Partner Study

Investigator meeting CROI
7th March 2012

Agenda

- Welcome - Jens Lundgren
- Status in PARTNER: - Jens Lundgren
  - Open sites
  - Recruitment
- Recruitments strategies - (Spain) – Vicente Estrada
- Presentation of PARTNER poster at CROI - Alison Rodger
- Loss to follow up rate and general discussion on follow up visit – Andrew Phillips
- Outreach initiatives and Community Lead - Guilio Maria Corbelli,

Welcome
Jens Lundgren

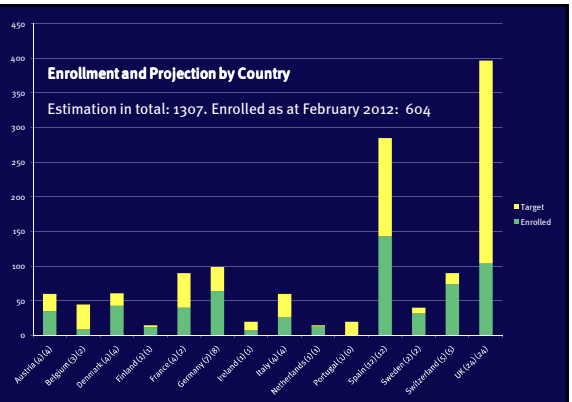
Executive Committee

- 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)

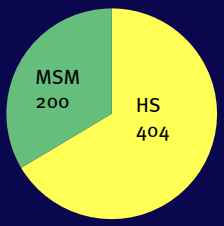
National Coordinators

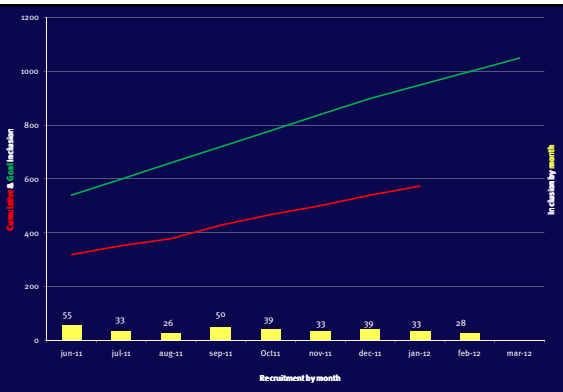
Amin Rieger,	Austria
Nathan Clumeck,	Belgium
Lars Mathiesen,	Denmark
Matti Ristola,	Finland
Christian Pradier,	France
Jan Van Lunzen,	Germany
Gráinne Courtney,	Ireland
Antonella d'Arminio Monforte,	Italy
Francisco Antunes,	Portugal
Vincente Estrada,	Spain
Katarina Westling,	Sweden
Pietro Vernazza,	Switzerland
JM Prins,	The Netherlands
Alison Rodger,	UK

Recruitment update
Jens Lundgren



MSM/Heterosexual





Recruitment strategies in Spain
Vicente Estrada

Barriers for recruitment

1. Discussion about partnerships with patients
2. Discussion about condom use is in many cases obviated
3. Busy clinics don't have enough time to discuss the study with patients & couples

Barriers for recruitment
Potential solutions

Discussion about partnerships with patients

- Ask simple questions to identify sero-different stable couples of your patients
  - Have you got an stable partner?
  - Is he/she HIV negative?
  - Does he/she routinely screen for HIV?
- Give a very short introduction to the PARTNER study and refer to the research nurses/staff
- If possible, integrate routine HIV testing to the HIV neg- partner of your patient
  - Clinics most successful in recruiting couples into the Partner study do so

Barriers for recruitment
Potential solutions

- Discussion about condom use is in many cases obviated
- Don't obviate it
  - In the past we made strong recommendations about its use
  - Some HIV positive people may not feel comfortable discussing this with their physician
  - Partner study does not recommend avoiding of condoms
  - HIV+ve persons don´t use condoms all the times
  - Reduced risk of transmission of HIV when VL is negative
  - The information derived from Partner study will help patients to take decisions

Busy clinics
Nurse collaboration

- The role of research nurses/staff is essential
- Clinics most successful in recruiting couples into the Partner study have dedicated staff
  - Information about the study
  - HIV samples
  - Questionnaires
  - Data management (e-CRF)
  - Follow-up schedules

Summary

Barriers for recrutiment

1. Discussion about partnerships with patients
2. Discussion about condom use is in many cases obviated
3. Busy clinics don´t have time enough to discuss the study with patients & couples

Potential solutions

1. Discuss about partners
2. Don't obviate discussion about condom use
3. Nurse/staff collaboration

Congratulations!
Top recruiters in Spain

- Dr. Pompeyo Viciana.
  - Hospital Virgen del Rocío, Seville: 39 couples
- Dr. Félix Gutiérrez
  - Hospital Elche, Alicante: 24 couples

PARTNER Poster
Alison Rodger

Understanding why serodifferent couples do not always use condoms when the HIV positive partner is on ART

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

CROI 2012 SEATTLE Poster # 564

Background

- People do not always use a condom when having sex with partners of neg/unknown HIV status
- One reason for not using condoms may be the person being ART with the VL< 50 copies/mL and statements on likely reduced infectiousness in this situation have been issued
- The secondary aim of the PARTNER study is to study HIV serodifferent partnerships to understand why some partnerships do not use condoms and factors associated with this

Design and Methods

- The PARTNER study is an international, observational multi-centre study, taking place in 72 European sites from 2010 to 2014
- Recruits serodifferent partnerships who had CL penetrative sex in the past 4 weeks, +ve partner on ART, to assess risk behaviours, reasons for non-condom use, attitudes to use of ART for prevention, and to estimate the absolute risk of HIV transmission on ART with a viral load <50 copies/mL with 4-6 monthly follow up
- We report baseline risk behavior data on first 565 couples (373 HS and 192 MSM) recruited to 02/02/2012

Results: HIV acquisition route, adherence and VL knowledge

	HIV+ heterosexual men (n=179)	HIV+ women (n=190)	HIV+ MSM (n=191)	p-value
HIV Acquisition route				
Heterosexual Sex	62 (36.3)	115 (66.1)	0(0)	<0.0001
Homosexual Sex	12 (7.0)	0	168 (96.5)	
IVDU	62 (36.3)	10(5.7)	0(0)	
Years HIV diagnosis, median (IQR)	12.5 (7.3-19.3)	10.4(6.2-16.4)	6.8(4.3-12.7)	<0.0001
Years on ART, median (IQR)	9 (4.1-14.7)	7.4 (3.3-13.6)	5.0(1.8-11.3)	<0.0001
Self-reported adherence >=90%	157(92.9)	156 (95.1)	166 (97.0)	0.2079
Missed ART for >4 cons days	9 (5.2)	10 (5.7)	3 (1.7)	0.1072
Informed partner if missed ART	86 (85.1)	84 (88.4)	61 (85.9)	0.7869
Thought had undetectable VL	142 (84.5)	147 (86.0)	163 (95.3)	0.0030
Undetectable VL (<50 copies)	163 (90.1)	180 (95.7)	181 (94.7)	0.0742
CD4 count >350 mm³	150 (82.9)	167(88.8)	169 (88.8)	0.1669

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Years having condomless sex with current partner

	Heterosexual couples (n=373)				MSM couples (n=192)	
	HIV+		HIV-			
	M (n=179)	W (n=190)	M (n=191)	W (n=182)	HIV+ (n=191)	HIV- (n=192)
Years having CL sex, median (IQR, range)	4.1 (1.3-11.1)	3.1 (1.0-8.3)	3.3 (1.1-8.9)	4.3 (1.4-10.6)	1.7 (0.6-4.1)	1.6 (0.7-3.4)

Condomless vaginal sex with ejaculation in previous 4/12

	Heterosexual couples (n=373)			
	HIV+		HIV-	
	M (n=179)	W (n=190)	M (n=191)	W (n=182)
Yes	11 (66%)	173(99%)	162 (100%)	113(70%)

Anal condomless sex (receptive/insertive) by sexual orientation and HIV status in previous 4/12

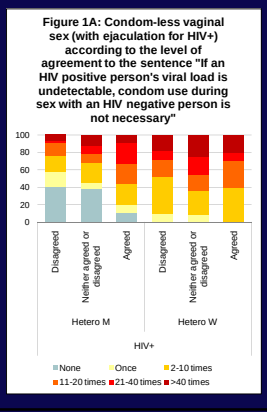
	Heterosexual couples (n=373)				MSM couples (n=192)	
	HIV+		HIV-			
	M (n=179)	W (n=190)	M (n=191)	W (n=182)	HIV+ (n=191)	HIV- (n=192)
CL receptive anal sex (with ejaculation if man HIV+)						
Yes		23 (16%)		14 (9.9%)	149 (87%)	41 (25%)
CL insertive anal sex (with ejaculation if man HIV+)						
Yes	19 (13%)		28 (21%)		46 (28%)	129(87%)

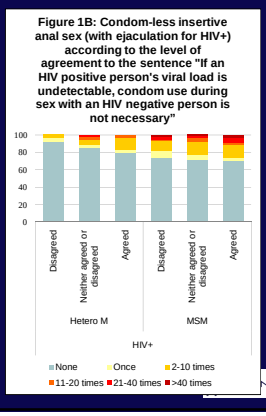
Reasons given for not using a condom

The main reasons given for not using a condom :

- A belief that the risk of transmission was low (52% +ve, 54% -ve)
- HIV –ve partner did not want to use a condom (48% HS, 27% MSM)
- Trying for a pregnancy (43% HS)
- Didn't think about it (21% MSM and 30% HS)
- Greater pleasure without a condom (46% +ve, 47% -ve)

Beliefs about ART and associations with condom use





Conclusions

- In MSM we found the HIV positive partner was more likely to be anal receptive and, if insertive, avoided ejaculation
- A significant proportion of HS HIV –ve women had anal sex with ejaculation with their HIV +ve male partners.
- The decision not to use condoms in HS men was significantly related to a belief that condoms are not necessary when VL is undetectable.
- Results from the HPTN 052 trial and growing awareness of the prevention role of ART, 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

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

Loss to follow up rate and general discussion on follow up

Andrew Phillips

Projected couple years according to monthly recruitment rate and % lost to follow-up per year

Couple years required: 2500

Recruitment per month until Feb 2014	% ending follow-up per year	Cumulative recruitment by Feb 2014	Total follow-to Aug 2014
30	15%	1256	2244
30	20%	1256	2131
30	25%	1256	2021
40	15%	1476	2562
40	20%	1476	2434
40	25%	1476	2309

Projected couple years according to monthly recruitment rate and % lost to follow-up per year MSM

Couple years required: 1250

Recruitment per month until Feb 2014	% ending follow-up per year	Cumulative recruitment by Feb 2014	Total follow-to Aug 2014
13	15%	486	850
13	20%	486	807
13	25%	486	766
30	15%	860	1390
30	20%	860	1322
30	25%	860	1255

Follow up

Guidelines:

- Emphasize the 6 month visits
- Explain the reasons for the 6-month HIV test
- Schedule dates for follow-up visits at the baseline visit
- Rapid testing – this can minimize the number of visits for the HIV negative partner
- If the HIV negative partner refuses to continue to participate in the study an exception can be made and they are allowed to come in for testing only once a year. In such cases it is important to have the HIV negative partner fill in follow up questionnaires every 6 months.

Outreach initiatives and Community Lead

Guilio Maria Corbelli

Why a Community Lead for the Partner study?

- The Partner Study is important for the community
- Reaching sero-different couples for recruitment can be not easy
- The community lead can be a *trait-d'union* between researcher and the community
- Cooperation is useful and necessary

Community Lead for the Partner study - 2012

- Italy: Giulio Maria Corbelli
- Spain: Michael Meulbroek
- Finland: Kimmo Karsikas
- Switzerland: David Haerry
- Portugal: Wim Vandevelde
- UK: Simon Collins
- Austria: Frank Michael Amort
- France: Laurent Rossignol
- Denmark: Klaus Legau
- Belgium: Koen Block?
- Germany: Dirk Sanders
- Sweden: Helena Granlund

No Community Lead:

- The Netherlands: Decided not to appoint

Actions

- articles on community-based media
- facebook “business card”
- meeting with gay or hiv associations
- informing helpline volunteers
- meeting self-help groups
- more…

PARTNER: Website for study participants

www.partnerstudy.eu