



Use of PEP and PrEP among HIV negative MSM in the PARTNER study

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for the PARTNER Study Group

EACS 2017, Milan, 27th October, 2017
Session “PS11 Understanding our Evolving Epidemic”

Presenter Disclosure Information

In compliance with the Conflict of Interest Policies, the European AIDS Clinical Society (EACS) requires the following disclosure from the presenters:

Valentina Cambiano

received personal fees by Merck Sharp & Dohme Limited in April 2015.



PARTNER Study

- Partners of People on ART-A New Evaluation of the Risks
- observational multi-centre study of HIV serodifferent couples (MSM and HT) in which the positive partner is on ART
- 75 clinical sites across 14 European countries

Primary Aim

To evaluate the rate of within-couple HIV transmission during periods of sex without condoms and when the HIV-positive partner had HIV-1 RNA load less than 200 copies/mL.



Background

Original Investigation

Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy

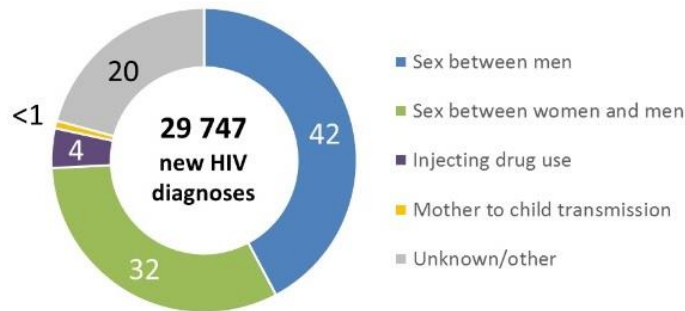
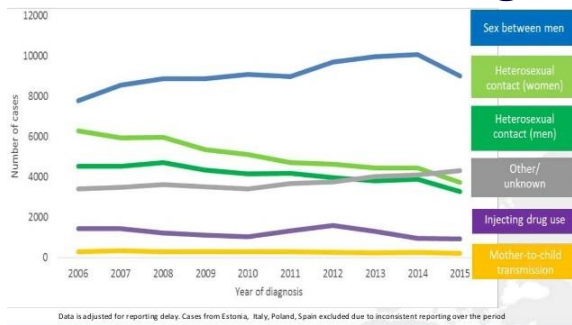
Alison J. Rodger, MD; Valentina Cambiano, PhD; Tina Bruun, RN; Pietro Vernazza, MD; Simon Collins; Jan van Lunzen, PhD; Giulio Maria Corbelli; Vicente Estrada, MD; Anna Maria Geretti, MD; Apostolos Beloukas, PhD; David Asboe, FRCP; Pompeyo Viciana, MD; Félix Gutiérrez, MD; Bonaventura Clotet, PhD; Christian Pradler, MD; Jan Gerstoft, MD; Rainer Weber, MD; Katarina Westling, MD; Gilles Wandeler, MD; Jan M. Prins, PhD; Armin Rieger, MD; Marcel Stoeckle, MD; Tim Kömmerle, PhD; Teresa Bini, MD; Adriana Ammassari, MD; Richard Gilson, MD; Ivanka Krznaric, PhD; Matti Ristola, PhD; Robert Zangerle, MD; Pia Handberg, RN; Antonio Antela, PhD; Sris Allan, FRCP; Andrew N. Phillips, PhD; Jens Lundgren, MD; for the PARTNER Study Group

JAMA. 2016;316(2):171-181. doi:10.1001/jama.2016.5148

- PARTNER1: Sep 2010 – May 2014
- 11 HIV sero-conversions in negative partners observed during eligible couple-years of follow-up (CYFU): 10 were in MSM, 8 reported condomless sex outside the couple
- **0** phylogenetically linked transmissions occurred over eligible CYFU (95% CI: 0-0.3/100 CYFU) and 56,000 condomless sex acts
- Blinding on seroconversions outside eligible CYFU and from PARTNER2 (Jun 2014 – Mar 2018)

Background

- MSM contribute the largest number of new HIV diagnoses¹



- WHO recommends that decisions on Post-Exposure Prophylaxis (PEP) are based on assessment of the risk of HIV transmission²

1: ECDC/WHO 2016. HIV/AIDS Surveillance in Europe, 2015; 2: Post-exposure prophylaxis to prevent HIV infection : joint WHO/ILO guidelines on post-exposure prophylaxis (PEP) to prevent HIV infection, 2007; 3: WHO. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations, 2014

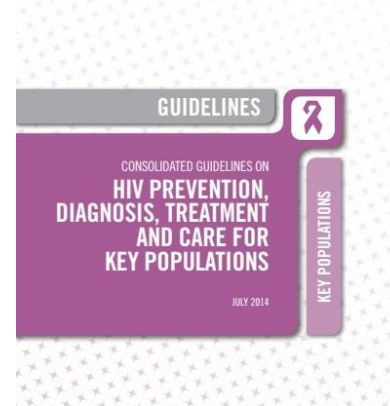
- WHO recommends Pre-Exposure Prophylaxis (PrEP) for MSM at increased risk of HIV infection³

Recommendations and guidance

NEW

ALL KEY POPULATION GROUPS

Oral PrEP (containing TDF) should be offered as an additional prevention choice for key populations at substantial risk of HIV infection as part of combination prevention approaches. (strong recommendation, high quality of evidence) (4).



“Offering PrEP should be a priority for populations with an HIV incidence of about 3 per 100 person-years or higher.”

- PrEP in Europe is currently available through the health system in France, Norway and Scotland



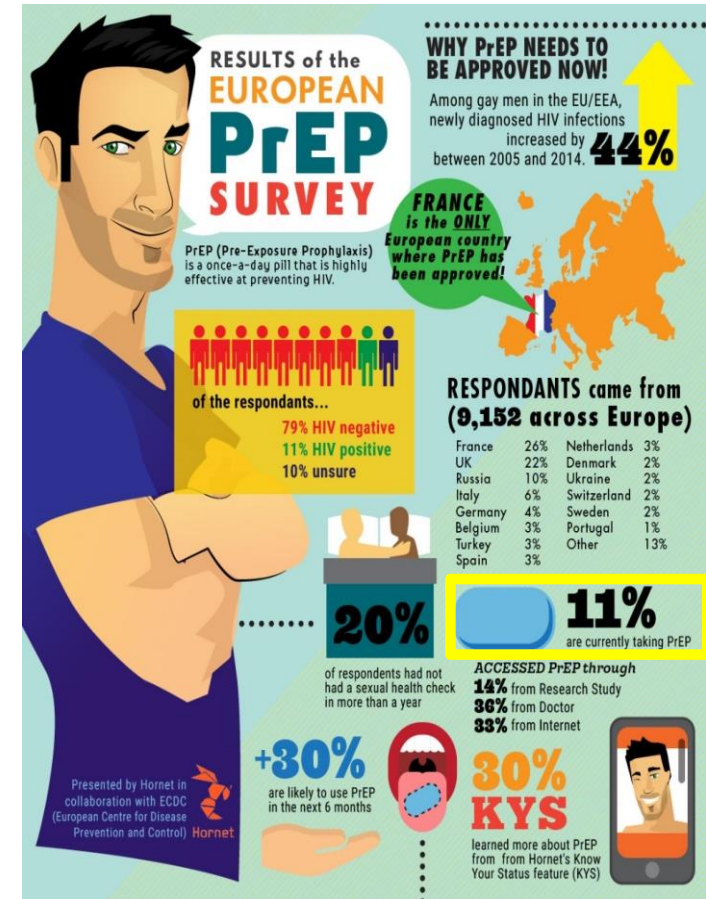
How many people are using PrEP in Europe?

- **April 2016:** ECDC in collaboration with Hornet launched a PrEP survey (n= 8048, excludes HIV-positive)¹



Ongoing work:

- Second Hornet survey of PrEP users in 2017
- EMIS-2017²: online survey of MSM (launch in Oct2017) in 50 countries



1 - European Centre for Disease Prevention and Control. Evidence brief: Pre-exposure prophylaxis for HIV prevention in Europe. Stockholm: ECDC; 2016; 2 - <http://sigmaresearch.org.uk/projects/item/project76>;

Aims

- To report HIV incidence among MSM over eligible CYFU where condomless anal sex (CLAS) outside the main partnership is reported by the negative partner during PARTNER1
- To evaluate whether PEP and PrEP use:
 - increased from PARTNER1 (Sep 2010 - May 2014) to PARTNER2 (Jun 2014 - ongoing)
 - whether it differs between HIV negative participants who report CLAS with other partners compared to those who don't
- To estimate the % of time PrEP is taken during periods where CLAS outside the couple is reported

Study procedures

Informed consent:

- Information on the need for consistent condom use (at consent and emphasized at each study contact)
- Explicit reference to the fact that HIV negative partners knew their partner was HIV positive and that there is a transmission risk through CLAS

4 to 6 months

Standardized case report form:

- Self completed confidential sexual behaviour questionnaire (CLAS with main partner and external partners, PEP/PrEP use)
- clinical data: HIV viral load (for +ve partner) and HIV test (for -ve partner)

Results aim 1

Eligible couple years of follow-up (CYFU) are periods of time between HIV tests in negative partners in which:

- condomless anal sex (CLAS) is reported
- no reported PEP or PrEP use
- plasma HIV-1 RNA load <200 copies/mL within last 12 month
- follow-up occurred before 31st May 2014 (censoring date for PARTNER 1)

HIV incidence in PARTNER1

- among MSM over eligible CYFU: **2.3/100 CYFU** (10/439 CYFU)¹
- among MSM over eligible CYFU where CLAS with other partners is reported: **7.2/100 CYFU** (8/111 CYFU)
(95% CI: 3.2 - 13.7 /100 CYFU)

1- Rodger AJ et al. Sexual activity without condoms and risk of HIV transmission in serodifferent couples when the HIV-positive partner is using suppressive antiretroviral therapy. *JAMA* 2016; **316**: 171–81

Outcomes and population

At study entry (baseline):

- *“Have you ever received post exposure prophylaxis (PEP)?”*
- *“Have you used PrEP (taking antiretroviral (anti-HIV) treatment before having unprotected sex)?”*

During follow-up (FU):

- *“Have you received PEP since your last visit?”*
- *“Have you used PrEP (taking ...) since your last visit?”*

 % who reported PEP/PrEP at least once during follow-up

By 1st September 2017

960

- HIV negative MSM completed the baseline questionnaire

737

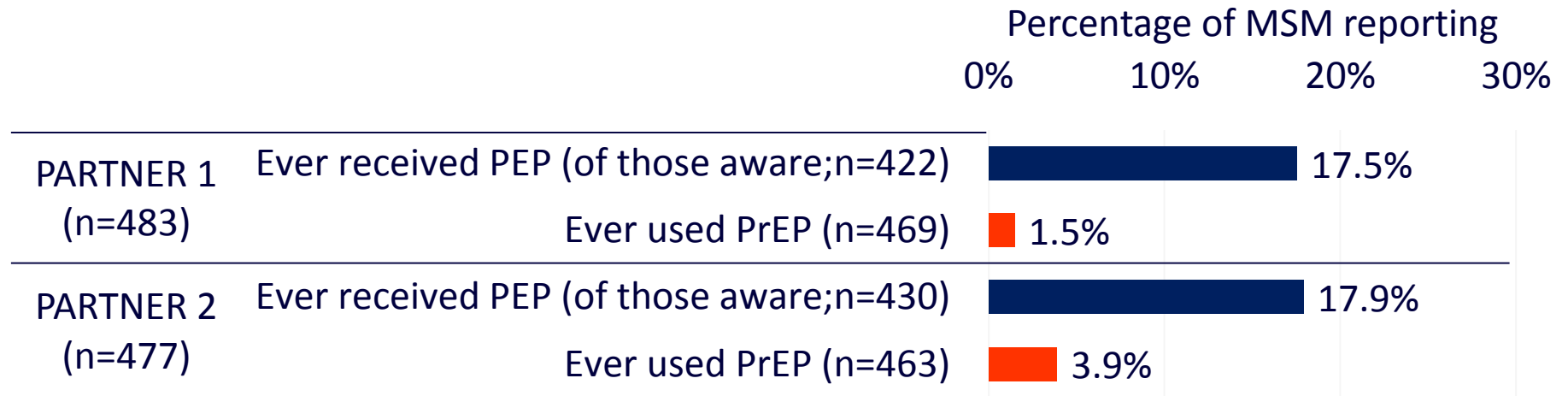
- ...and had at least one follow-up visit

HIV negative MSM partners

	With baseline questionnaire (n=960)	With at least one follow-up visit (n=737)
At study entry		
Age, median (IQR)	37.4 (30.5-45.0)	37.4 (30.8-45.2)
White ethnicity (%)	851 (89%)	653 (89%)
Years CLAS with the HIV positive study partner, median (IQR)	1.0 (0.4-2.8)	1.0 (0.4-2.9)
During follow up		
Years in the study, median (IQR)	-	1.6 (0.8-3.1)
Diagnosed with STI, %	-	22%
CLAS with other partners, %	-	35%
CLAS acts/year, median (IQR)	-	35 (14-67)
Estimated total number CLAS acts within the main partnerships	-	69,098

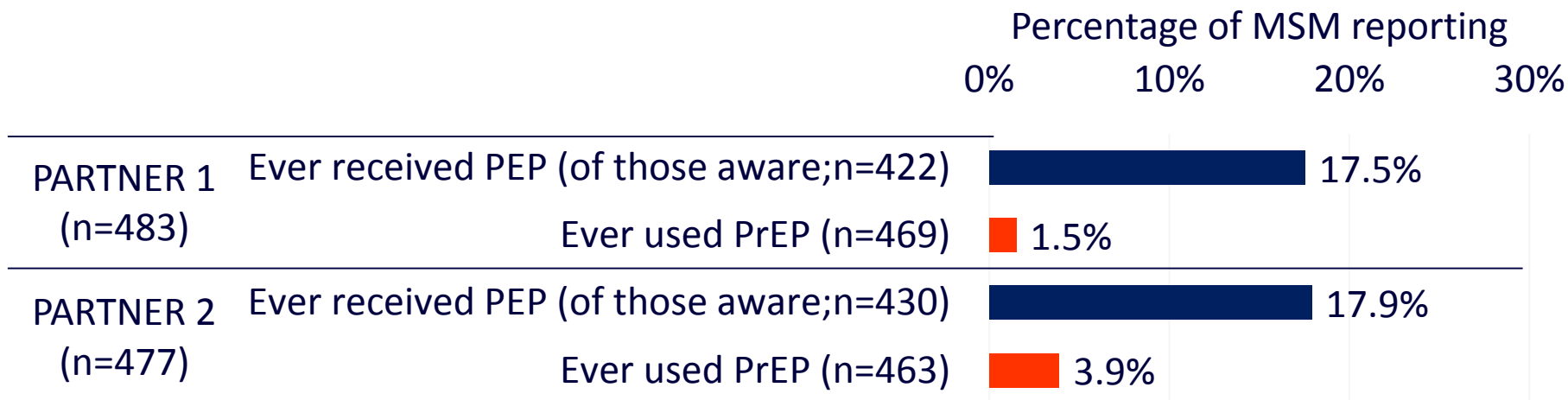
Results - PEP and PrEP use

At enrolment (N=960)

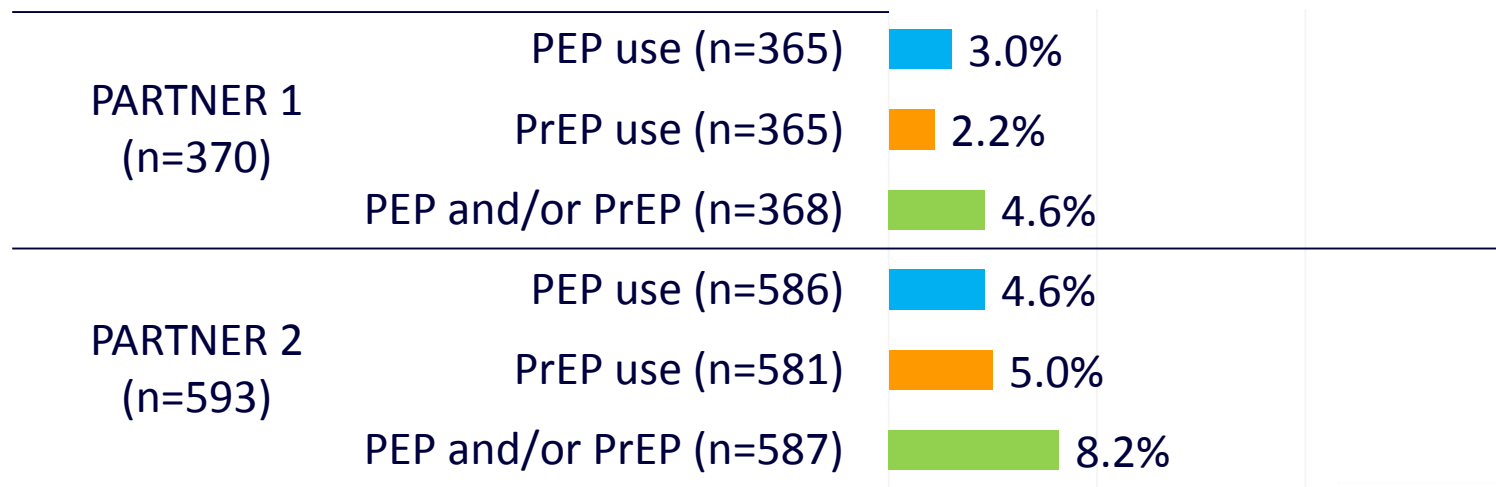


Results - PEP and PrEP use

At enrolment (N=960)

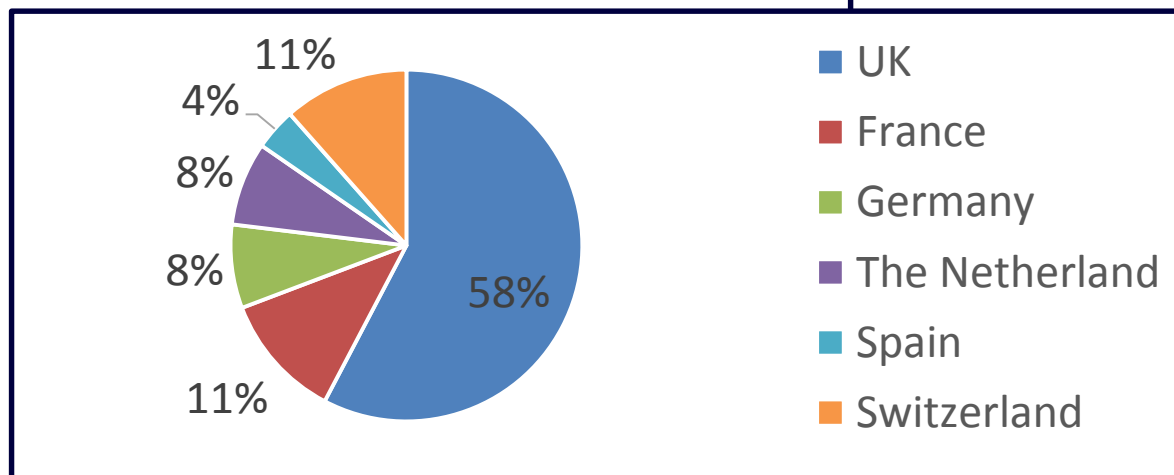
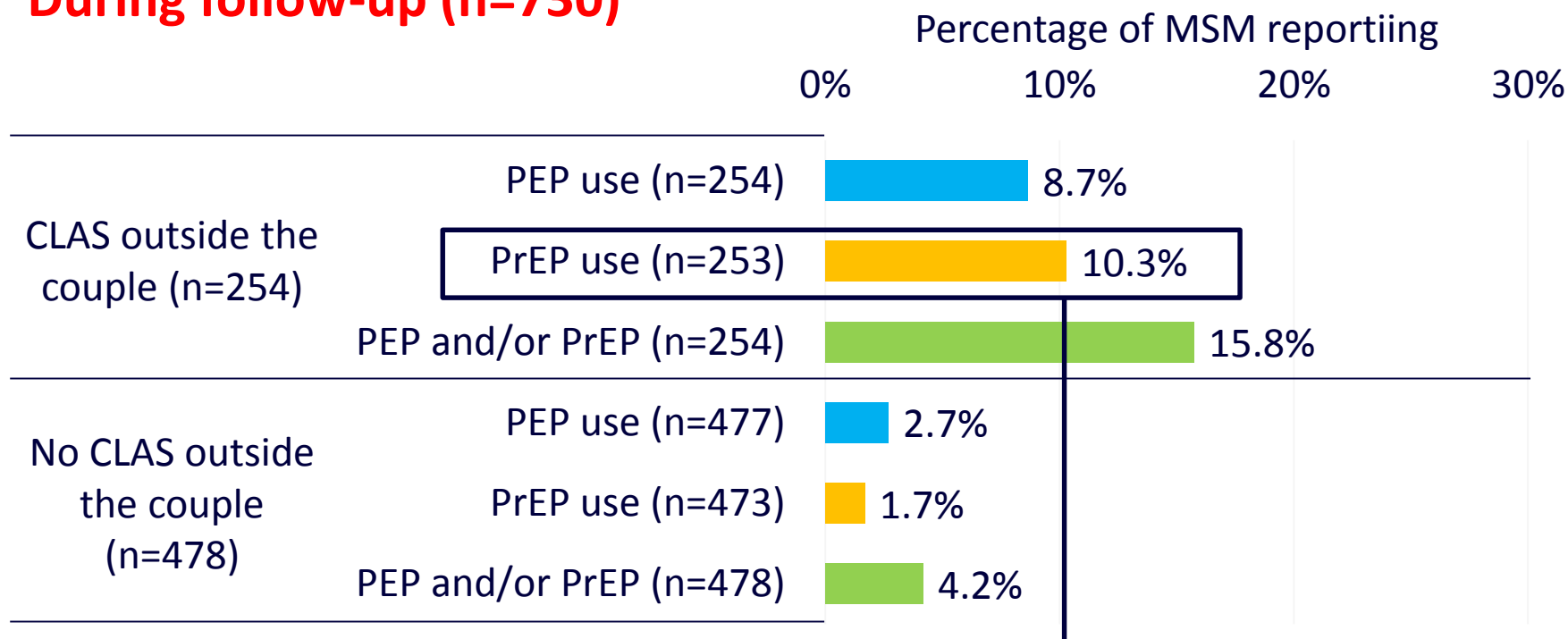


During follow-up (n=730)



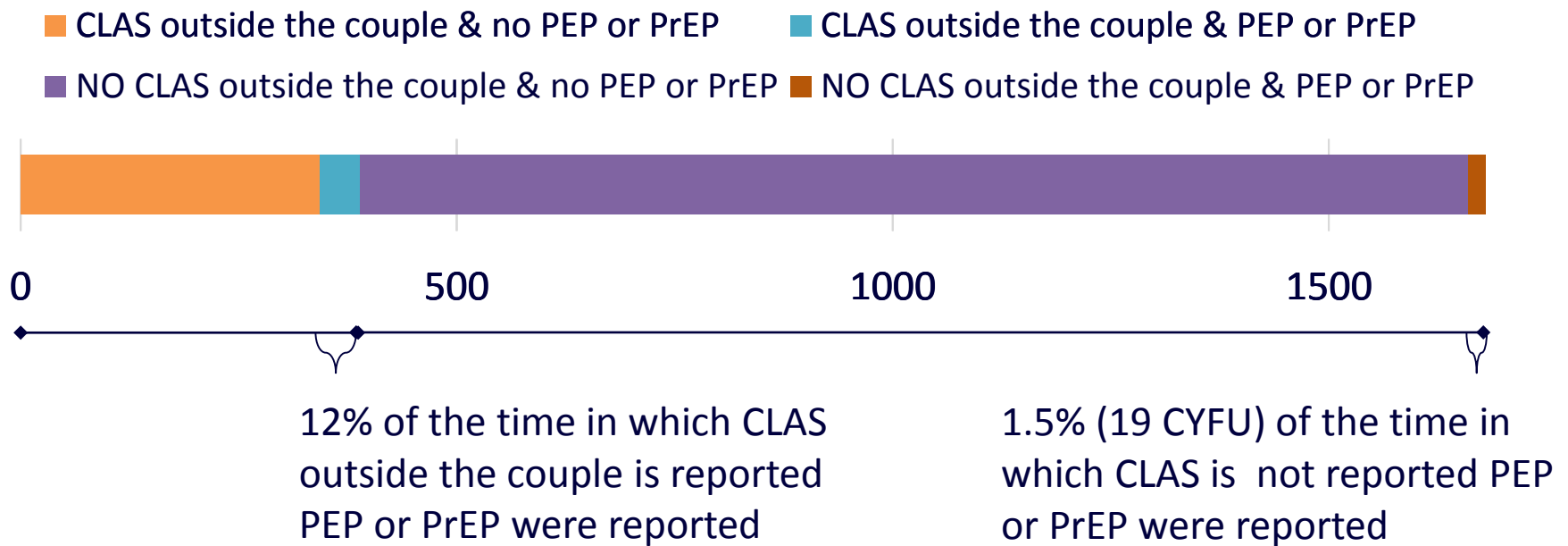
Results - PEP and PrEP use

During follow-up (n=730)



Results - PEP and PrEP use

Up to 1st September 2017: 1679 CYFU among MSM



Conclusions

- 35% of HIV negative MSM had CLAS with other partners.
- Despite high levels of awareness, only a minority of men having condomless anal sex with men outside their main relationship used either PEP or PrEP (16%).
- Only in 12% of CYFU in which CLAS occurred outside the main relationship was PEP or PrEP use reported.
- The HIV incidence among MSM having condomless sex with a sero-different long term partner who is virologically suppressed on ART and also with men outside the main relationship was 7.2/100 CYFU.
- PrEP eligibility discussions with HIV negative MSM should ensure that risks from all sexual contacts are taken into consideration and routes to securing PrEP including generics discussed if PrEP not freely available in country.

The PARTNER 2 Study:
a study for sero-different
gay couples



Understanding the risk of
HIV transmission when the
HIV+ partner is on therapy

**Thanks to all
PARTNER study
participants!**



Acknowledgments

PARTNER sites

Spain: Hospital Virgen del Rocío, Sevilla, Pompeyo Viciano, Monica Trastoy, Reyes Palacios. Hospital Universitario de Elche, Felix Gutiérrez, Mar Masiá, Sergio Padilla, Cati Garcia. Hosp. Universitari Germans Trias i Pujol, Bardalona, Bonaventura Clotet, Josep Coll Verd, Patricia Corbasi, Antonio Carrillo. Hospital La Paz, Madrid, José María Peña. Hospital Universitario San Carlos, Madrid, Vicente Perez Estrada, Maria Rodrigo Garcia, Eva Santiago Aroca. Hospital Universitario Reina Sofia De Cordoba, Antonio Rivero. Hospital Clínico Universitario de Santiago de Compostela, Antonio Antela, Elena Losada, Carmen Lires, Antonio Aguilera. Hospital Clínic de Barcelona, Barcelona, Jose M. Gatell Artigas, Agathe Leon, Lorna Leal. Centro Sanitario Sandoval, Madrid, Jorge Del Romero Guerrero, Mar Vera García. Hospital Ramon y Cajal, Madrid, Fernando Dronda. Hospital Carlos III, Madrid, Vincente Soriano. Bellvitge; D. Podzamczar.

United Kingdom: Chelsea & Westminster, London: David Asboe, Janey Sewell. Dean Street Clinic, London: Nneka Nwokolo. Mortimer Market Centre, London: Richard Gilson, Nahum De Esteban Sara McNamara. Royal Free; London: Alison Rodger, Kate Sturgeon. Southmead Hospital, Bristol: Mark Gompels, Louise Jennings. Imperial College London: Sarah Fidler. Coventry and Warwickshire Hospital: Sris Allan. King's College Hospital: Michael Brady, Lucy Campbell. Brighton and Sussex: Amanda Clarke. Leicester Royal Infirmary: Jyoti Dhar. Newham: Rebecca O'Connell. Birmingham Heartlands: David White. St Thomas's Hospital, London: Julie Fox, Juan Tiraboschi. St Mary's Hospital, London: Sarah Fidler. Bradford: Phillip Stanley, Earnsdale Clinic, Redhill: Usha Natarajan, Stephanie Allen. Northampton: Mohamed Ghanem. North Middlesex University Hospital, London : Jonathan Ainsworth, Anele Waters. North Manchester General Hospital: Ed Wilkins. St James's, Leeds: Jane Minton, James Calderwood. Hastings: Harish Patel. Whipps Cross Hospital, London: Monica Lascar. Western G. Hospital, Edinburgh, C. Leen.

Germany: University Clinic, Hamburg Eppendorf: Olaf Degen. University Hospital, Cologne: Tim Kümmerle, Gerd Fätkenheuer, Clara Lehmann, Eleonore Thomas. Praxis Driesener Straße, Berlin Ivanka Krznaric, Patrick Ingiliz, Janina Motsch. Medizinische Poliklinik, Munich, Johannes Bogner. Universitäts-Hautklinik, Bochum, Norbert H. Brockmeyer. ICH Study Center, Hamburg, Hans-Jürgen Stellbrink, Christian Hoffmann. Gemeinschaftspraxis Jessen-Jessen-Stein, Berlin, Heiko Jessen. University Hospital, Bonn, Jürgen Rockstroh, Christoph Boesecke.

Switzerland: University Hospital Zürich, Rainer Weber, Huldrych Günthard, Dominique Braun, Manuel Battegay, Christina Grube. University Hospital Bern, Hansjakob Furrer, Gilles Wandeler, Torsten Konrad, Andri Rauch. University Hospital Basel, Marcel Stoeckle, Philip E. Tarr. Kantonsspital, St. Gallen, Pietro Vernazza, Patrick Schmid. Ospedale Regionale Di Lugano, Enso Bernasconi, Beatrice Bernasconi. CP Zurich; B.Bertisch. CP Vaud: V. Christinet

Denmark: Rigshospitalet, Copenhagen, Jan Gerstoft, Tavs Qvist, Nurses from 8622. Hvidovre Universitets Hospital, Pia Handberg. Aarhus universitetshospital, Skejby Lars Oestergaard. Odense Universitetshospital, Svend Stenvang.

Finland: Helsinki University Central Hospital, Matti Ristola, Pia Susanna Kivelä.

Sweden: Karolinska University Hospital Huddinge, Stockholm, Katarina Westling, Eeva-Maija Frisén. Södersjukhuset, Venhälsan, Stockholm, Anders Blaxhult, Maarit Maliniemi, Ronnie Ask.

Ireland: St. James' Hospital, Dublin Gráinne Cortney.

Belgium: CHU Saint-Pierre, Bruxelles, Nathan Clumeck. University Ziekenhuis, Gent, Lino Vandekerckhove. Eersame, Bruxelles, JG. Goffard.

The Netherlands: AMC, Amsterdam, Jan Prins. OLVG, Amsterdam, Kees Brinkman. Medisch Centrum Jan van Goyen, Amsterdam, Dominique Verhagen. DC Klinieken, Amsterdam, Arne van Eeden, Wilma Brokking, Margo Groot, Arnhem; J. Gisolf.

France: Hopital de l' Archet 1, Nice, Christian Pradier, J. Durant, Sophie Breaud, Serini. CHU Hotel-Dieu, Nantes, Francois Raffi, Eric BILLAUD Veronique Reliquet. Hopital Tenon, Paris, Gilles Pialoux, Sophie Le Nagat, Pélégie Thibault. "190", Paris, Michel Ohayon. AIDES, Vincent COQUELIN.

Austria: Medical University of Vienna, Armin Rieger, Veronique Touzeau-Roemer. Medical University Innsbruck, Robert Zangerle, Martin Gisinger, Mario Sarcletti, Maria Kitchen. FA für Dermatologie/Venerologie, Linz, Maria Geit, Angela Oellinger.

Italy: San Paolo Hospital, Milan, Terease Bini, Laura Comi, Elisa Suardi, Alessandro Pandolfo. Ospedale Spallanzani, Roma Adriana Ammassari, Nicoletta Orchi, Paola Pierro, Gabriella De Carli. Malattie Infettive Università di Catania, Maurizio Celesia, Chiara Frasca. Università degli Studi di Modena Cristina Mussini. Universitaria San Martino, Genova, Antonio Di Biagio, Laura Nicolini.

Portugal: Hospital Santa Maria, Lisbon, Nuno Janerio.

The PARTNER study presents independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research funding scheme (RP-PG-0608-10142) and Research for Patient Benefit Grant Scheme (PB-PG-1013-32069). The views expressed in this presentation are those of the authors and not necessarily those of the NHS, NIHR or the Department of Health

