in Serodifferent Couples when the Positive Partner is on Antiretroviral Therapy: The PARTNER Study

Alison Rodger, Valentina Cambiano, Tina Bruun, Pietro Vernazza, Simon Collins, Vicente Estrada, Jan Van Lunzen, Giulio Maria Corbelli, Pompeyo Viciano, Andrew Phillips and Jens Lundgren for the PARTNER Study Group



Background

- People do not always use a condom when having sex with partners of neg/unknown HIV status
- Statements on likely reduced infectiousness with the use of ART have been issued
- A secondary aim of the PARTNER study is to study HIV serodifferent partnerships to understand condom use and associated factors
- We report longitudinal data in frequency and characteristics of condomless sex and reasons for not using condoms in the context of PARTNER study counseling on condom use and after the HPTN 052 study reported reduced transmission on ART

Ref: Cohen MS et al for the HPTN 052 Study Team. *NEJM* 2011.



Design and Methods

- The PARTNER study is an international, observational multi-centre study, taking place in 72 European sites from 2010 to 2014
- PARTNER follows serodifferent partners [heterosexual (HS) and men-who-have sex with men (MSM)] that have reported condom-less penetrative sex just prior to study entry, and where the HIV+ve partner is on ART
- The study assesses sexual behaviour and reasons for non-condom use during follow-up (FU) and will estimate the absolute risk of HIV transmission in this setting



Results I

- By Oct 2012, 783 couples are enrolled with 306 person-year of FU in HS couples and 149 in MSM couples.
- Median (IQR) years condomless sex in HS couples was 4.2 (1.9-11.0) and 2.7 (1.5-5.3) in MSM.
- VL <50 cps in 94% of both HS and MSM partnerships.
- 83% -ve HS and 91% -ve MSM knew their partner's current VL.
- PEP and PrEP use were low in all groups (< 1.6%)



Results II

Table: Changes between baseline and follow up in prevalence of risk behaviours reported by the HIV -ve partner

HIV status and sexual orientation of couples	Risk behaviour reported by HIV -ve partner	Study entry	Follow up	p-value*
HS m+/f- partners	Condomless vaginal sex with ejaculation	72%	63%	0.06
HS m+/f- partners	Condomless anal sex with ejaculation	12 %	8%	0.73
HS m-/f+ partners	Condomless vaginal sex	100%	93%	1.00
HS m-/f+ partners	Condomless anal sex	15%	14%	1.00
MSM	Condomless anal sex receptive	55%	46%	0.04
MSM	Condomless anal sex receptive with ejaculation	26%	30%	0.39
MSM	Condomless anal sex insertive	88%	86%	0.51
MSM	Condomless receptive oral sex with ejaculation	36%	31%	0.33

*McNemar test

- Overall there was little change in sexual behaviour after study entry
- However the % of HIV-ve HS men and MSM who did not use a condom because of the belief that risk of HIV transmission was low when VL is undetectable increased during FU (55% vs. 66%, p=0.003)



Conclusions

- There was little change in sexual behaviours during FU despite in-study counselling in this cohort of couples with a history of condom-less sex
- The decision not to use condoms due to a belief that they are unnecessary when VL is undetectable increased significantly in -ve HS men and -ve MSM, possibly reflecting growing awareness of the prevention role of ART.



Contact

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