Corso di formazione per operatori del BLQ Checkpoint

29 ottobre 2016

Giulio Maria Corbelli,
European AIDS Treatment Group,
Plus onlus

Chi sono

Giulio Maria Corbelli
Giornalista free lance

Membro di:
EATG – European AIDS Treatment Group;
ECAB (European Community Advisory Board)
Executive Committee for the PARTNER Study
Community Advisory Group for INSIGHT network
AVAC's project pxROAR Europe
Consiglio direttivo di Plus
Panel per le linee guida per il trattamento antiretrovirale

Programma

9:00 – 9:15 Introduzione

9:15 – 10:00 Trasmissione e prevenzione di HIV

10:00 – 11:00 PrEP

pausa

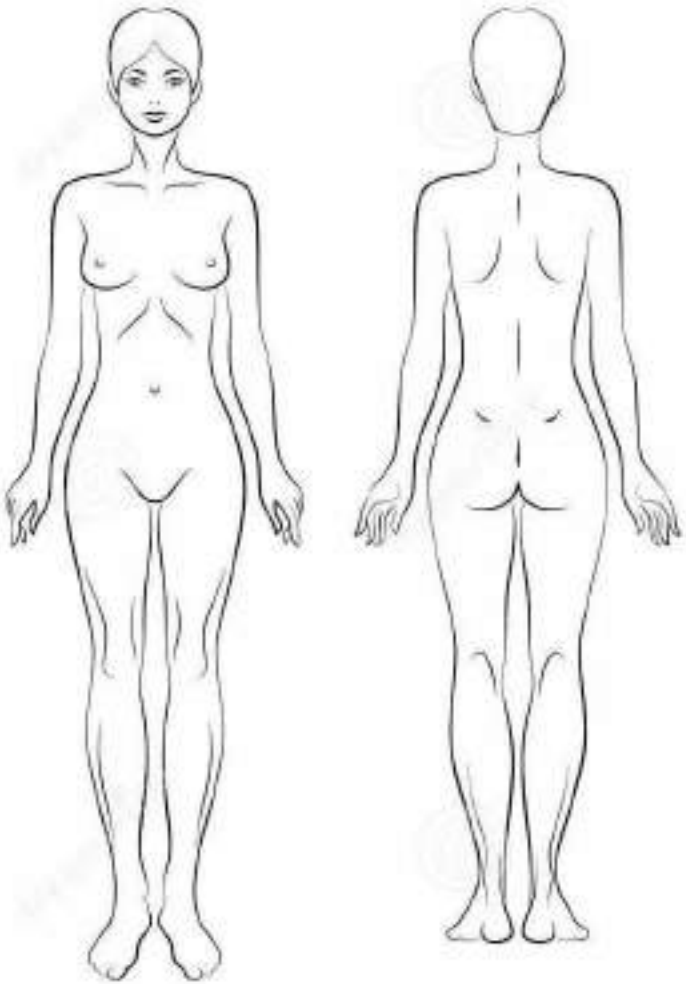
11:30 – 12:00 PEP

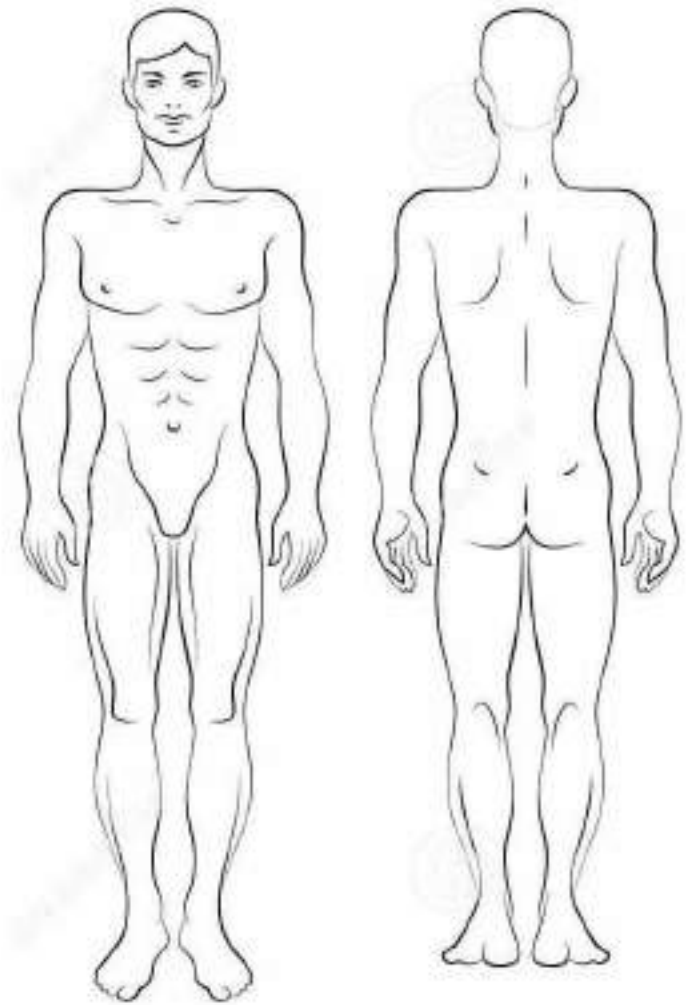
12:00 – 12:30 ChemSex

12:30 – 14:00 comunicazione

HIV transmission: the basics

Where can HIV be found?





Source: AIDS.gov, How do you get HIV or AIDS?: https://www.aids.gov/hiv-aids-basics/hiv-aids-101/how-you-get-hiv-aids/ Accessed Sept. 2015

HIV transmission: the basics

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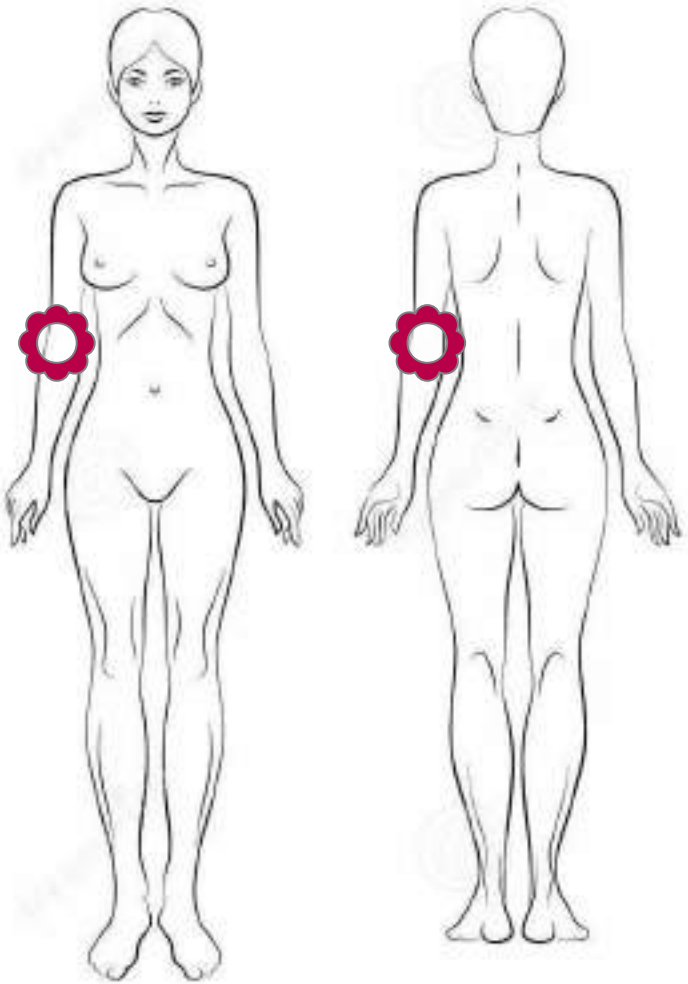
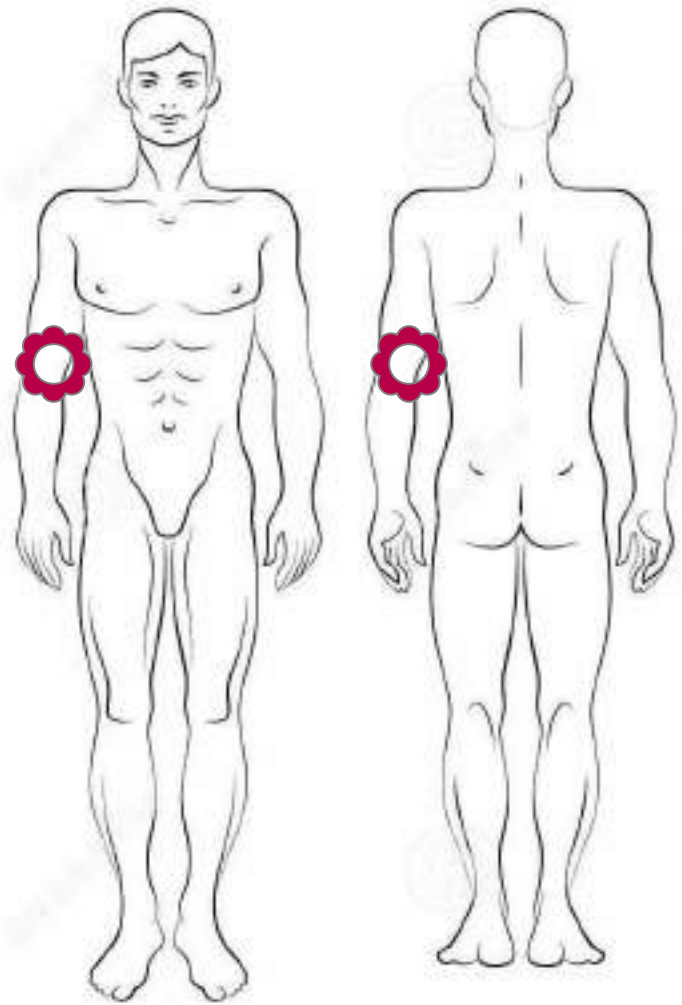


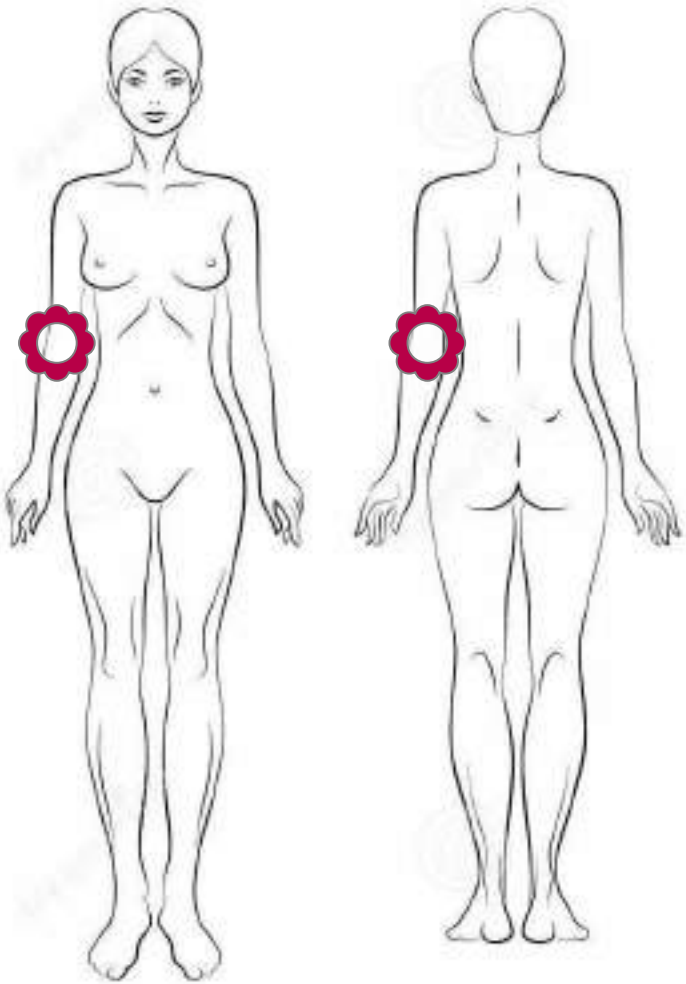
Blood



Coombs RW, Collier AC, Allain JP, Nikora B, Leuther M, Gjerset GF, Corey L. Plasma viremia in human immunodeficiency virus infection. N Engl J Med. 1989 Dec 14;321(24):1626–1631.

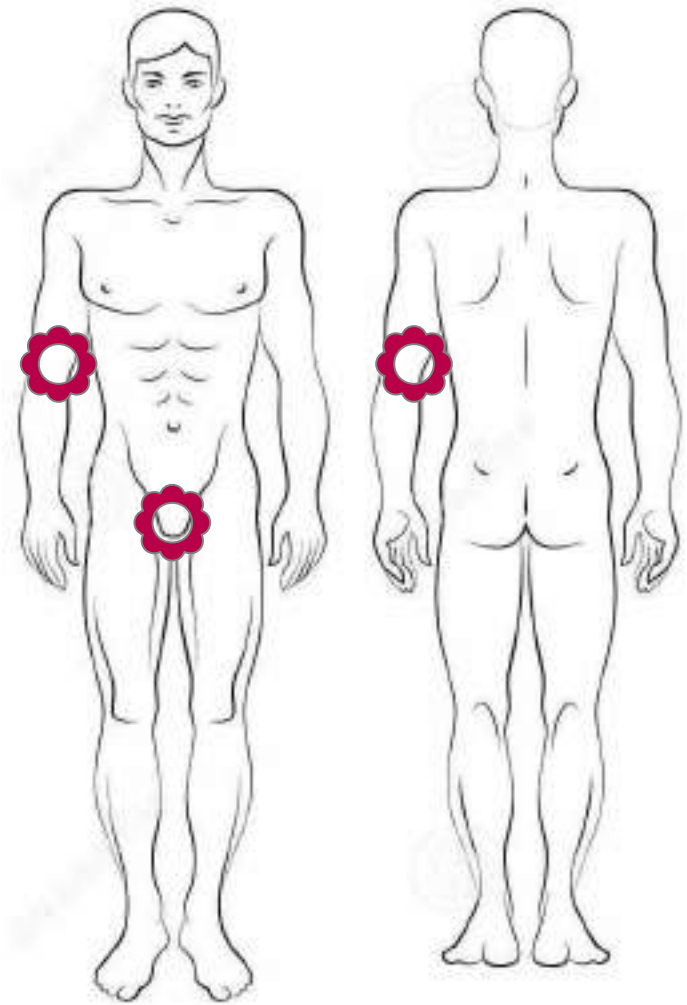
HIV transmission: the basics

Where can HIV be found?



Blood

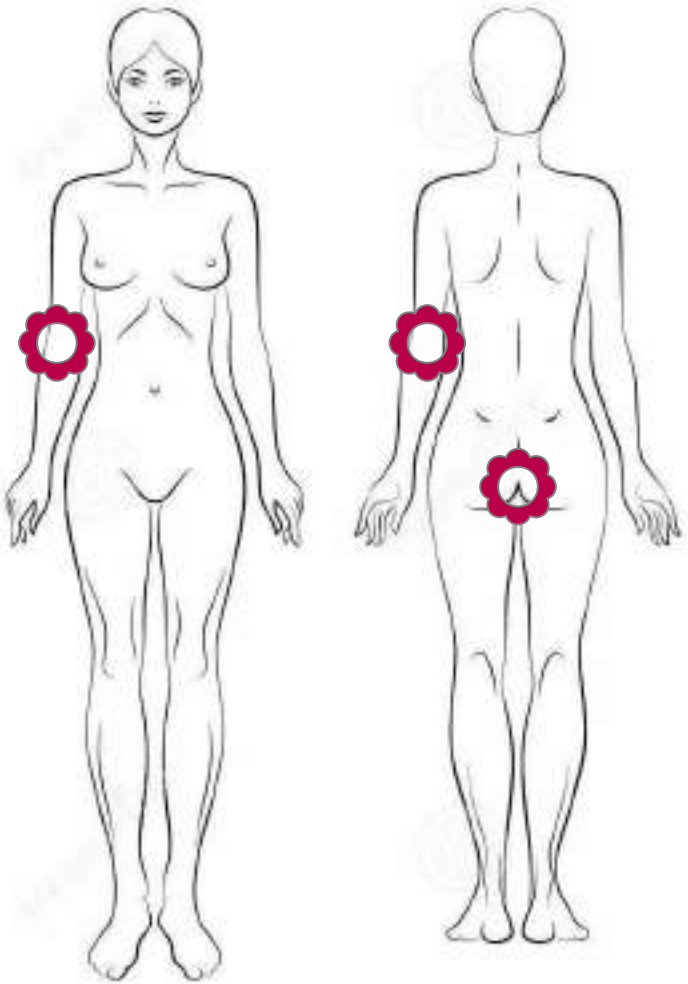
Semen



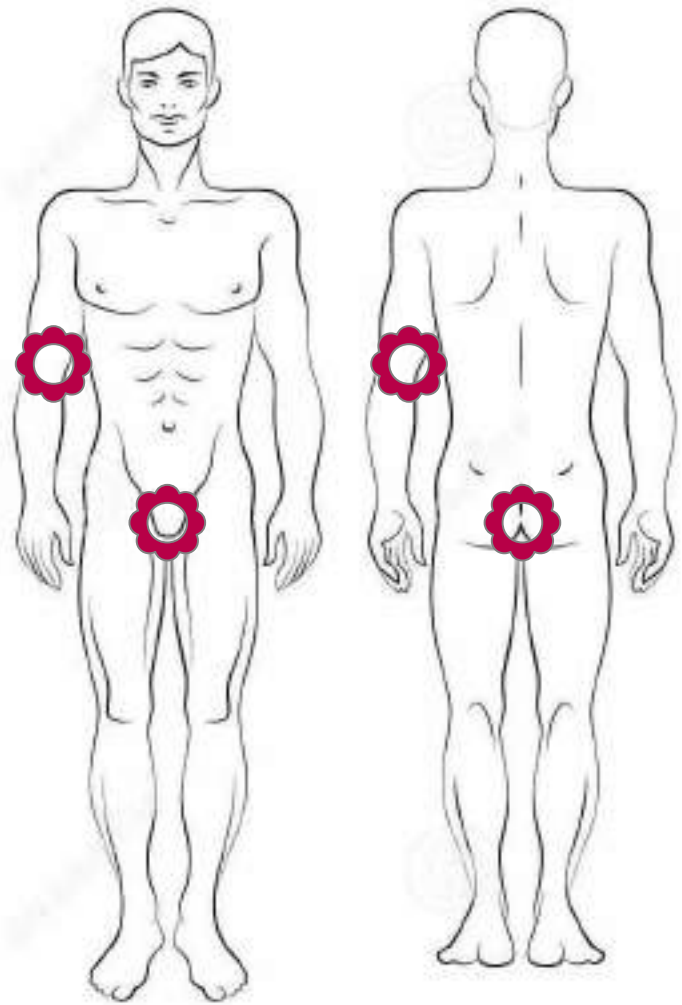
Vernazza PL, Eron JJ, Cohen MS, van der Horst CM, Troiani L, Fiscus SA. Detection and biologic characterization of infectious HIV-1 in semen of seropositive men. AIDS. 1994;8:1325–1329.

HIV transmission: the basics

Where can HIV be found?



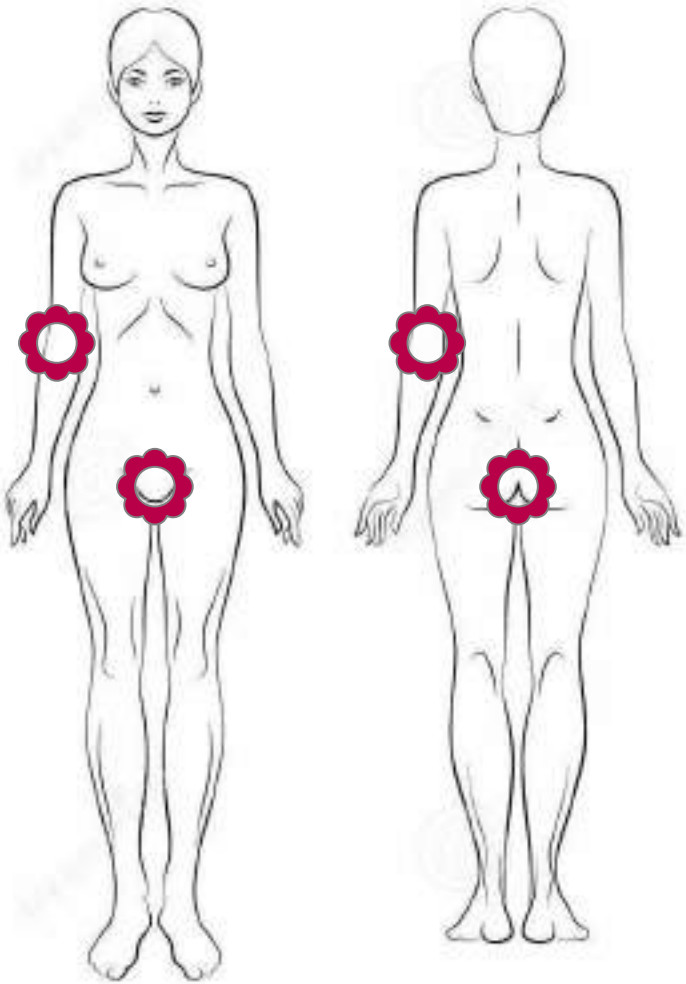
Blood
Semen
Rectal fluids



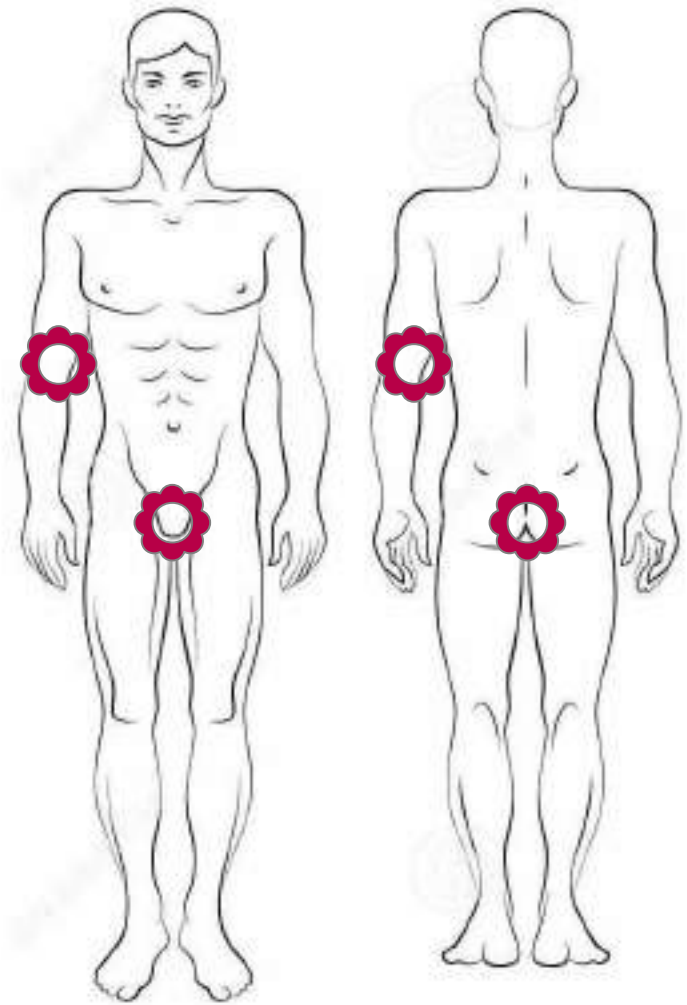
Gill MJ, Sutherland LR, Church DL, University of Calgary Gastrointestinal/HIV Study Group. Gastrointestinal tissue cultures for HIV in HIV-infected/AIDS patients. AIDS 1992;6:553–6.

HIV transmission: the basics

Where can HIV be found?



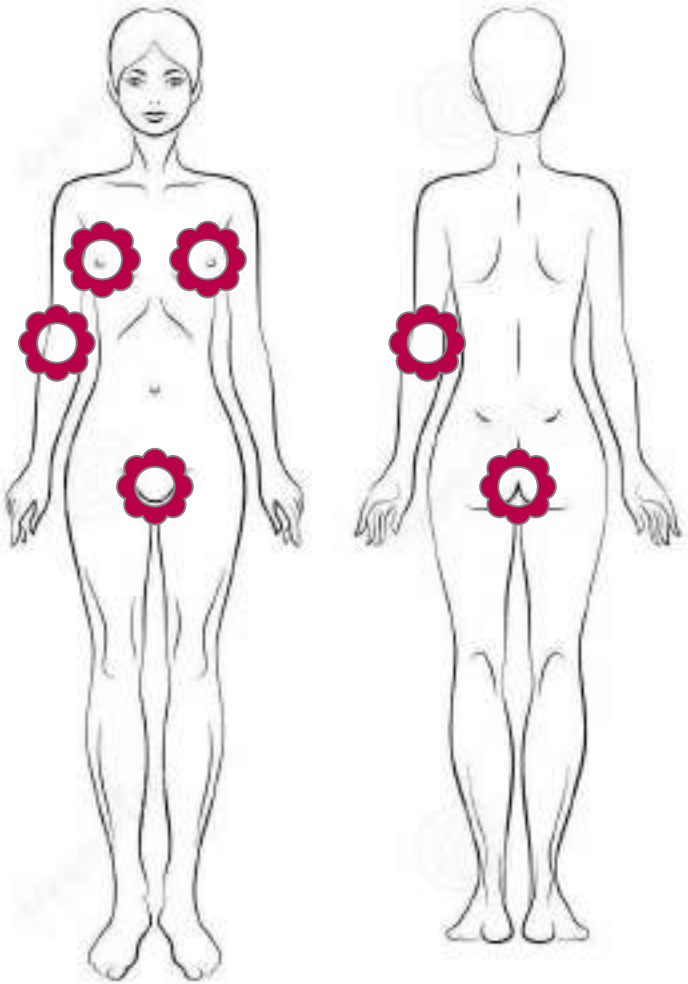
Blood
Semen
Rectal fluids
Vaginal fluids



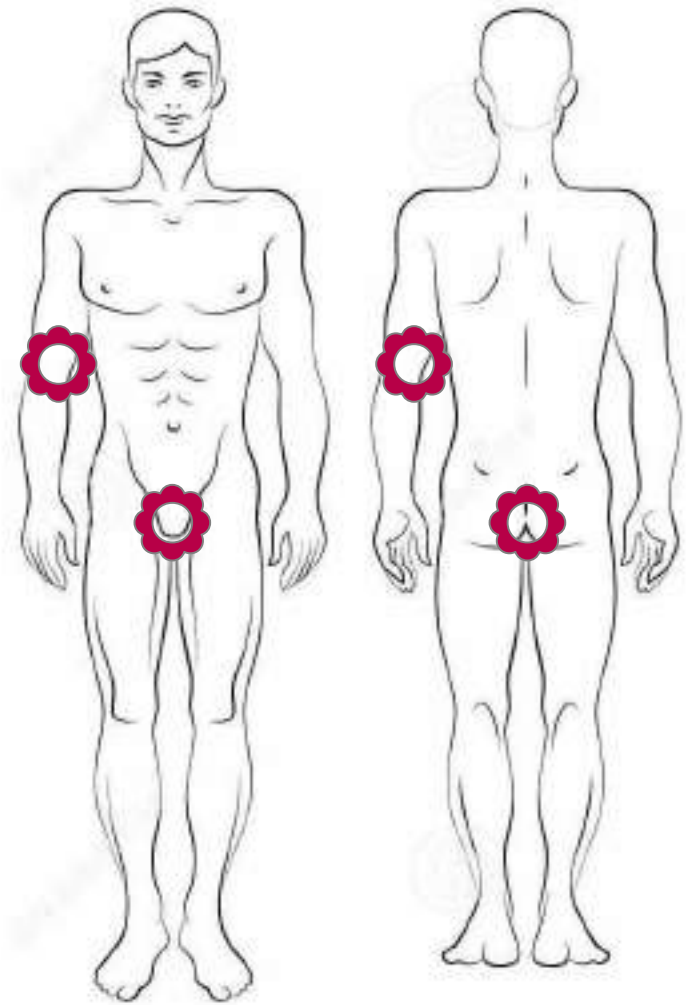
Wofsy CB, Cohen JB, Hauer LB, et al. Isolation of AIDS-associated retrovirus from genital secretions of women with antibodies to the virus. Lancet 1986;1:527–9.

HIV transmission: the basics

Where can HIV be found?



Blood
Semen
Rectal fluids
Vaginal fluids
Breast milk

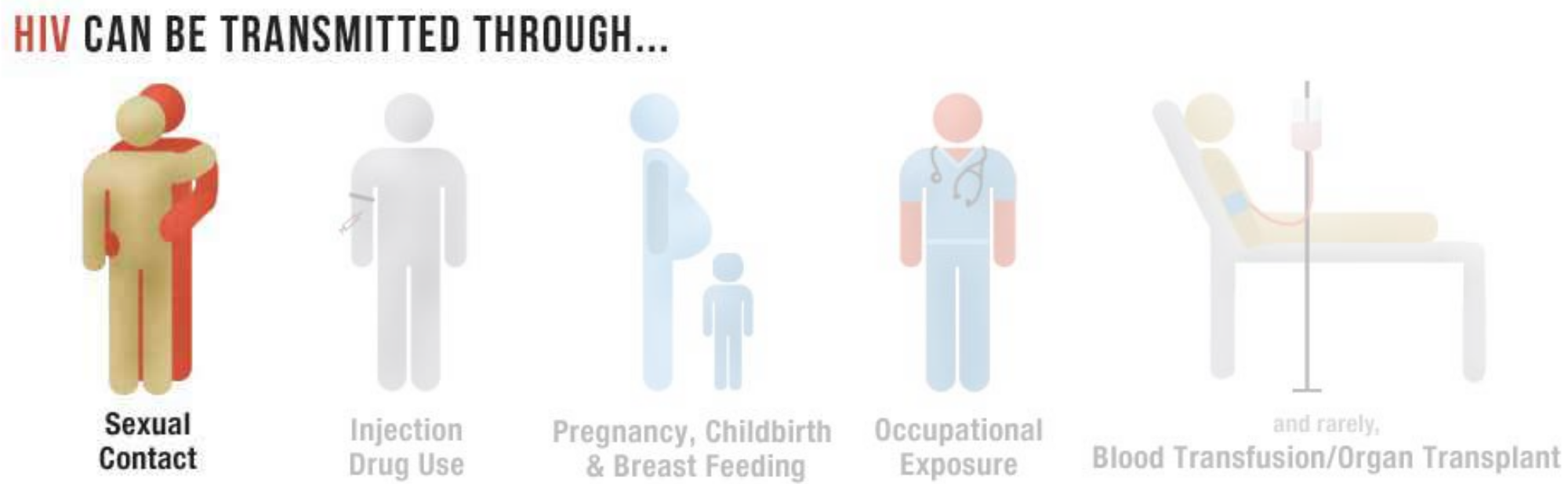


Thiry L, Sprecher-Goldberger S, Jonckheer T, et al. Isolation of AIDS virus from cell-free breast milk of three healthy virus carriers. Lancet. 1985;2:891–2

HIV transmission

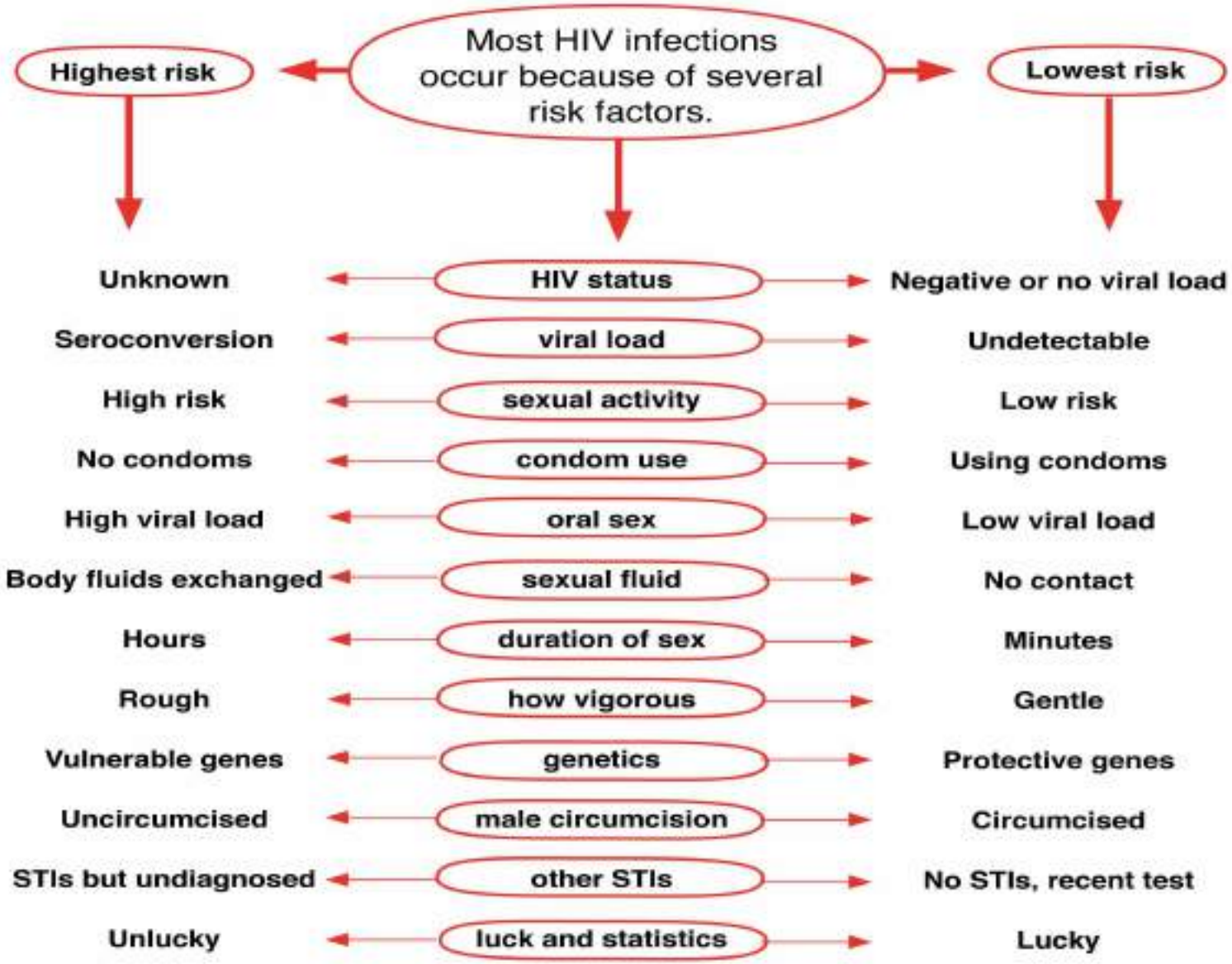
Source: AIDS.gov, How do you get HIV or AIDS?: https://www.aids.gov/hiv-aids-basics/hiv-aids-101/how-you-get-hiv-aids/ Accessed Sept. 2015

HIV sexual transmission



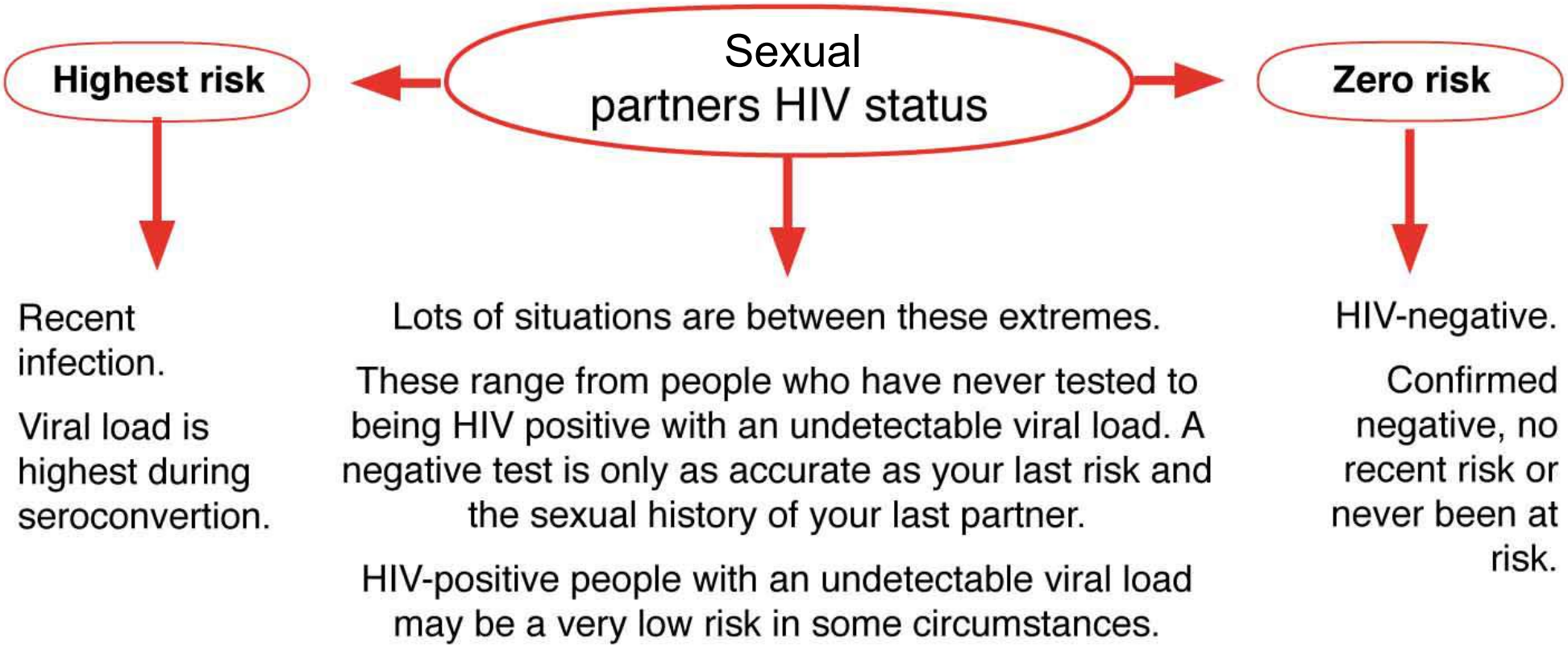
Source: AIDS.gov, How do you get HIV or AIDS?: https://www.aids.gov/hiv-aids-basics/hiv-aids-101/how-you-get-hiv-aids/ Accessed Sept. 2015

HIV sexual transmission: the risk



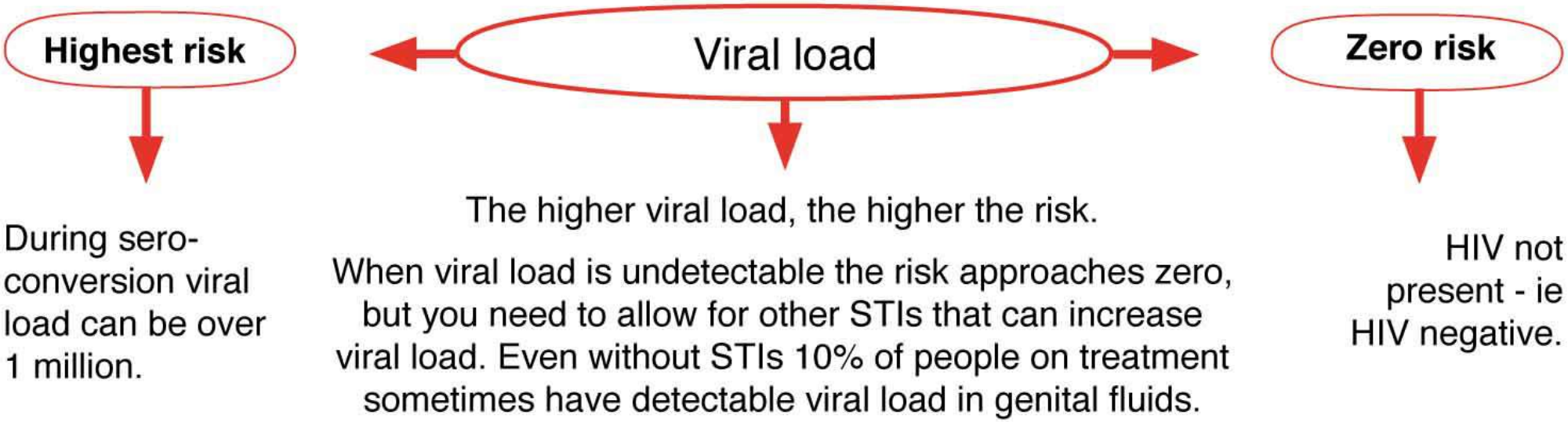
Source: i-Base, Guide to HIV testing and risks of sexual transmission 2013:http://i-base.info/guides/wp-content/uploads/2013/01/Testing-and-transmission-guide-2013.pdf Accessed Sept. 2015

Risk of HIV sexual transmission according to partner HIV status



Source: i-Base, Guide to HIV testing and risks of sexual transmission 2013:http://i-base.info/guides/wp-content/uploads/2013/01/Testing-and-transmission-guide-2013.pdf Accessed Sept. 2015

Risk of HIV sexual transmission according to HIV viral load



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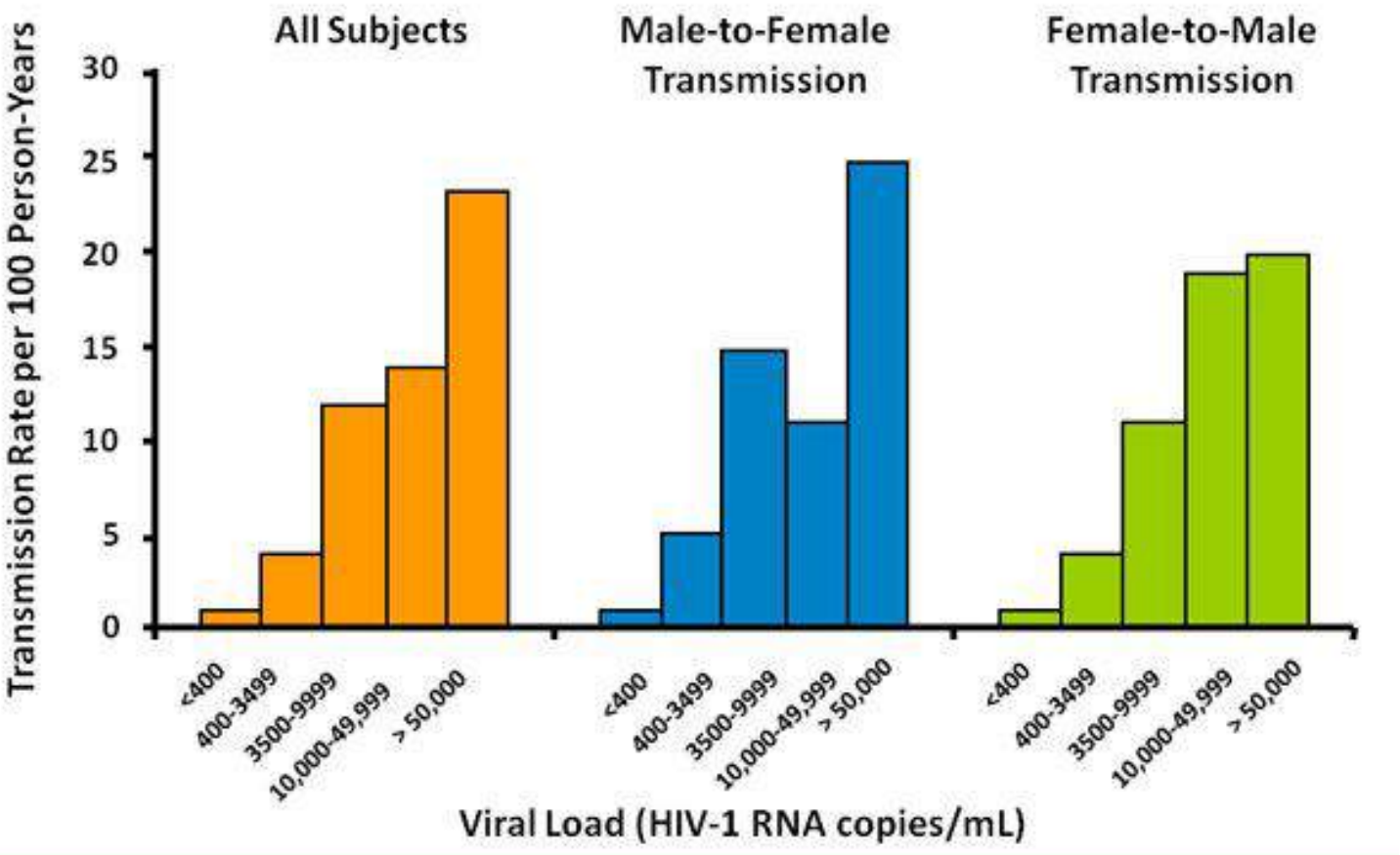

Source: Quinn TC, Wawer MJ, Sewankambo N, et al. Viral load and heterosexual transmission of human immunodeficiency virus type 1. N Engl J Med. 2000;342:921-929. Figure from Susan P. Buchbinder, MD. ART to Prevent Sexual Transmission of HIV: Expert Insights by Susan P. Buchbinder, MD, Medscape Education HIV/AIDS

Terapia come prevenzione (TasP) – La dichiarazione svizzera (2008)

Les personnes séropositives ne souffrant d'aucune autre MST et suivant un traitement antirétroviral efficace ne transmettent pas le VIH par voie sexuelle

Pietro Vernazza[a], *Bernard Hirschel*[b], *Enos Bernasconi*[c], *Markus Flepp*[d]

Commission fédérale pour les problèmes liés au sida (CFS), Commission d'experts clinique et thérapie VIH et sida de l'Office fédéral de la santé publique (OFSP)

a Prof. Dr méd., président de la Commission fédérale pour les problèmes liés au sida (CFS) et responsable de la Division des mala-

Après avoir pris connaissance des faits scientifiques, à la demande de la Commission d'experts clinique et thérapie VIH et sida (CCT) de l'Office fédéral de la santé publique (OFSP) et après avoir longuement délibéré, la Commission fédérale pour les problèmes liés au sida (CFS) arrive à la conclusion suivante:

Une personne séropositive ne souffrant d'aucune autre MST et suivant un traitement antirétroviral (TAR) avec une virémie entièrement supprimée (condition désignée par «TAR efficace» ci-après) ne transmet pas le VIH par voie

prouvent pas qu'un TAR efficace *empêche* toute infection au VIH (en effet, il n'est pas possible de prouver la non-survenance d'un événement certes improbable, mais théoriquement envisageable). Reste que du point de vue de la CFS et des organisations concernées, les informations disponibles à ce jour sont suffisantes pour justifier ce message. La situation est comparable à celle de 1986, lorsqu'il a été communiqué publiquement que le VIH ne se transmet pas par un baiser avec la langue. Si cette constatation n'a jamais pu être prouvée, plus de vingt années d'expérience du VIH ont néanmoins permis d'étayer sa forte plau-

Source: Vernazza P, Hirschel B, Bernasconi E, Flepp MSchweizerische Ärztezeitung | Bulletin des médecins suisses | Bollettino dei medici svizzeri | 2008;08:05:165-169

Terapia come prevenzione (TasP) – La dichiarazione svizzera (2008)

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EPIDEMIOLOGY

Swiss statement that 'undetectable equals uninfectious' creates more controversy in Mexico City

Edwin J. Bernard

Published: 05 August 2008

Nikos Dedes, European AIDS Treatment Group (EATG)

- Non ci considereremo più una minaccia costante per gli altri
- Aiuta a rimuovere la paura della trasmissione quando si rompe il preservativo
- Contribuisce a ridurre lo stigma e la discriminazione
- Permette alle persone con HIV di riottenere il diritto a una esperienza di piacere sessuale senza inibizioni

Source:Edwin J. Bernard, Swiss statement that 'undetectable equals uninfectious' creates more controversy in Mexico City, AidsMap 5 August 2008, http://www.aidsmap.com/Swiss-statement-that-undetectable-equals-uninfectious-creates-more-controversy-in-Mexico-City/page/1431075/

Risk of HIV sexual transmission according to HIV viral load

Partner Infections (ITT)

	April 2005-May 2011			May 2011-May 2015			Overall		
	PY f/u	All partner infections # (rate)	Linked partner infections# (rate)	PY f/u	All partner infections # (rate)	Linked partner infections # (rate)	PY f/u	All partner infections # (rate)	Linked partner infections # (rate)
Total	3482	46 (1.32)	37 (1.06)	5012	32 (0.64)	9 (0.18)	8494	78 (0.92)	46 (0.54)
Early arm	1751	4 (0.23)	1 (0.06)	2563	15 (0.59)	2 (0.08)	4314	19 (0.44)	3 (0.07)
Delayed arm	1731	42 (2.43)	36 (2.08)	2449	17 (0.69)	7 (0.29)	4180	59 (1.41)	43 (1.03)
Rate ratio		0.09	0.03		0.86	0.28		0.31	0.07
Risk reduction		**91%**	**97%**		**14%**	**72%**		**69%**	**93%**

Rate = # of events/ 100 PY
Risk reduction = 1 – rate ratio

Linked = index to partner transmission

Source: Cohen M & the HPTN 052 study team, *Antiretroviral Treatment Prevents HIV Transmission: Final Results from the HPTN 052 Randomized Controlled Trial, 8th IAS Conference on HIV Pathogenesis, Treatment, and Prevention Vancouver, Canada, July 20, 2015*

Terapia come prevenzione (TasP) – studio HPTN 052

Table 2. Characteristics of Eight Linked Partner Infections Diagnosed after the Index Participant Initiated ART.*

Case	Age at ART Initiation		Index Viral Suppression 6 Mo after ART Initiation†	No. of Days before or after ART Initiation‡				No. of Days between Last Measure of Index Viral Load and Estimated Infection Date	Last Index Viral Load before Estimated Infection Date
	Index Participant	Partner		ART Failure§	Partner's Last Negative HIV-1 Test	Partner's First Positive HIV-1 Test	Estimated Infection Date (95% CI)¶		
	yr								*copies/ml*
A	43	52	Yes	NA	−35	35	−5 (−18 to 10)	34	278,398
B	24	24	Yes	NA	−1	84	0 (−32 to 19)	1	87,202
C	50	54	Yes	NA	0	59	5 (−4 to 22)	5	48,316
D	34	34	No	261	−42	49	4	4	>750,000
E	25	29	No	208	1019	1106	1062	43	65,128
F	30	22	Yes	441	1617	1716	1667	50	617
G	46	26	No	362	2095	2228	2162	67	43,486
H	28	19	No	891	860	1419	1140	ND‖	ND‖

Source: Cohen M & the HPTN 052 study team, *Antiretroviral Treatment Prevents HIV Transmission: Final Results from the HPTN 052 Randomized Controlled Trial, 8th IAS Conference on HIV Pathogenesis, Treatment, and Prevention Vancouver, Canada, July 20, 2015*

Terapia come prevenzione (TasP) – studio PARTNER

PARTNER

Studio ossservazionale (nessuna procedura speciale)

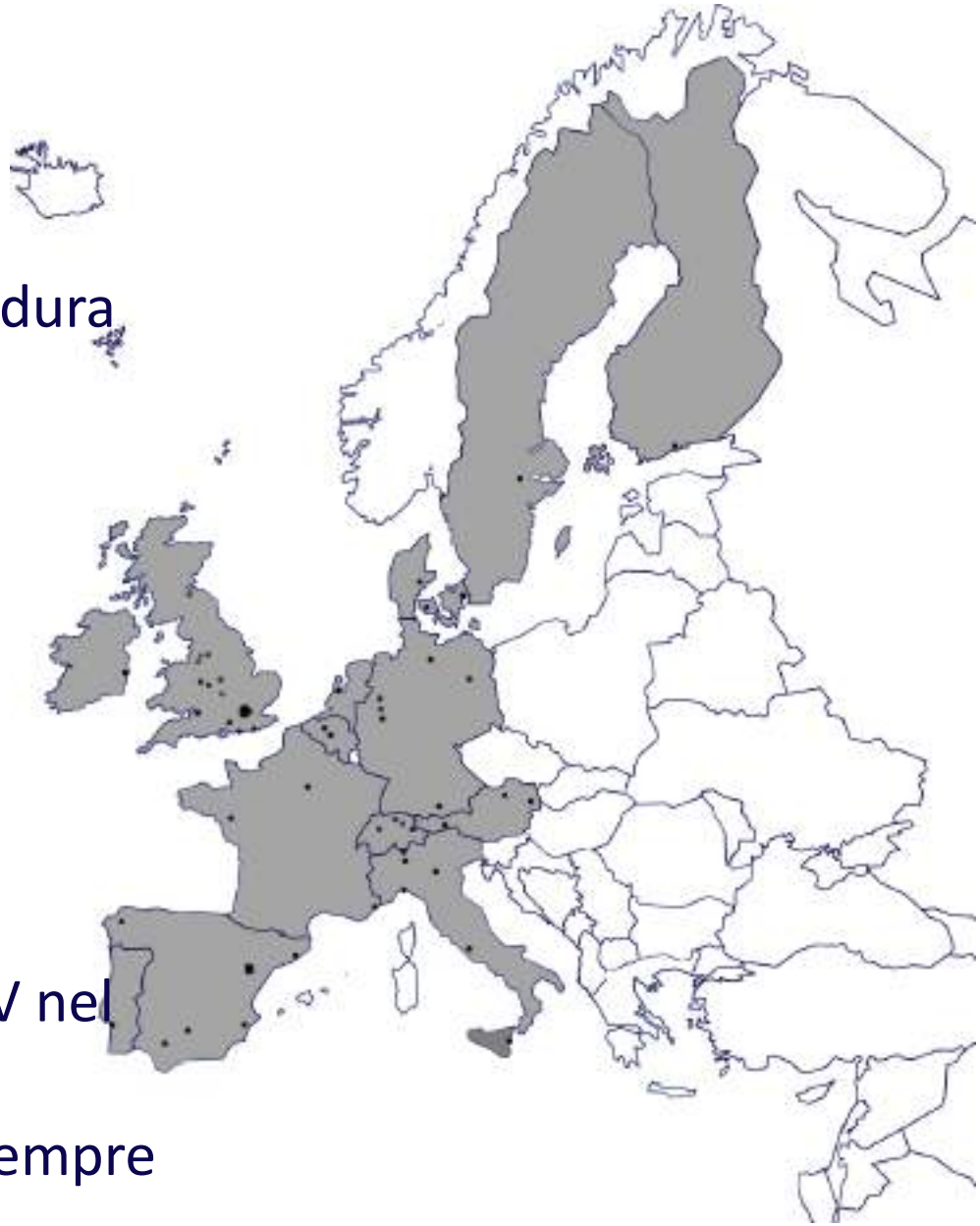
Coppie gay in cui un partner è HIV+ in terapia, l'altro HIV-

In autonomia, fanno sesso anale senza usare sempre i preservativi

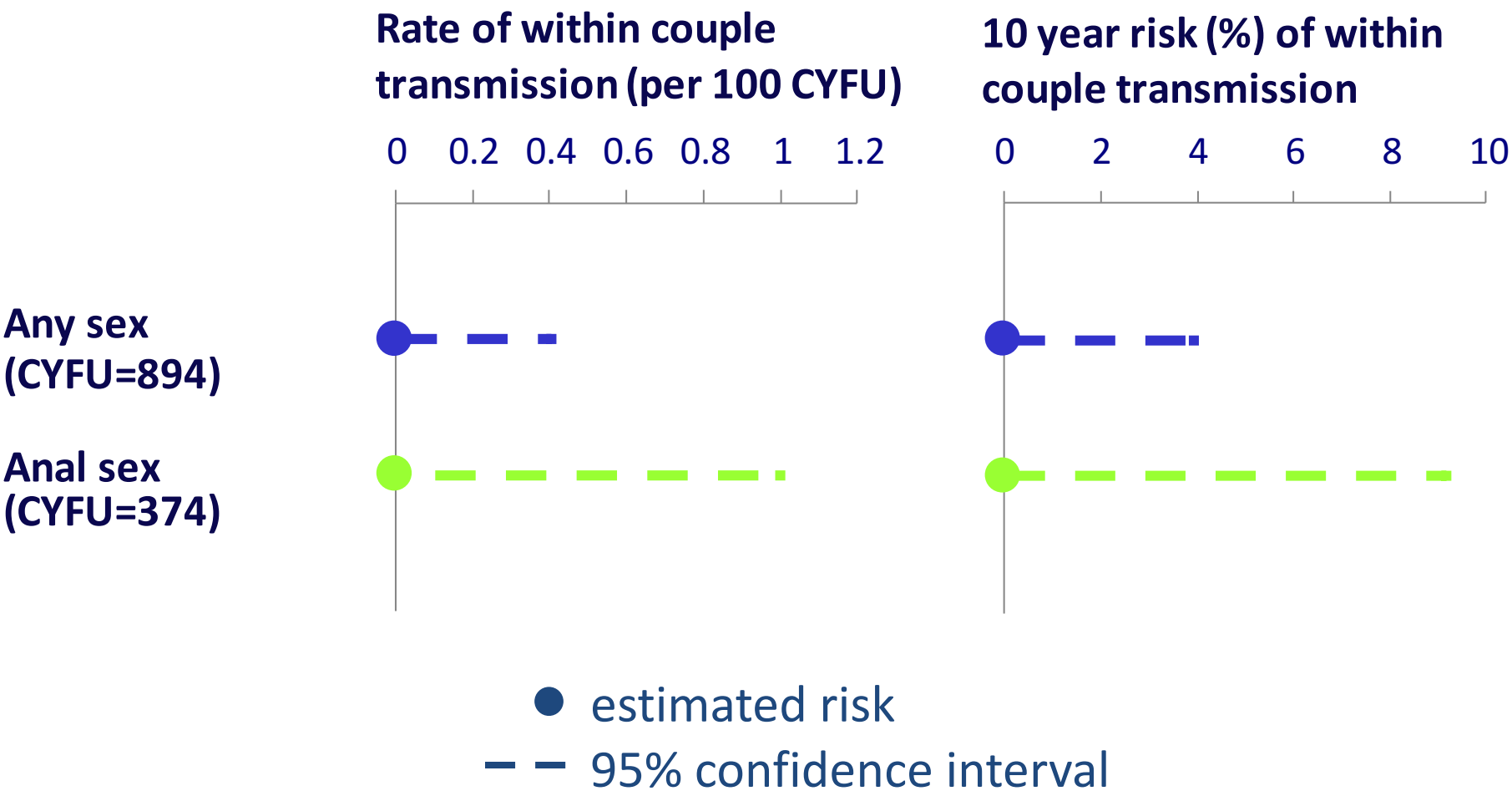
75 centri in Europa

Obiettivo

Valutare il rischio di trasmissione di HIV nel sesso anale da partner HIV+ in terapia quando i condom non vengono usati sempre



Terapia come prevenzione (TasP) – studio PARTNER

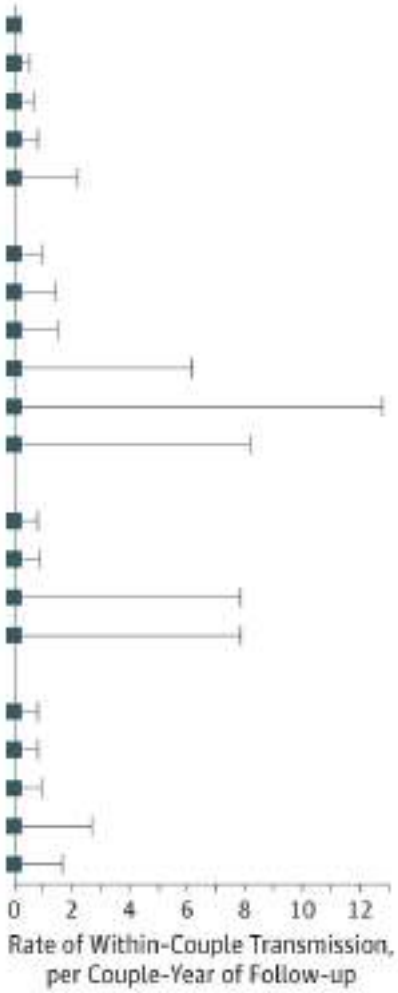


PARTNER

Terapia come prevenzione (TasP) – studio PARTNER

Figure 1. Rate of HIV Transmission According to Sexual Behavior Reported by the HIV-Negative Partner

	HIV-Negative Members of Eligible Couples Reporting Specific Sex Act, No./Total (%)	Couple-Years of Follow-up	Upper 95% Confidence Limit
All			
Any sex	863/866 (99.7)	1238	0.30
Vaginal sex	532/878 (60.6)	629	0.59
Anal sex	449/849 (52.9)	522	0.71
Insertive anal sex	363/862 (42.1)	417	0.88
Receptive anal sex with ejaculation	185/864 (21.4)	166	2.23
Heterosexual women			
Any sex	261/262 (99.6)	381	0.97
Vaginal sex with ejaculation	193/259 (74.5)	246	1.50
Vaginal sex without ejaculation	207/257 (80.5)	238	1.55
Anal sex	61/256 (23.8)	60	6.16
Receptive anal sex with ejaculation	37/255 (14.5)	29	12.71
Receptive anal sex without ejaculation	55/253 (21.7)	45	8.14
Heterosexual men			
Any sex	272/274 (99.3)	418	0.88
Vaginal sex	271/275 (98.5)	383	0.96
Anal sex	60/264 (22.7)	47	7.85
Insertive anal sex	60/264 (22.7)	47	7.85
Men who have sex with men			
Any sex	330/330 (100)	439	0.84
Anal sex	328/329 (99.7)	415	0.89
Insertive anal sex	303/329 (92.1)	370	1.00
Receptive anal sex with ejaculation	148/329 (45.0)	137	2.70
Receptive anal sex without ejaculation	217/324 (67.0)	220	1.68



PARTNER

Risk of HIV sexual transmission according to sexual activity

Source: i-Base, Guide to HIV testing and risks of sexual transmission 2013:http://i-base.info/guides/wp-content/uploads/2013/01/Testing-and-transmission-guide-2013.pdf Accessed Sept. 2015

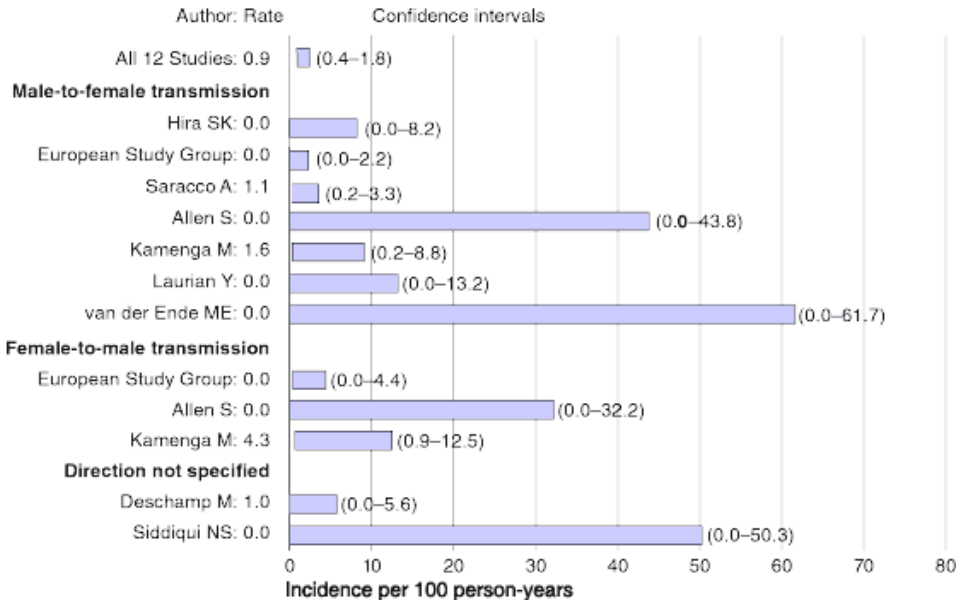
Risk of HIV sexual transmission according to type of sex

Type of sex	Risk of HIV transmission per exposure	Ref.
Receptive oral sex	0 – 0.04 %	Risk of Oral Acquisition of HIV Infection and oral behavior Among men Who Exclusively Practice Oral sex in San Francisco, CA. Page-Shafer K; Shiboski C; Dilley J; Balls J and al. 2001 National HIV prevention Conf., August 12-15, 2001 Atlanta. Abstract 975. Review of the evidence on Risk of HIV Transmission associated with oral Sex. The report of a Working group of the UK Chief Medical Officers' Expert Advisory Group on AIDS. 12 June 2000 In: http://www.doh.gov.uk/eaga [visit:02/18/2002]
Insertive vaginal sex	≤ 0.01 %	Vittinghoff E, Douglas J, Judson F, McKirnan D, MacQueen K, Buchbinder SP. Per-contact risk of human immunodeficiency virus transmission between male sexual partners. Am J Epidemiol. 1999 Aug 1;150(3):306-11. Keet IP, Albrecht van Lent N, Sandfort TG, Coutinho RA, van Griensven GJ. Orogenital sex and the transmission of HIV among homosexual men. AIDS. 1992 Feb;6(2):223-6. Downs AM, De Vincenzi I. Probability of heterosexual transmission of HIV: relationship to the number of unprotected sexual contacts. European Study Group in Heterosexual Transmission of HIV. J Acquir Immune Defic Syndr Hum Retrovirol. 1996 Apr 1;11(4):388-95 De Gruttola V, Fineberg HV. Estimating prevalence of HIV infection: considerations in the design and analysis of a national seroprevalence survey. J Acquir Immune Defic Syndr. 1989;2(5):472-80.
Insertive anal sex	≤ 0.01 %	
Receptive vaginal sex	0.01 – 0.15 %	Vittinghoff E, Douglas J, Judson F, McKirnan D, MacQueen K, Buchbinder SP. Per-contact risk of human immunodeficiency virus transmission between male sexual partners. Am J Epidemiol. 1999 Aug 1;150(3):306-11. Downs AM, De Vincenzi I. Probability of heterosexual transmission of HIV: relationship to the number of unprotected sexual contacts. European Study Group in Heterosexual Louria DB, et al. HIV heterosexual transmission: a hypothesis about an additional potential determinant. Int J Infect Dis. 2000;4(2):110-6. Royce R, Sena A, Cates W Jr, Cohen MS. Sexual transmission of HIV. N Engl J Med. 1997 Apr 10;336(15):1072-8.
Receptive anal sex	≤ 3 %	Review of the evidence on Risk of HIV Transmission associated with oral Sex. The report of a Working group of the UK Chief Medical Officers' Expert Advisory Group on AIDS. 12 June 2000 In: http://www.doh.gov.uk/eaga [visit:02/18/2002] De Gruttola V, Fineberg HV. Estimating prevalence of HIV infection: considerations in the design and analysis of a national seroprevalence survey. J Acquir Immune Defic Syndr. 1989;2(5):472-80. Royce R, Sena A, Cates W Jr, Cohen MS. Sexual transmission of HIV. N Engl J Med. 1997 Apr 10;336(15):1072-8.

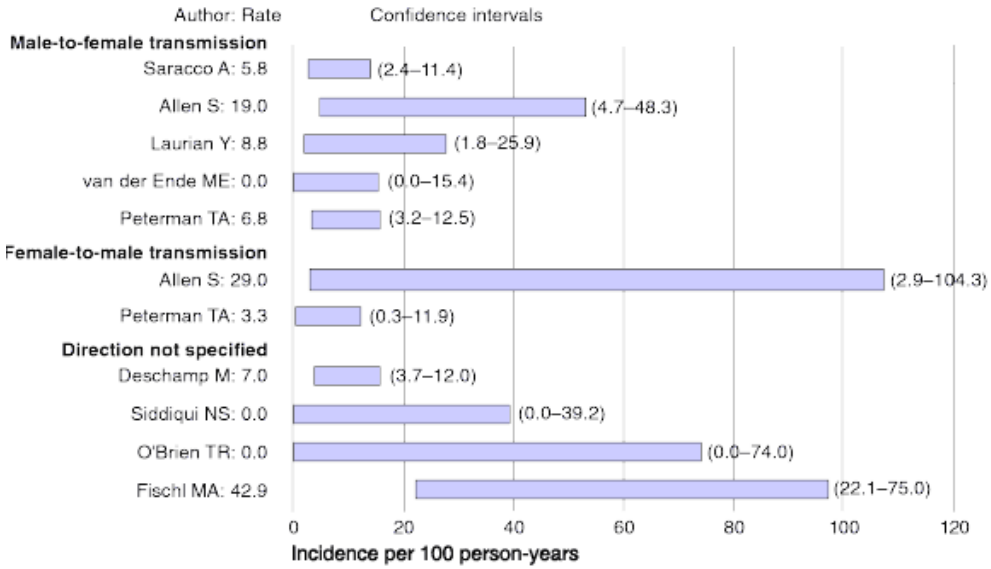
Source: Almeda J, Casabona Barbarà J, Simon B, Gérard M, Rey D, Puro V, Thomas T. Proposed recommendations for the management of HIV post-exposure prophylaxis after sexual, injecting drug or other exposures in Europe. Euro Surveill. 2004;9(6):pii=471. Available online: http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=471

Risk of HIV sexual transmission according to condom use

HIV incidence rates and confidence intervals for always-users, by study



HIV incidence rates and confidence intervals for never-users, by study

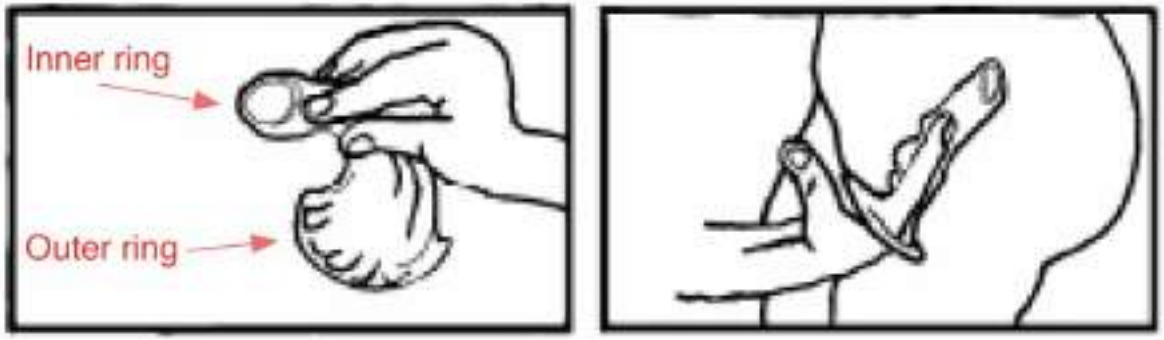


"The overall estimate of condom effectiveness for HIV prevention is 86.6%, but true effectiveness may be between 60.0 and 95.8%."

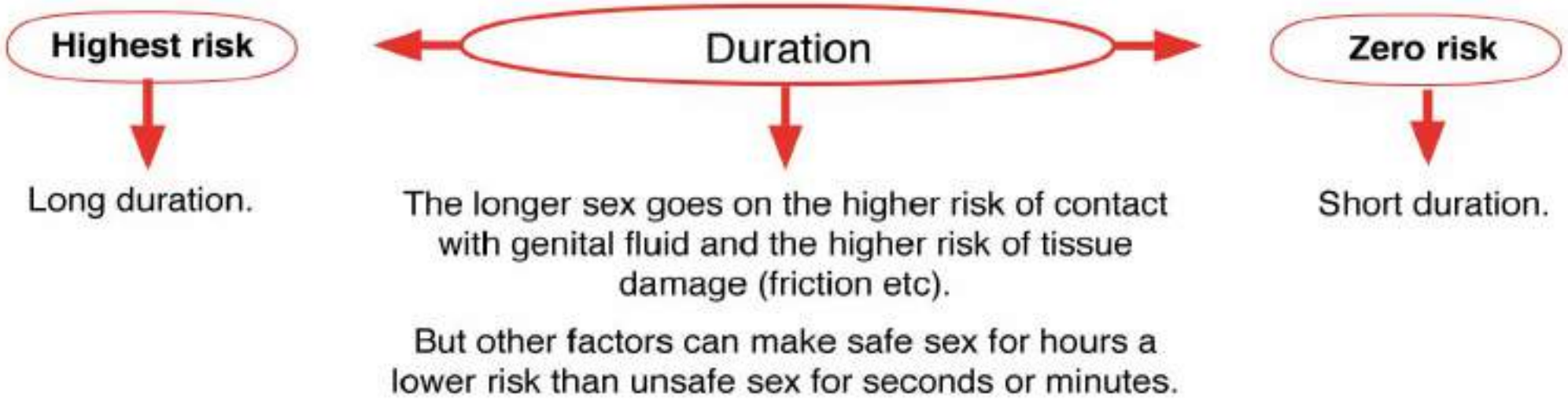
Source: Karen R. Davis and Susan C. Weller. The Effectiveness of Condoms in Reducing Heterosexual Transmission of HIV. Family Planning Perspectives. Volume 31, Number 6, November/December 1999

Female condoms

Female condoms

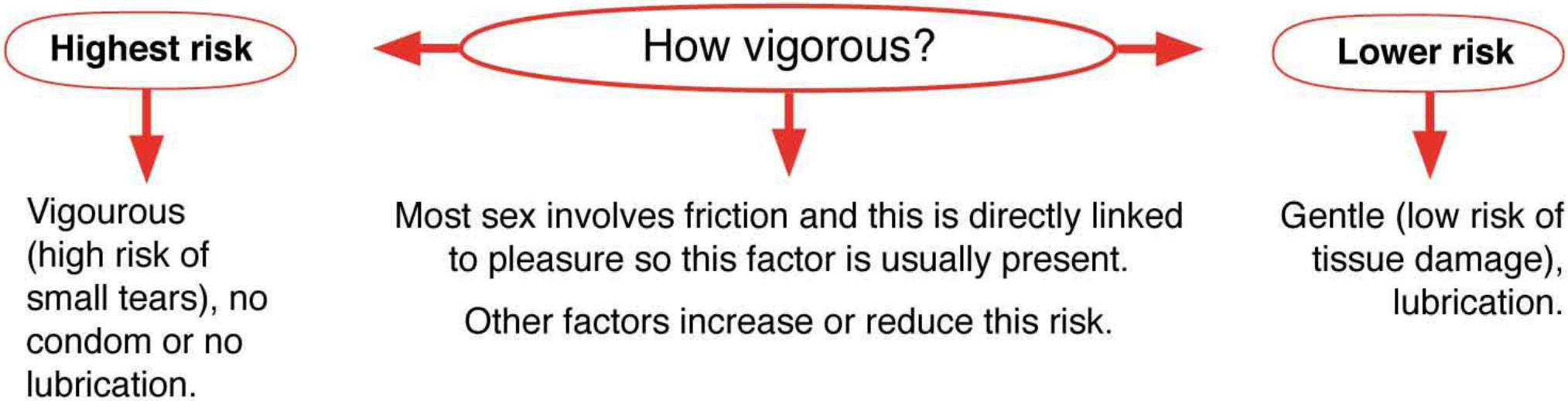


Risk of HIV sexual transmission according to the duration of sex



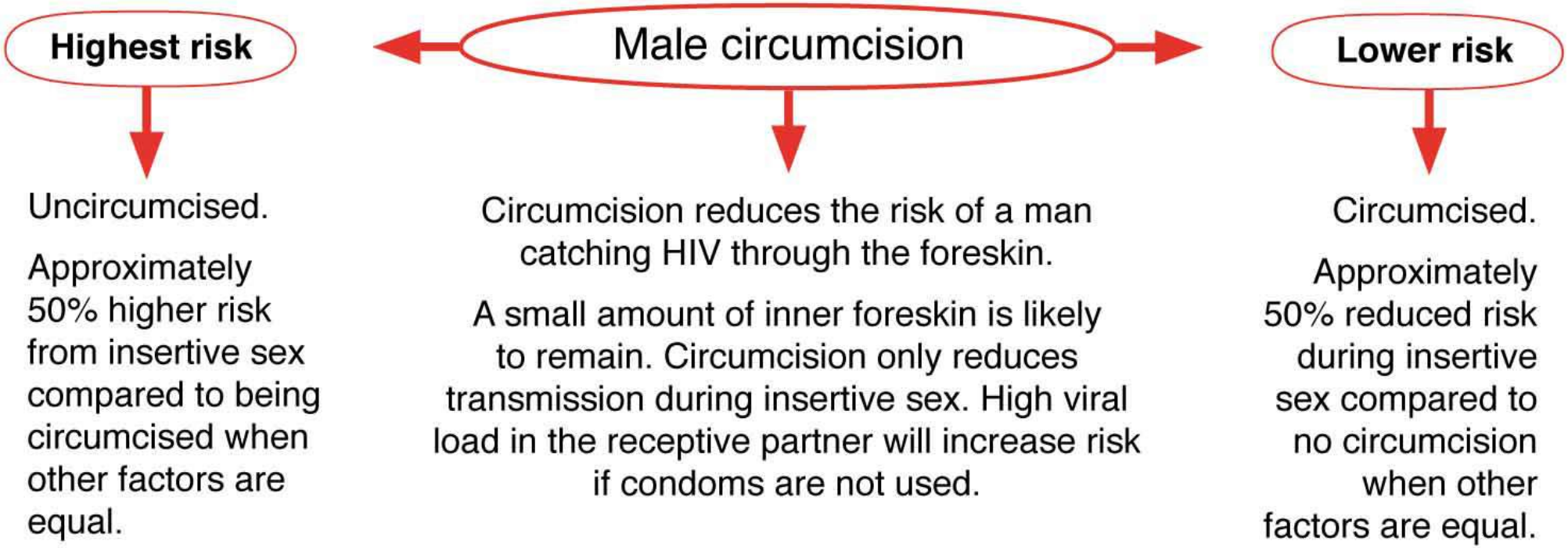
Source: i-Base, Guide to HIV testing and risks of sexual transmission 2013:http://i-base.info/guides/wp-content/uploads/2013/01/Testing-and-transmission-guide-2013.pdf Accessed Sept. 2015

Risk of HIV sexual transmission according to vigorousness of sex



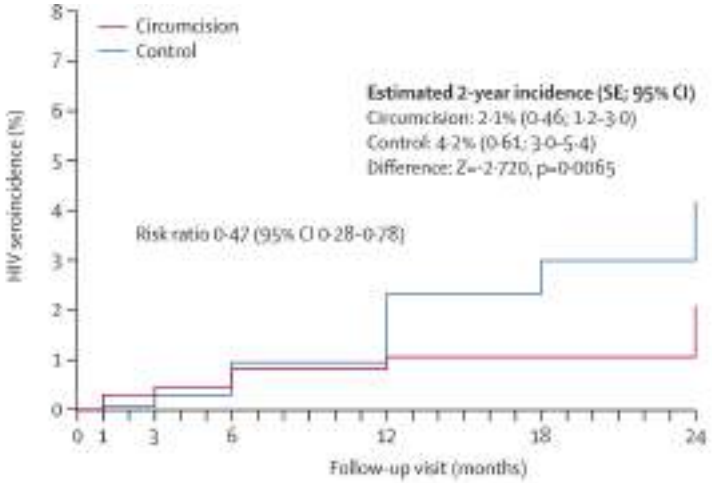
Source: i-Base, Guide to HIV testing and risks of sexual transmission 2013:http://i-base.info/guides/wp-content/uploads/2013/01/Testing-and-transmission-guide-2013.pdf Accessed Sept. 2015

Risk of HIV sexual transmission according to male circumcision

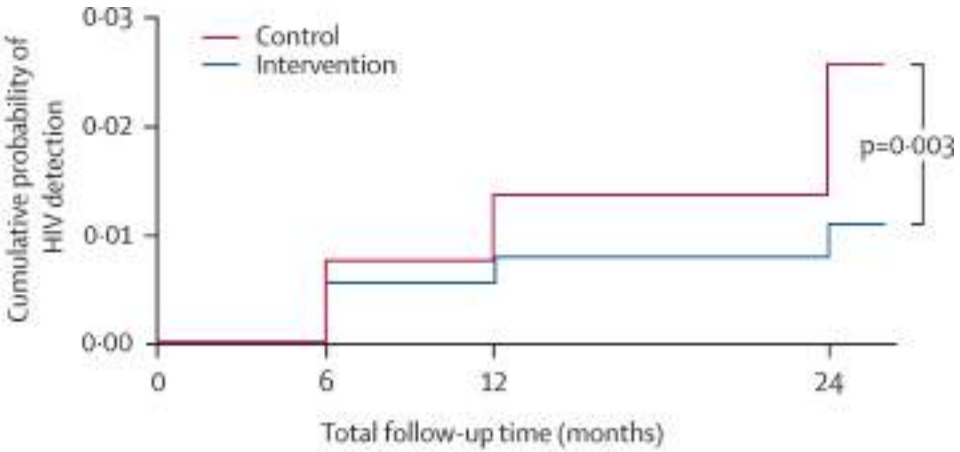


Source: i-Base, Guide to HIV testing and risks of sexual transmission 2013:http://i-base.info/guides/wp-content/uploads/2013/01/Testing-and-transmission-guide-2013.pdf Accessed Sept. 2015

Risk of HIV sexual transmission according to male circumcision



Circumcision (n=1391)						
Number at risk	1367	1351	1323	1287	1029	764
Number HIV positive	4	2	5	3	0	8 (22 total)
Control (n=1393)						
Number at risk	1380	1368	1350	1302	1035	740
Number HIV positive	1	3	9	18	7	9 (47 total)

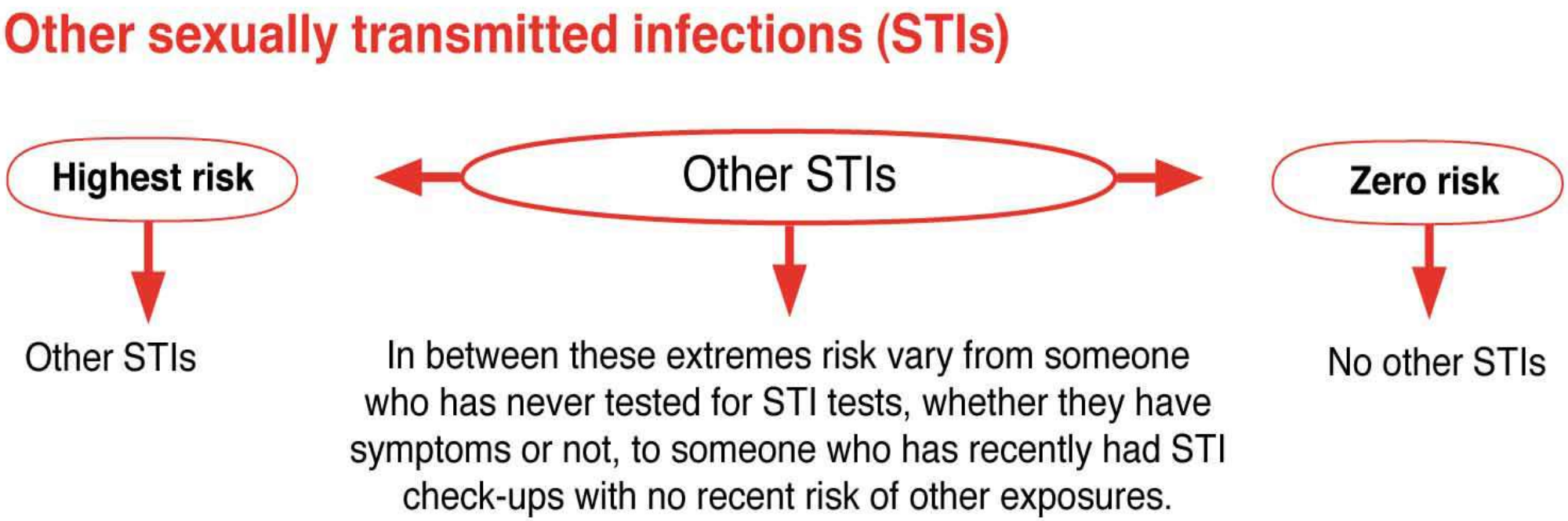


Cases of HIV/total participants				
Intervention	0/2474	14/2387	5/2274	3/964
Control	0/2522	19/2430	14/2279	12/980

Bailey C, Moses S, Parker CB, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomized controlled trial. Lancet 2007;369: 643-56.

Gray H, Kigozi G, Serwadda D, et al. Male circumcision for HIV prevention in young men in Rakai, Uganda: a randomized trial. Lancet 2007;369:657-66.

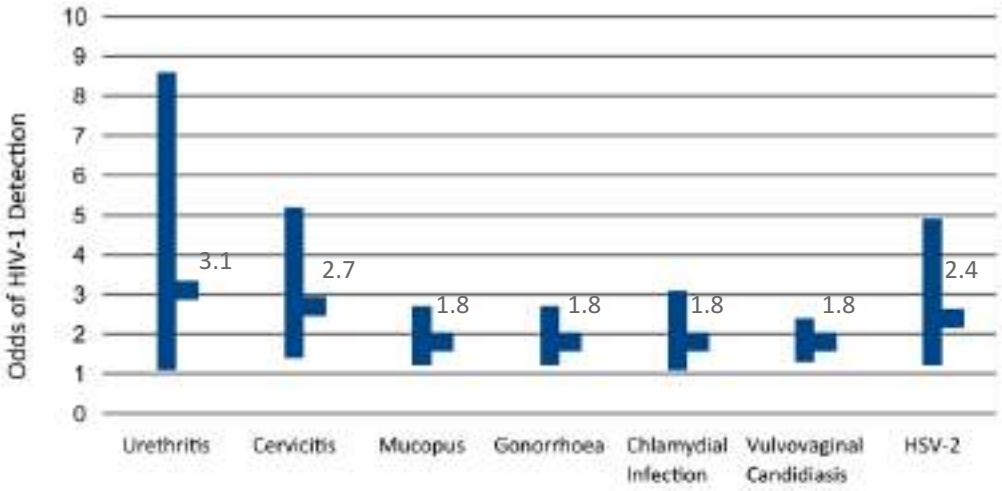
Risk of HIV sexual transmission according to the presence of STIs



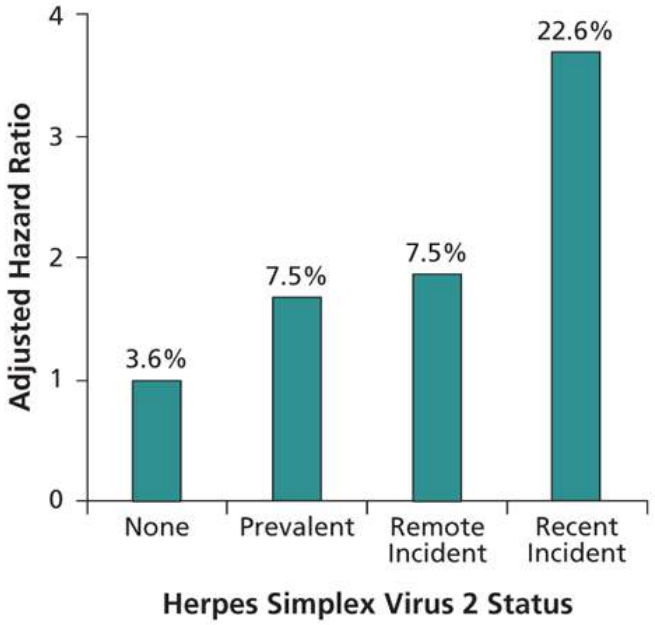
Source: i-Base, Guide to HIV testing and risks of sexual transmission 2013:http://i-base.info/guides/wp-content/uploads/2013/01/Testing-and-transmission-guide-2013.pdf Accessed Sept. 2015

Risk of HIV sexual transmission according to the presence of STIs

Effect of genital tract infections on HIV-1 shedding in the genital tract



Risk of acquiring HIV-1 by herpes simplex virus type 2 (HSV-2) infection status



Johnson LF, Lewis DA. The effect of genital tract infections on HIV-1 shedding in the genital tract: a systematic review and meta-analysis. Sexually Transmitted Diseases. 2008 Nov;35(11):946-59.

Reynolds et al, J Infect Dis, 2003. Figure adapted by Cohen M, HIV and Sexually Transmitted Diseases: Lethal Synergy

HIV prevention: using ART

Pre-exposure Prophylaxis – **PrEP**

- For HIV negative people at high risk of acquiring HIV
- Taking Truvada before exposure to be protected against infection
- Effective in recent trials
- Only available in the USA, Canada
- Implementation challenges
- See specific lesson

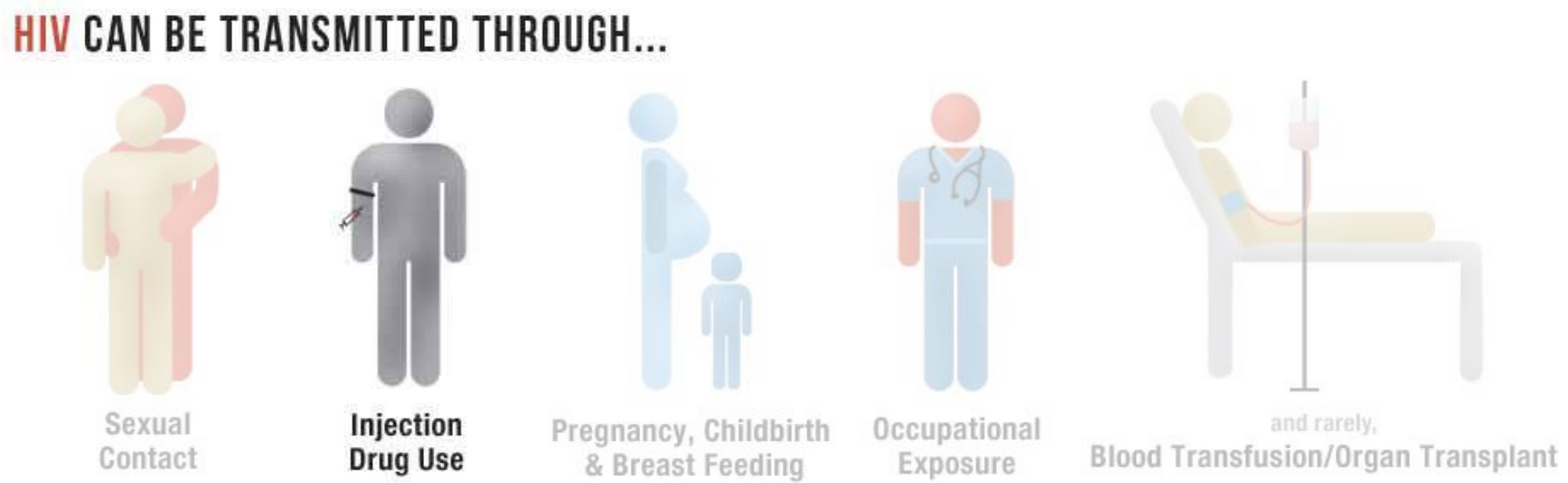
Post-exposure Prophylaxis – **PEP**

- For HIV negative people exposed to HIV
- Need to be initiated soon after exposure (maximum 72 hours)
- Taking an antiretroviral regimen for 28 days to avoid establishment of infection
- Available for both sexual and occupational exposure

HIV sexual transmission: the risk

Prevention option for HIV sexual transmission	Challenges
Being sure the partner is HIV negative	Faithful? Recent HIV test?
Undetectable viral load in HIV + partner	Adherence? Blips? Recent viral load test?
Using condom consistently	Available? Reduced pleasure? Break?
Engaging in low-risk sexual activities	Reduced pleasure? Parenthood?
Reduce duration and vigorousness in sex	Reduced pleasure?
Male circumcision	Only for insertive men...
Treat Sexually Transmitted Infections (STIs)	Diagnosis? Treatment access/availability?
Use antiretrovirals	Cost? Implementation?

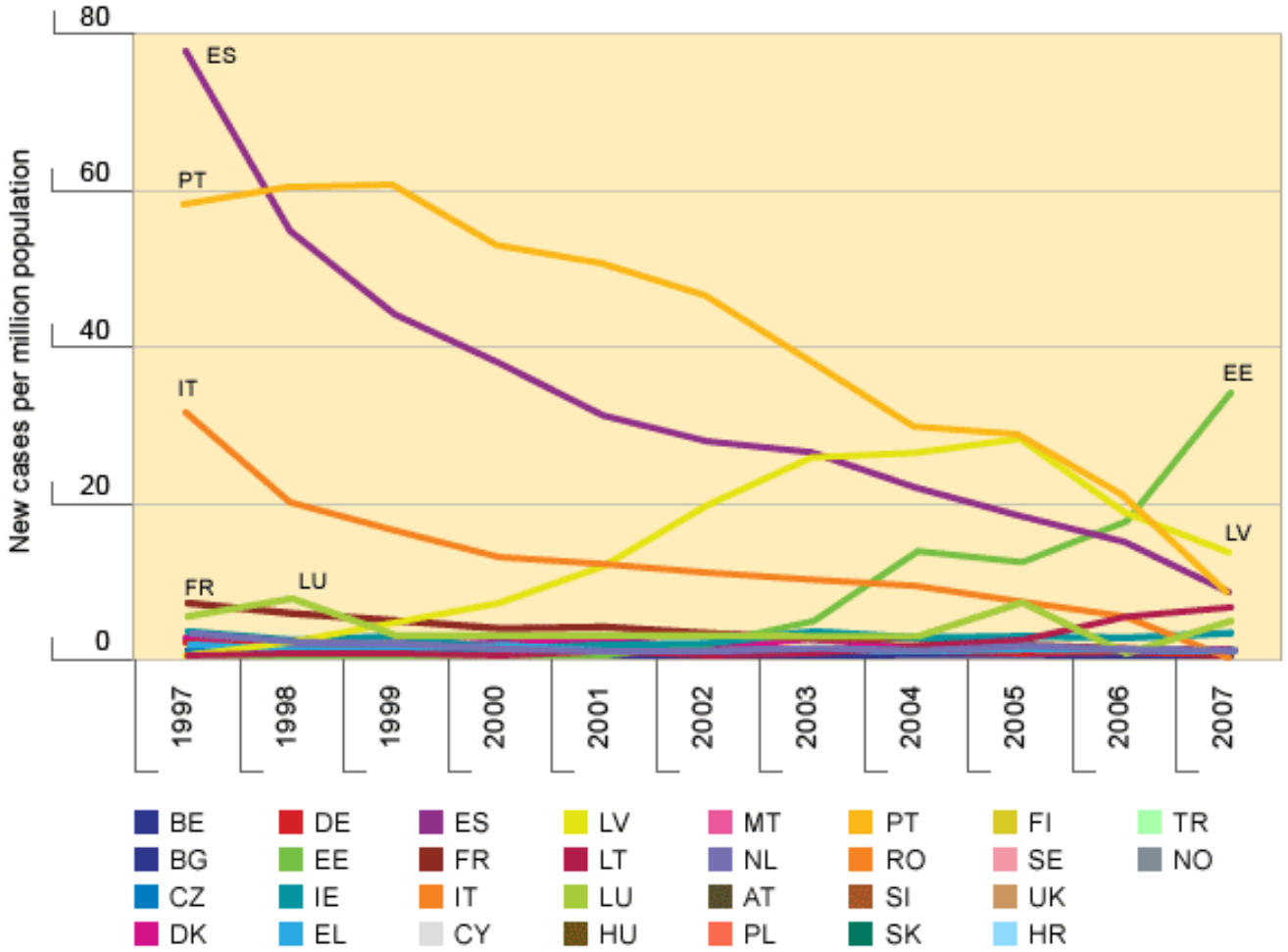
HIV transmission among IDUs



Source: AIDS.gov, How do you get HIV or AIDS?: https://www.aids.gov/hiv-aids-basics/hiv-aids-101/how-you-get-hiv-aids/ Accessed Sept. 2015

HIV prevention among IDUs

AIDS incidence by year of diagnosis among injecting drug users by country, cases per million, 1997 to 2007



Source: European Monitoring Centre for Drugs and Drug Addiction (EMCDDA): Statistical bulletin 2008. Accessed Sept. 2015

HIV prevention among IDUs

A Comprehensive Package of interventions for the prevention, treatment and care of HIV among people who inject drugs

WHO, UNAIDS, UNODC, the UN General Assembly, the Economic and Social Council, the UN Commission on Narcotic Drugs, the UNAIDS Programme Coordinating Board, the Global Fund and PEPFAR.

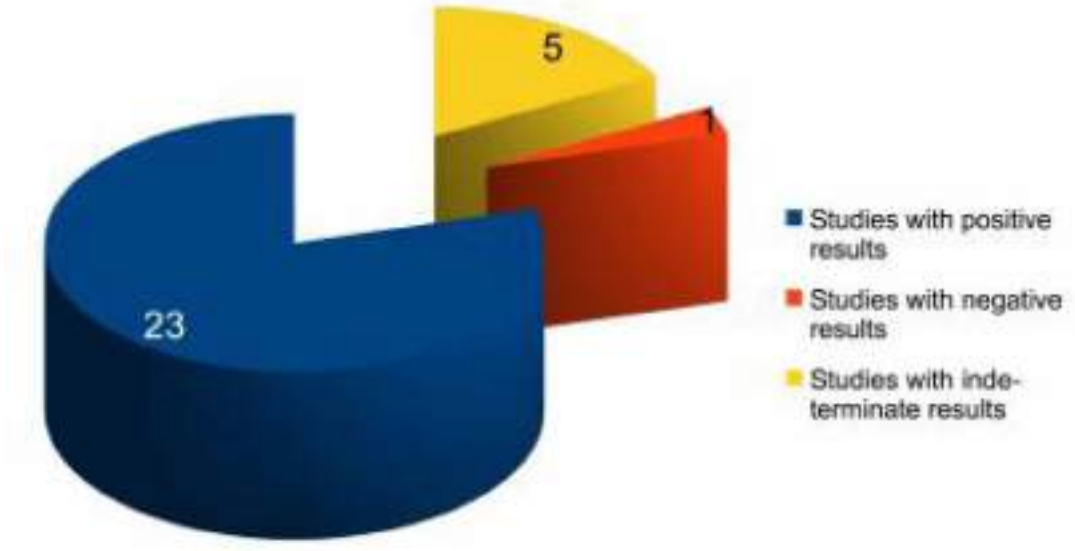
1 Needle and syringe programmes (NSPs)
2 Opioid substitution therapy (OST) and other evidence-based drug dependence treatment
3 HIV testing and counselling (HTC)
4 Antiretroviral therapy (ART)
5 Prevention and treatment of sexually transmitted infections (STIs)
6 Condom programmes for people who inject drugs and their sexual partners
7 Targeted information, education and communication (IEC) for people who inject drugs and their sexual partners
8 Prevention, vaccination, diagnosis and treatment for viral hepatitis
9 Prevention, diagnosis and treatment of tuberculosis (TB).

Source: UNAIDS; *Preventing HIV among drug users*; http://www.unaids.org/en/targetsandcommitments/preventinghivamongdrugusers Accessed Sept. 2015

HIV prevention among IDUs

Efficacy of needle syringe programming.
NSP use and HIV risk behaviour outcomes

Review of HIV 29 studies examining risk behaviour outcomes
(syringe sharing, borrowing, lending or reuse)
after the implementation of Needle Syringe Programmes (NSPs)



Source: UNODC; *Effectiveness Of Sterile Needle And Syringe Programming*; https://www.unodc.org/documents/hiv-aids/EFA%20effectiveness%20sterile%20needle.pdf Accessed Sept. 2015

HIV prevention among IDUs

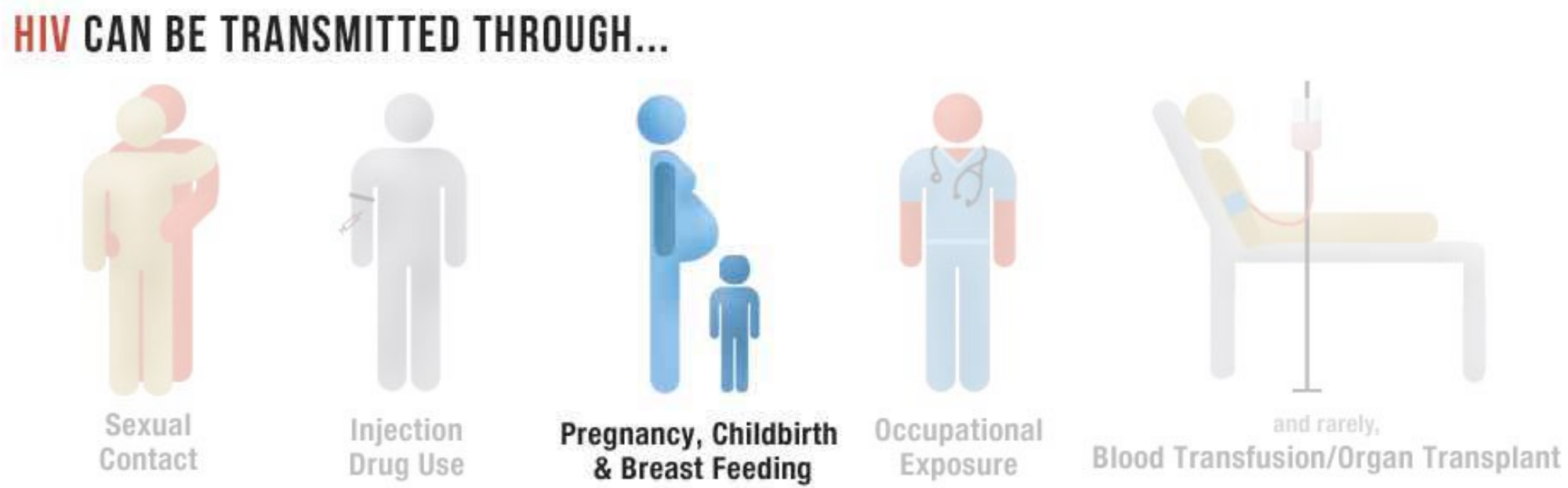
Do Needle and Syringe Programs increase drug use?

A 2004 review of potential unintended negative consequences associated with Needle and Syringe Programs found that the Programs:

- Do not encourage more frequent injection of drugs[1,2]
- Do not increase syringe lending to other injecting drug users[3,1]
- Do not increase recruitment of new injecting drug users[4,2,5]
- Do not increase social network formation[6]
- Do not increase transition from non-injecting drug use to injecting drug use[7]
- Do not affect injecting drug users' motivation to reduce drug use[8].

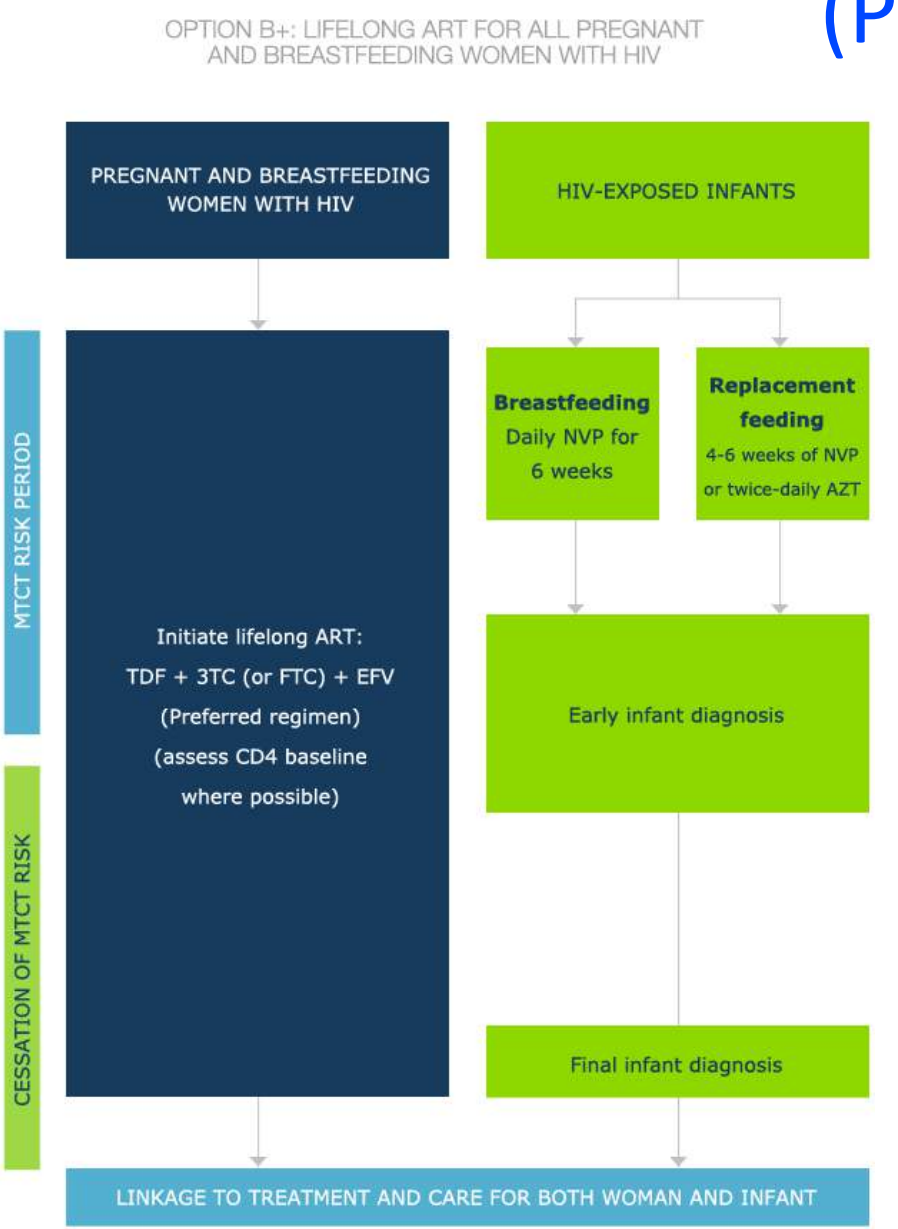
References: **1** Hartgers, C., Buning, E.C., van Santen, G.W., Verster, A.D. and Coutinho, R.A. 1989. The impact of the needle and syringe-exchange program in Amsterdam on injecting risk behaviour. AIDS. 3(9): 571-576. **2** Watters, J.K., Estilo, M.J., Clark, G.L. and Lorvick, J. 1994. Syringe and needle exchange as HIV/AIDS prevention for injection drug users. Journal of the American Medical Association. 271: 115-120. **3** Schechter, M.T., Strathdee, S.A., Cornelisse, P.G.A., Currie, S., Patrick, D.M., Rekart, M.L. and O'Shaughnessy, M.V. 1999. Do needle exchange programs increase the spread of HIV among injection drug users: An investigation of the Vancouver outbreak. AIDS. 13(6): F45-F51. **4** Heimer, R., Kaplan, E.H., Khoshnood, K., Jariwala, B. and Cadman, E.C. 1993. Needle exchange decreases the prevalence of HIV-1 proviral DNA in returned syringes in New Haven, Connecticut. American Journal of Medicine. 95: 214-220. **5** van Ameijden, E.J. and Coutinho, R.A. 2001. Large decline in injecting drug use in Amsterdam, 1986-1998: explanatory mechanisms and determinants of injecting transitions. Journal of Epidemiology & Community Health. 55(5): 356-363. **6** Junge, B., Valente, T., Latkin, C., Riley, E. and Vlahov, D. 2000. Syringe exchange not associated with social network formation: results from Baltimore. AIDS. 14(4): 423-426. **7** Guydish, J., Bucardo, J., Young, M., Woods, W., Grinstead, O. and Clark, W. 1993. Evaluating needle exchange: Are there negative effects? AIDS. 7: 871-876. **8** Bluthenthal, R.N., Gogineni, A., Longshore, D. and Stein, M. 2001. Factors associated with readiness to change drug use among needle exchange users. Drug & Alcohol Dependence. 62: 225-230.

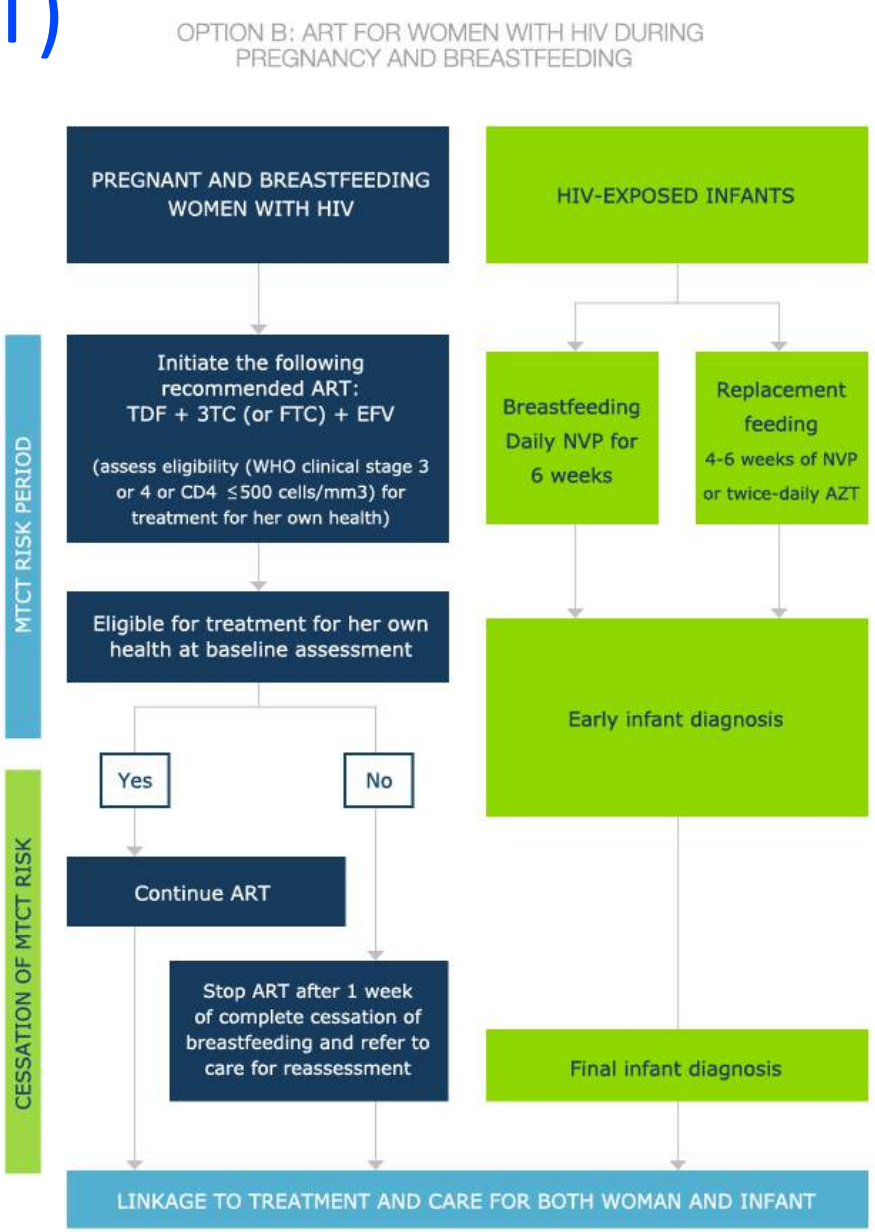
HIV vertical transmission



Source: AIDS.gov, How do you get HIV or AIDS?: https://www.aids.gov/hiv-aids-basics/hiv-aids-101/how-you-get-hiv-aids/ Accessed Sept. 2015

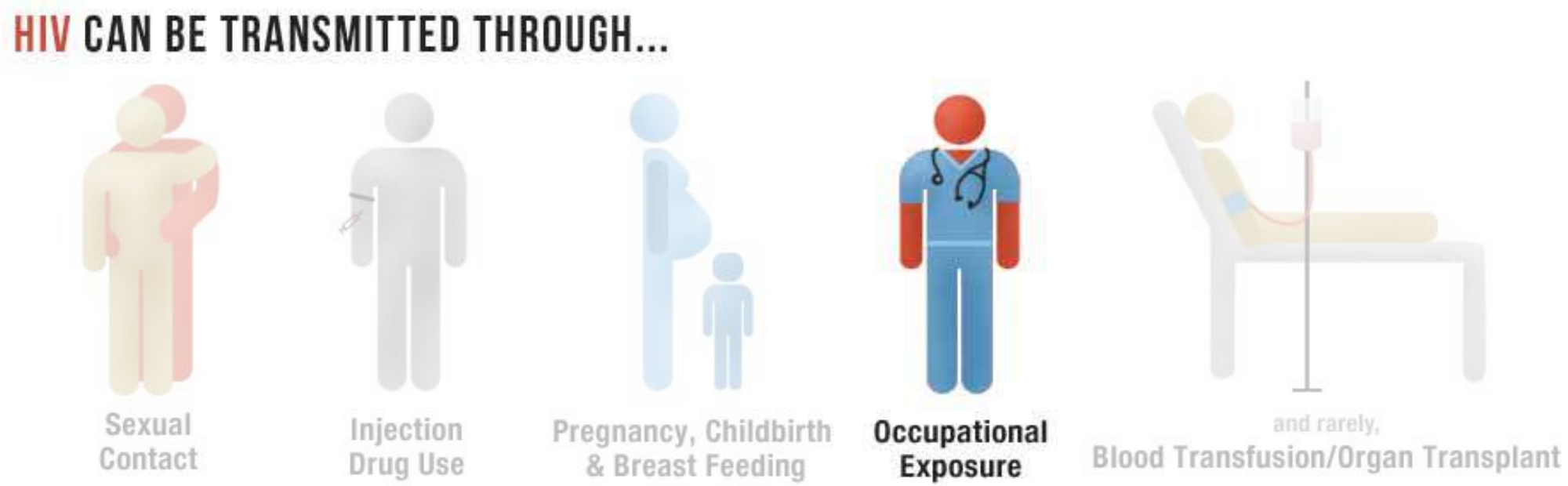
Prevention of Mother-To-Child Transmission (PMTCT)





Source: WHO; *Use of antiretrovirals for treatment and prevention of HIV infection*; http://www.avert.org/prevention-mother-child-transmission-pmtct-hiv.htm; Accessed Sept 2015

Occupational exposure to HIV



Source: AIDS.gov, How do you get HIV or AIDS?: https://www.aids.gov/hiv-aids-basics/hiv-aids-101/how-you-get-hiv-aids/ Accessed Sept. 2015

HIV prevention for occupational exposure

To prevent transmission of HIV to health care workers in the workplace[1]:

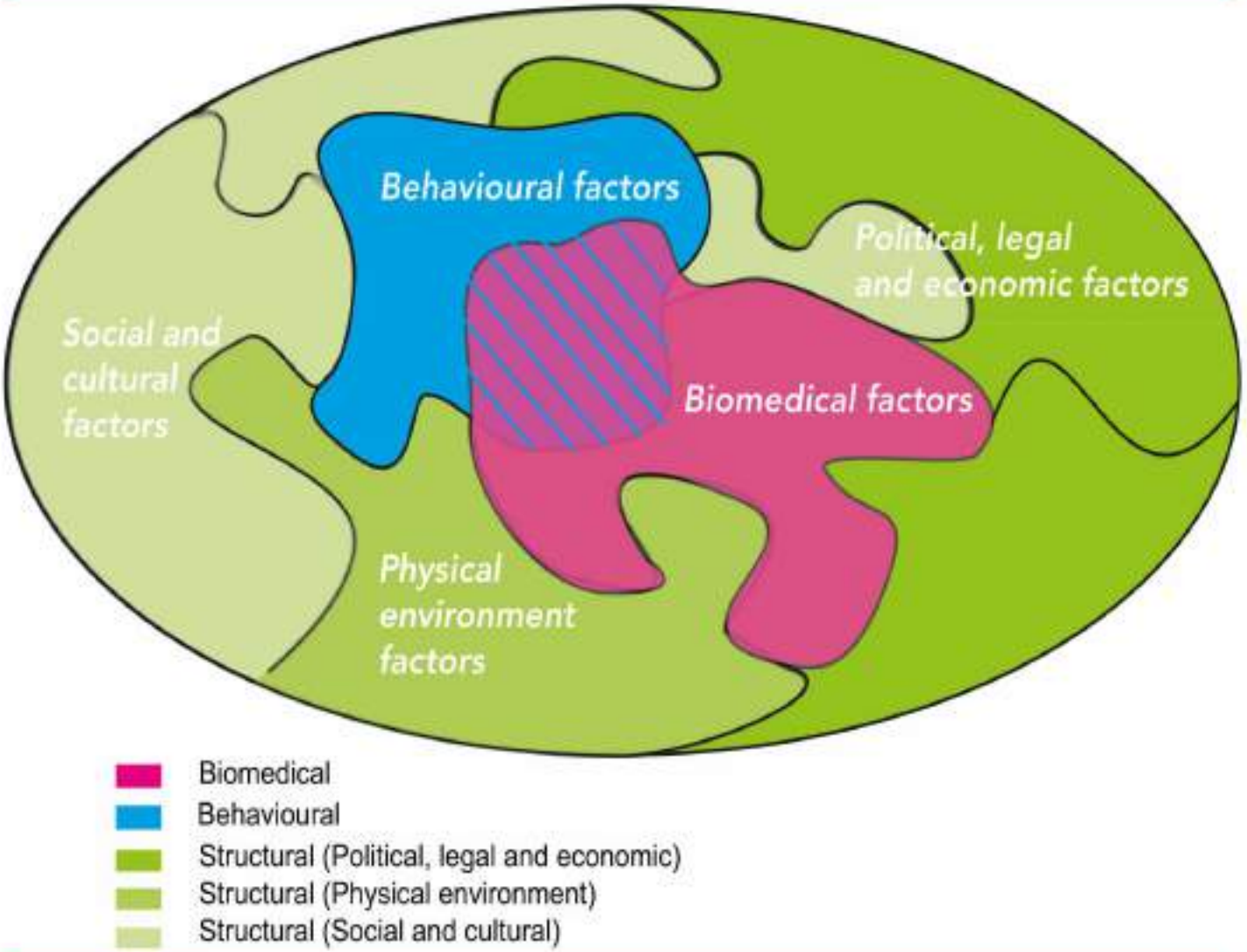
- Routinely use barriers (such as gloves and/or goggles) when anticipating contact with blood or body fluids.
- Immediately wash hands and other skin surfaces after contact with blood or body fluids.
- Carefully handle and dispose of sharp instruments during and after use.

- **Post-exposure prophylaxis** (PEP) [2]
  - duration 28 days
  - first dose should be offered as soon as possible within 72 hours after exposure
  - the choice of post-exposure prophylaxis drugs should be based on the country's first-line ArV regimen for HIV.

References: **1** Centers for Disease Control and Prevention (CDC); *Occupational HIV Transmission and Prevention Among Health Care Workers*; http://www.cdc.gov/hiv/workplace/occupational.html; accessed Sept 2015. **2** WHO: *Consolidated Guidelines On The Use Of Antiretroviral Drugs For Treating And Preventing Hiv Infection*; 2013

HIV transmission: different risks

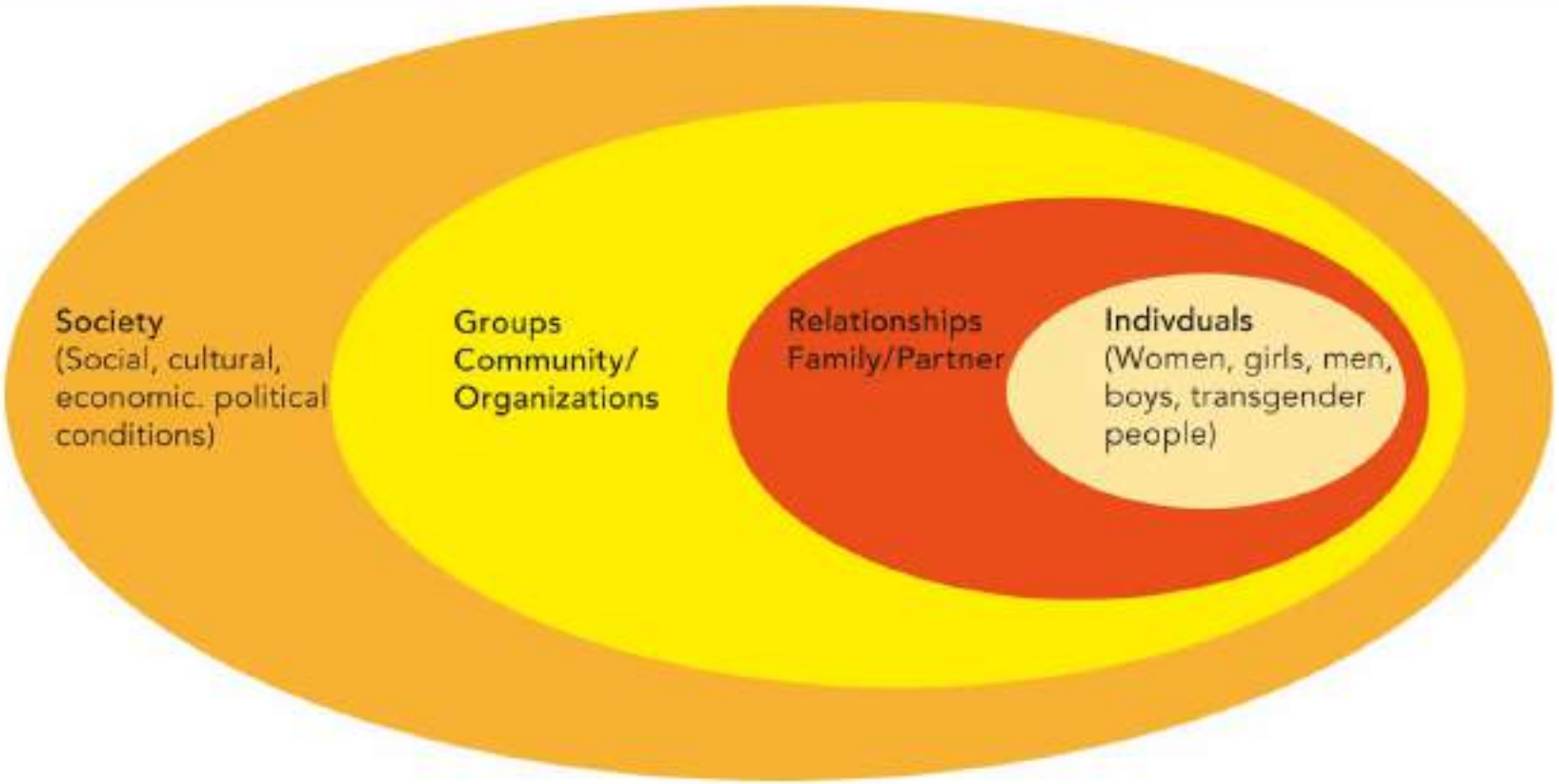
Figure 1. Interacting causes of HIV risk and vulnerability



Source: UNAIDS, *Combination HIV Prevention: Tailoring and Coordinating Biomedical, Behavioural and Structural Strategies to Reduce New HIV Infections A UNAIDS Discussion Paper*, 2010: http://www.unaids.org/sites/default/files/media_asset/JC2007_Combination_Prevention_paper_en_0.pdf Accessed Sept. 2015

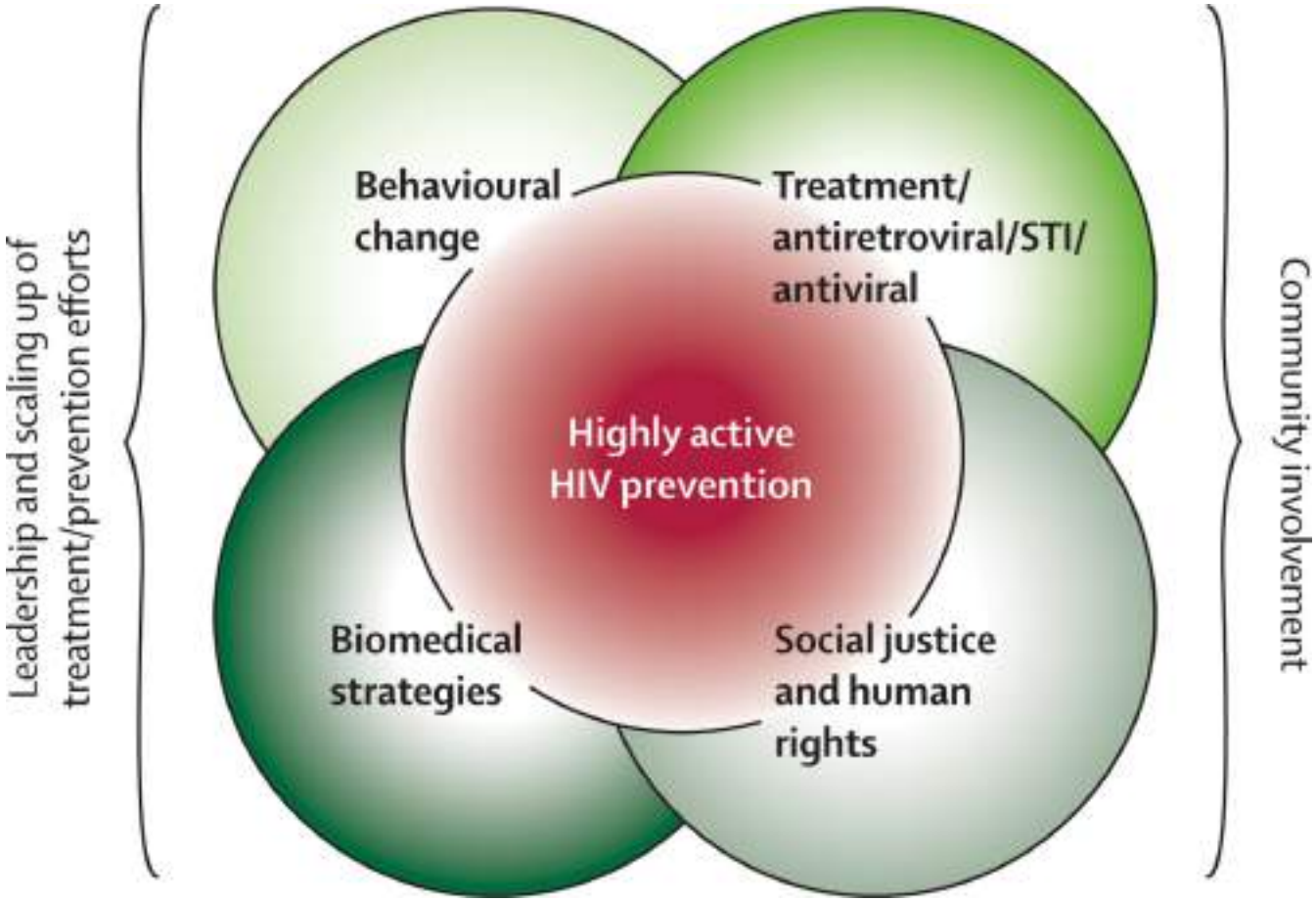
HIV prevention: from society to individual

Figure 5: **A Social Ecological Framework** - indivdual action is shaped by immediate life conditions, including relationships, community and occupational groups and organizations, and by broader societal factors



Source: UNAIDS, *Combination HIV Prevention: Tailoring and Coordinating Biomedical, Behavioural and Structural Strategies to Reduce New HIV Infections A UNAIDS Discussion Paper*, 2010:
http://www.unaids.org/sites/default/files/media_asset/JC2007_Combination_Prevention_paper_en_0.pdf Accessed Sept. 2015

HIV combination prevention



Source: *Behavioural strategies to reduce HIV transmission: how to make them work better*, Thomas J Coates, Linda Richter, Carlos Caceres; The Lancet, Volume 372, No. 9639, p669–684, 23 August 2008

HIV combination prevention

HIV risk target levels to consider for combination HIV prevention packages

Individual

Host factors
- Acquired immunity (vaccine)
- Medical male circumcision
- STI treatment

Sexual behaviors
- Delay coitarche (first sexual intercourse)
- Increase consistency & correctness of condom use
- Reduce number of sex partners
- Reduce age-mixing/intergenerational sex
- Contraceptive use
- Antiretroviral-based preventive strategies

Substance use behaviors
- Opioid substitution, needle exchange

HIV serostatus knowledge
- Antiretroviral therapy if HIV+

Epidemiologic context
- Stage of STI/HIV epidemic
- Demographics of population
- Micro-epidemic patterns of HIV transmission

Dyad/network
- Reduce concurrency (overlapping sexual partnerships)
- Reduce needle sharing
- Reduce HIV & STI co-infection prevalence
- ART prophylaxis in pregnancy (mother–child dyad)

Structural

Economic
- Income differential related to gender inequality
- Conditional cash transfers

Legal
- Laws & policies (homophobia, sex work, drug use)

Public health & health care infrastructure
- Access to screening, prevention, and treatment

Source: *Combination HIV Prevention: Significance, Challenges, and Opportunities*; Ann E. Kurth, Connie Celum, Jared M. Baeten, Sten H. Vermund, and Judith N. Wasserheit, 2011

HIV prevention

Summary of recommendations:

- Several options are available for prevention of HIV transmission;
- Use an evidence-based approach to provide specific recommendations;
- Providers need to be flexible, given their particular client base, setting HIV prevalence level, and available resources;
- The person lifestyle, circumstances and preferences should be taken into consideration when counselling about HIV prevention;
- It is highly recommended to avoid any judgmental attitude when discussing HIV prevention;
- Circumstances may change and a prevention strategy can stop working for that person after some period;
- A peer-operator can help in addressing some more sensitive issues.

PrEP
La profilassi pre-esposizione in HIV

- Gli studi scientifici
- La posizione della community

Nuove e meno nuove tecniche di prevenzione HIV

La profilassi pre-esposizione - PrEP

Cos'è?

- Farmaci antiretrovirali assunti da una persona Hiv negativa per abbassare il rischio di contrarre l'infezione da Hiv
- Studiata in persone ad alto rischio di infezione (maschi gay, donne transgender e altri MSM con uso non costante del preservativo e molti partner sessuali; lavoratori e lavoratrici del sesso; persone che usano droghe per via iniettiva)
- Sempre accompagnata da counseling e fornitura di preservativi e lubrificanti: non è in "competizione" con i condom, vuole rispondere ai bisogni di prevenzione di chi non può, non riesce o non vuole usare costantemente i condom

La profilassi pre-esposizione - PrEP

FAQ!
Frequently Asked Questions…

Le domande e i dubbi più frequenti…

La profilassi pre-esposizione - PrEP

"È troppo nuova… bisogna aspettare!"

- Primo studio nelle scimmie nel 1995

Daily weight-based daily PMPA (tenofovir) SC for one month in 35 macaques inoculated IV with SIV (10 x 50% infectious dose): 5 arms, follow up 40-56 weeks.

Dose	Day started	n	% infected
20mg/kg	48 hrs pre	n=5	0
30mg/kg	48 hrs pre	n=10	0
30mg/kg	4 hrs post	n=5	0
30mg/kg	24 hrs post	n=5	0
Control	48 hrs pre	n=10	100

1. Tsai C-C et al, Prevention of SIV Infection in Macaques by (R)-9-(2-Phosphonylmethoxypropyl)adenine. Science 1995. (NIH funded).

PrEP Initiative / Iniciativa PrEx

Sponsored by

NIH/NIAID/DAIDS

with co-funding by the

Bill & Melinda Gates Foundation

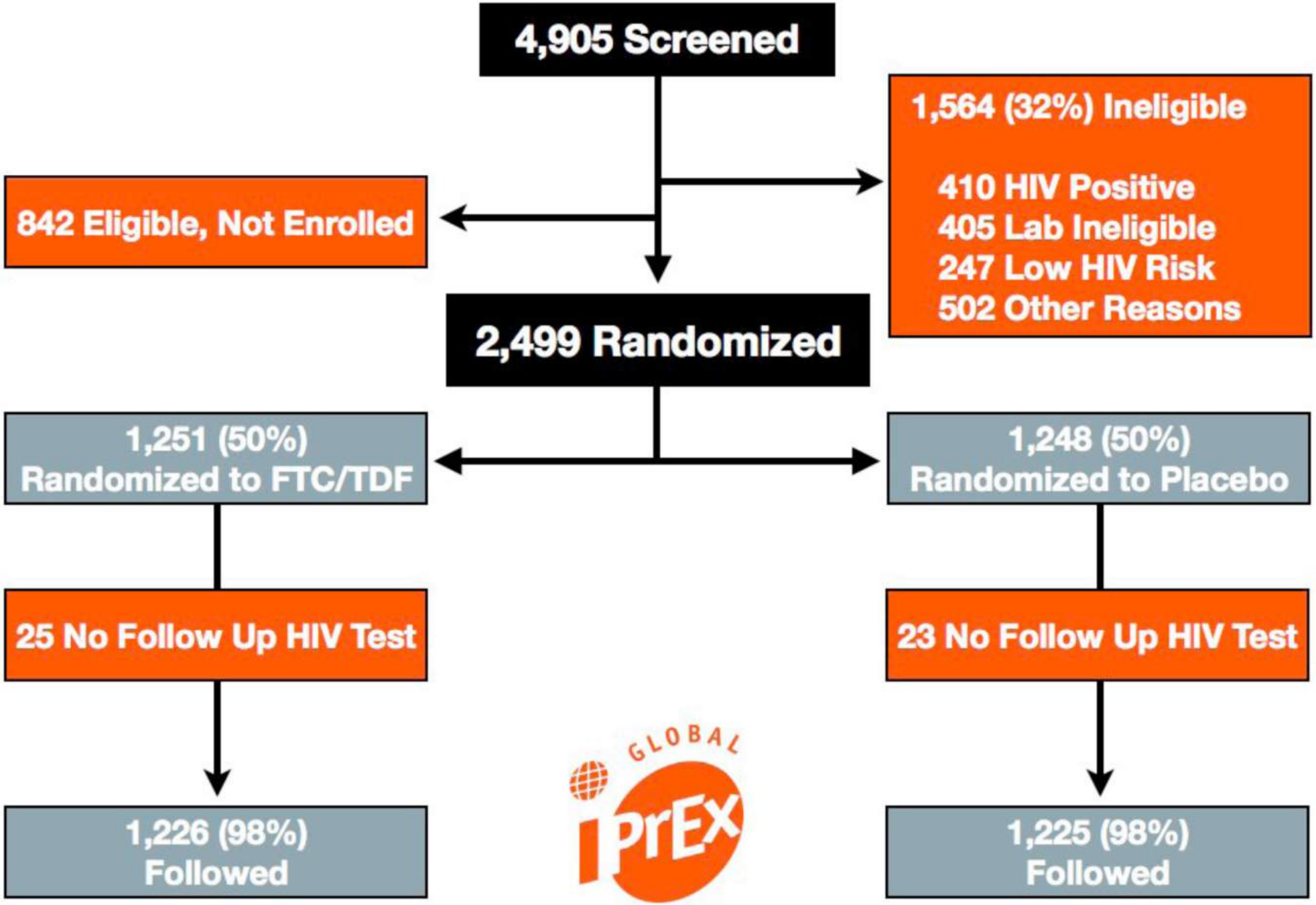
and drug donated by

Gilead Sciences

Fully enrolled as of December 2009

Sites	11
Participants	2499

New England Journal of Medicine, online Nov 23, 2010



New England Journal of Medicine, online Nov 23, 2010

Baseline Characteristics of the Participants, According to Study Group

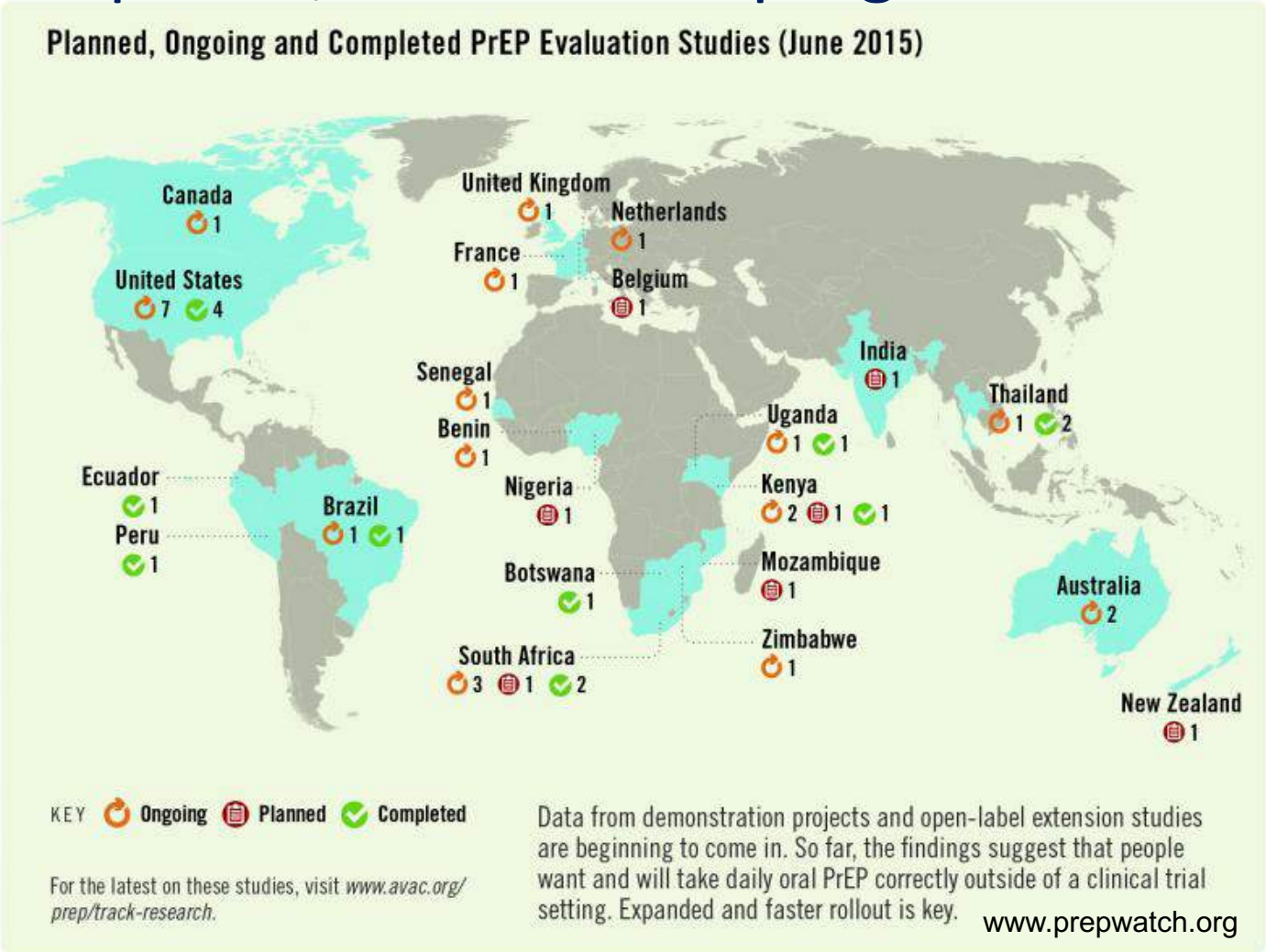
Characteristic	FTC/TDF	PLACEBO
Age - no. (%) P=0.04	**(n=1,251)**	**(n=1,248)**
18-24	591 (47)	662 (53)
25-29	274 (22)	241 (19)
30-39	249 (20)	224 (18)
≥40	137 (11)	121 (10)

New England Journal of Medicine, online Nov 23, 2010

La profilassi pre-esposizione - PrEP

"Non abbiamo abbastanza dati…"

- più di 40 studi completati, in corso o in programma



Public Health England

PROUD

MRC Clinical Trials Unit

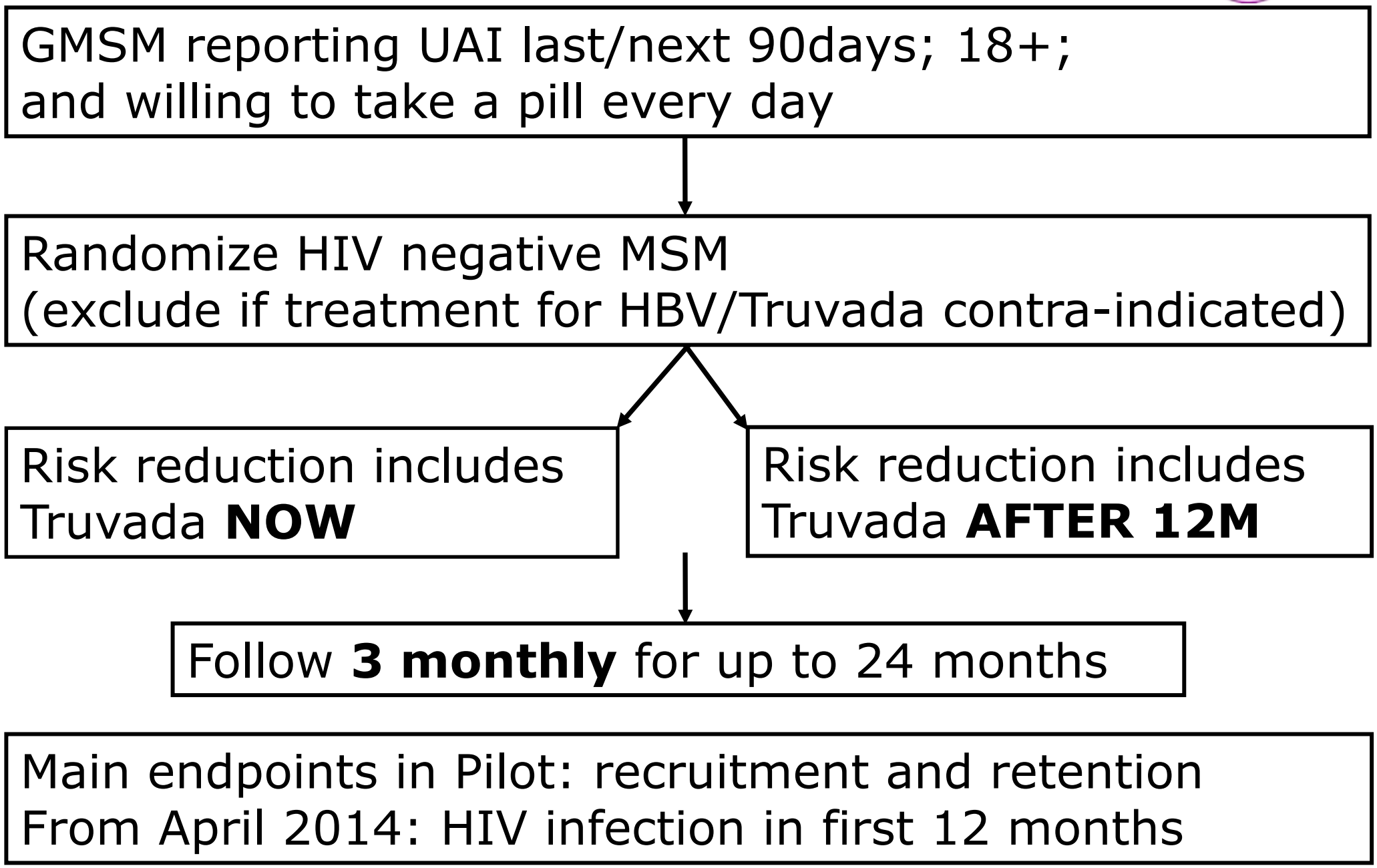
Pragmatic Open-Label Randomised Trial of Pre-Exposure Prophylaxis: the PROUD study

http://www.proud.mrc.ac.uk/

Sexual health service in England

- ~220 sexual health clinics, linked through professional guidelines
- Accessed by 110,000 HIV negative gay men per year
- Diagnoses made and services provided reported to Public Health England

PROUD Pilot


GMSM reporting UAI last/next 90days; 18+;
and willing to take a pill every day
Randomize HIV negative MSM
(exclude if treatment for HBV/Truvada contra-indicated)
Risk reduction includes
Truvada **NOW**
Risk reduction includes
Truvada **AFTER 12M**
Follow **3 monthly** for up to 24 months
Main endpoints in Pilot: recruitment and retention
From April 2014: HIV infection in first 12 months

Designed to mimic real-world

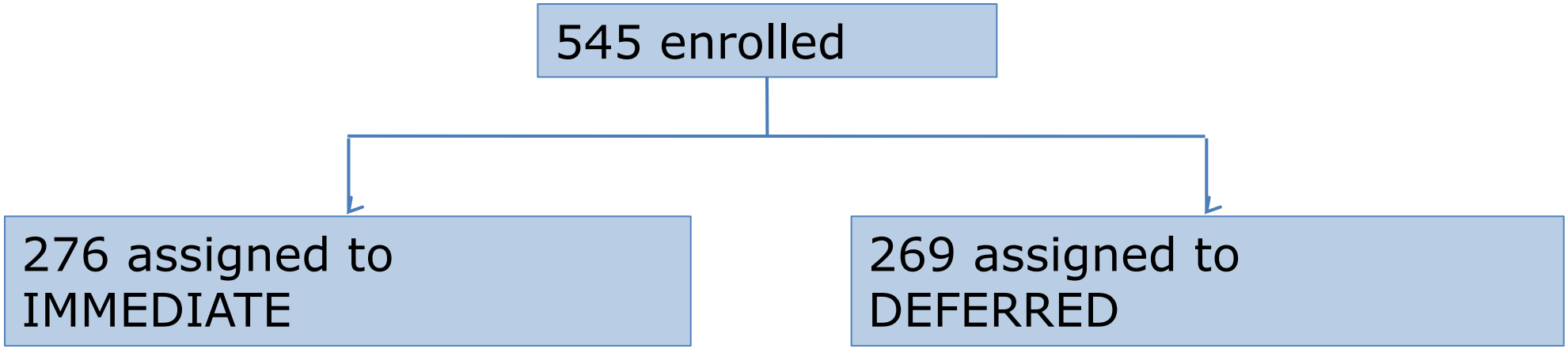
- Eligibility: routine clinic data and p24Ag/Ab serology at enrolment (no PCR)
- Safety: serum creatinine when starting and annually; additional tests if 1+ protein on dipstick
- STIs: (mainly) quarterly HIV, syphilis, HCV, gonorrhoea and chlamydia according to routine clinic
- Behaviour change interventions according to routine clinic (sexual risk, adherence, addiction)

- **Study procedures: web-randomisation, data entry, participant-completed questionnaires**

PROUD

Results:
Population, Prescribing, Tolerability

Participant randomization



Baseline demographics1

Characteristics		Immediate	Deferred
Age, median (IQR)		35 (30 – 43)	35 (29 – 42)
Ethnicity	White	80%	82%
Born UK	No	40%	40%
Education	University	59%	60%
Employment	Full-time	70%	73%
Sexuality	Gay	96%	94%
Current relationship	No	53%	55%
Recreational drug use2	Yes	76%	64%

1 539/545 (99%) questionnaires returned
2 in the last 90 days

Ipergay: "On-Demand" PrEP Study Design

- Double blind, randomized placebo controlled trial to prevent HIV infection in France and Canada

- HIV negative MSM
- Anal sex without condoms with ≥2 partners in past 6 months
- eGRF >60 mL/min

→

- Prevention services
- TDF/FTC before and after sex* (n=199)

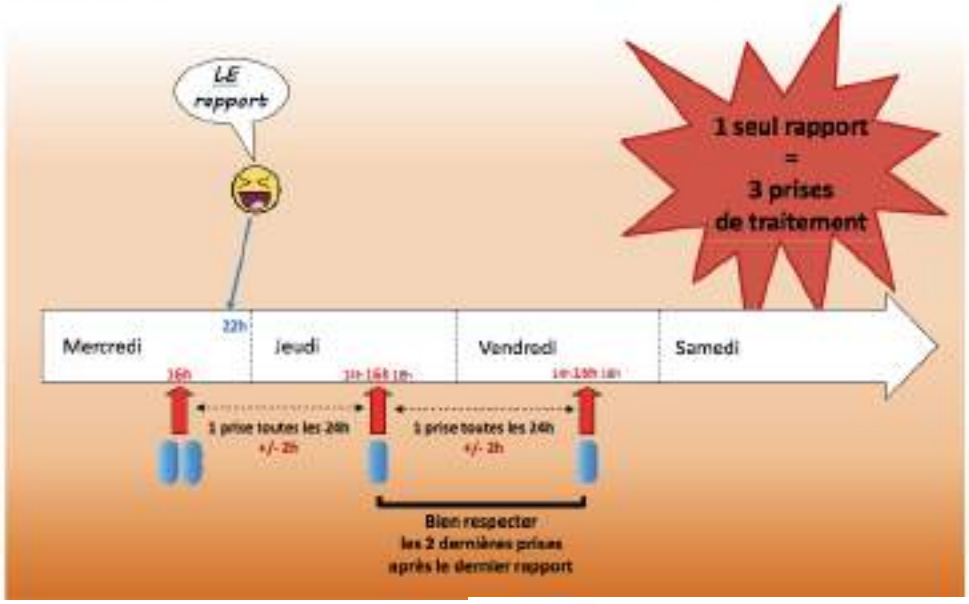
- Prevention services
- Placebo before and after sex* (n=201)

- Follow-up visits: month 1, 2, and every 2 months thereafter
- Endpoint driven study – with 64 infections there is 80% power to detect 50% reduction in infection rate in active arm
- Expected incidence 3/100 PY with placebo

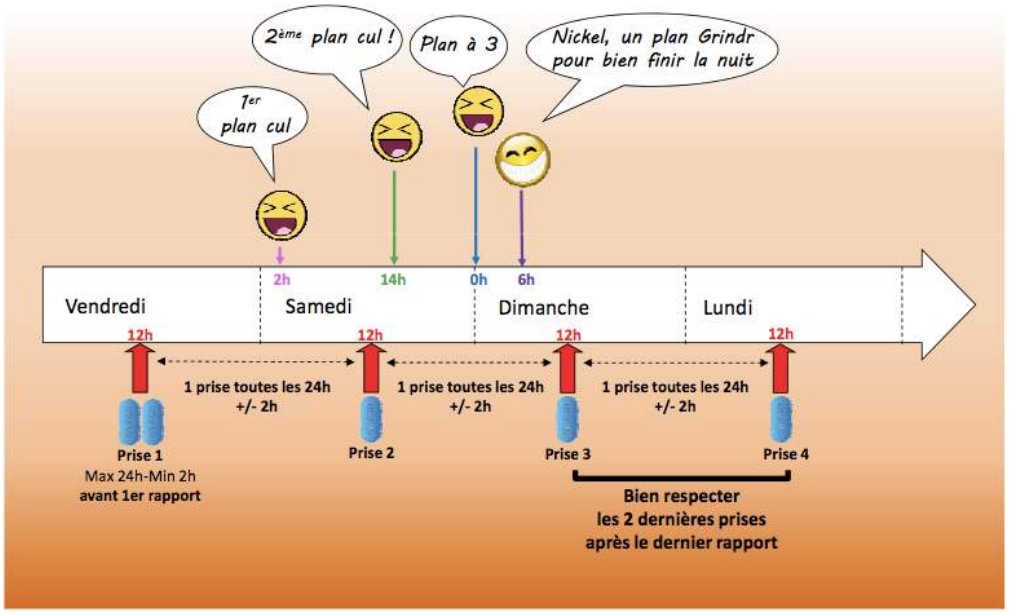
*Two tablets 2-24 hours before sex; 1 tablet 24 hours later; 1 table 48 hours later

Molina JM, et al. 22nd CROI; Seattle, WA; February 23-26, 2015. Abst. 23LB

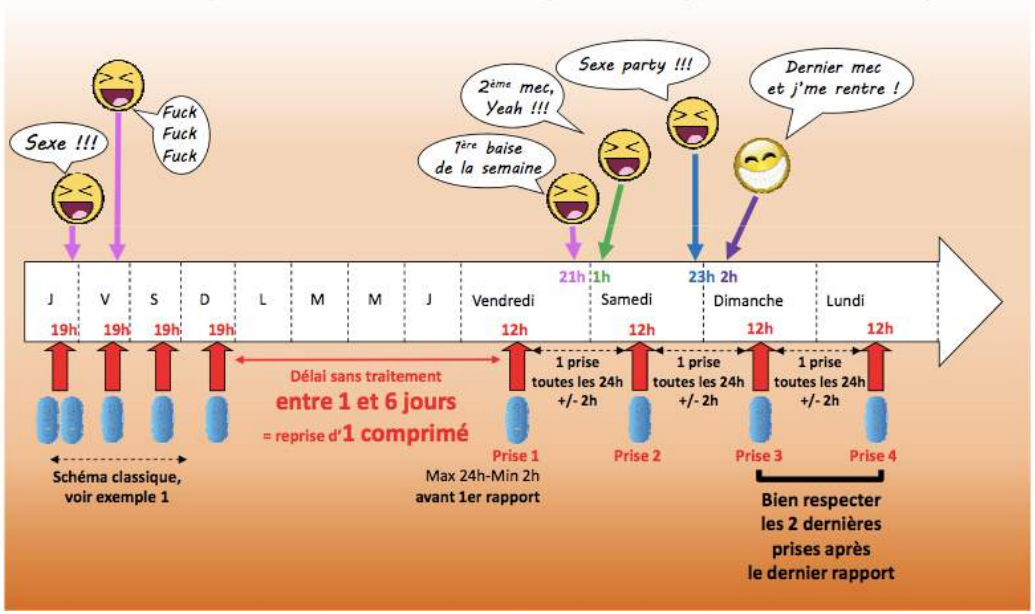
Exemple 1 :
Tu as un seul rapport sexuel dans la semaine



Exemple 2 :
Tu as plusieurs rapports sexuels le week-end



Exemple 3 :
Tu reprends une activité sexuelle
et tu as pris ton dernier comprimé il y a moins de 7 jours



Ipergay: Baseline Characteristics

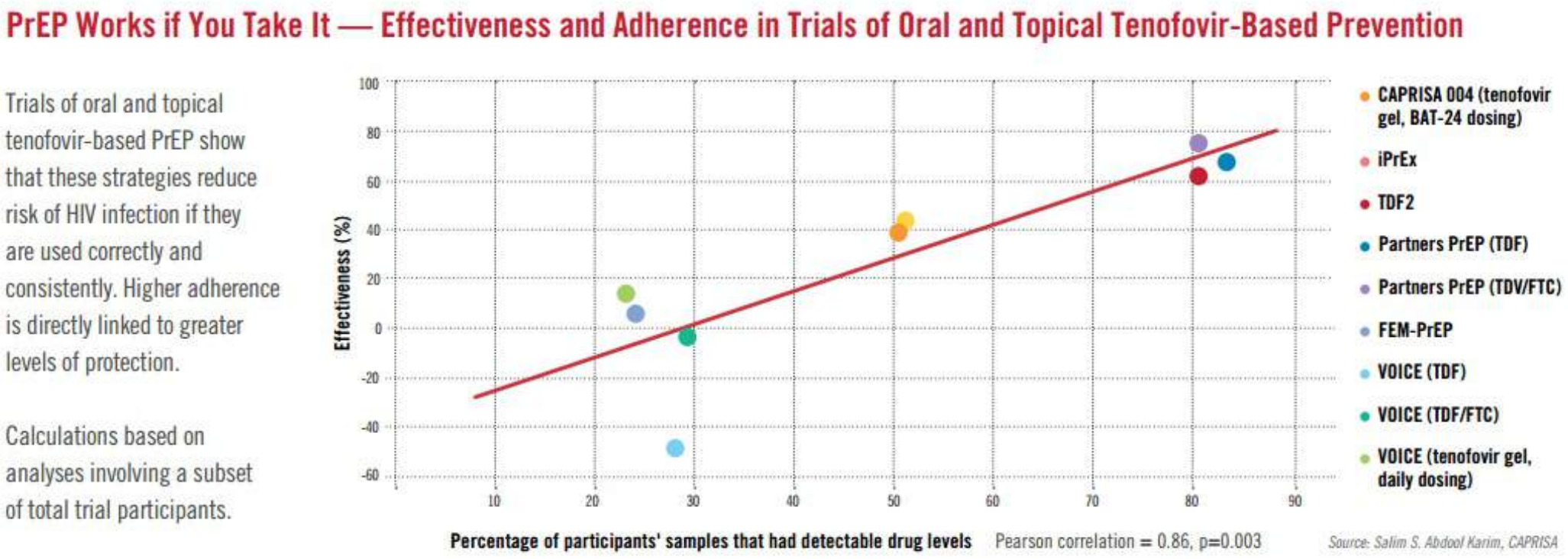
Characteristics (Median, IQR) or (n, %)	TDF/FTC n=199	Placebo n=201
Age (Years)	35 (29-43)	34 (29-42)
White	190 (95)	184 (92)
Completed Secondary Education	178 (91)	177 (89)
Employed	167 (85)	167 (84)
Single	144 (77)	149 (81)
History of PEP Use	56 (28)	73 (37)
Use of Psychoactive Drug in Past 12 Months	85 (44)	92 (48)
Circumcised	38 (19)	41 (20)
Infection with Gonorrhea, Chlamydia, Syphilis	43 (22)	59 (29)
# Sexual Acts in Prior 4 Weeks	10 (6-18)	10 (5-15)
# Sexual Partners in Prior 2 Months	8 (5-17)	8 (5-16)

Molina JM, et al. 22nd CROI; Seattle, WA; February 23-26, 2015. Abst. 23LB.

La profilassi pre-esposizione - PrEP

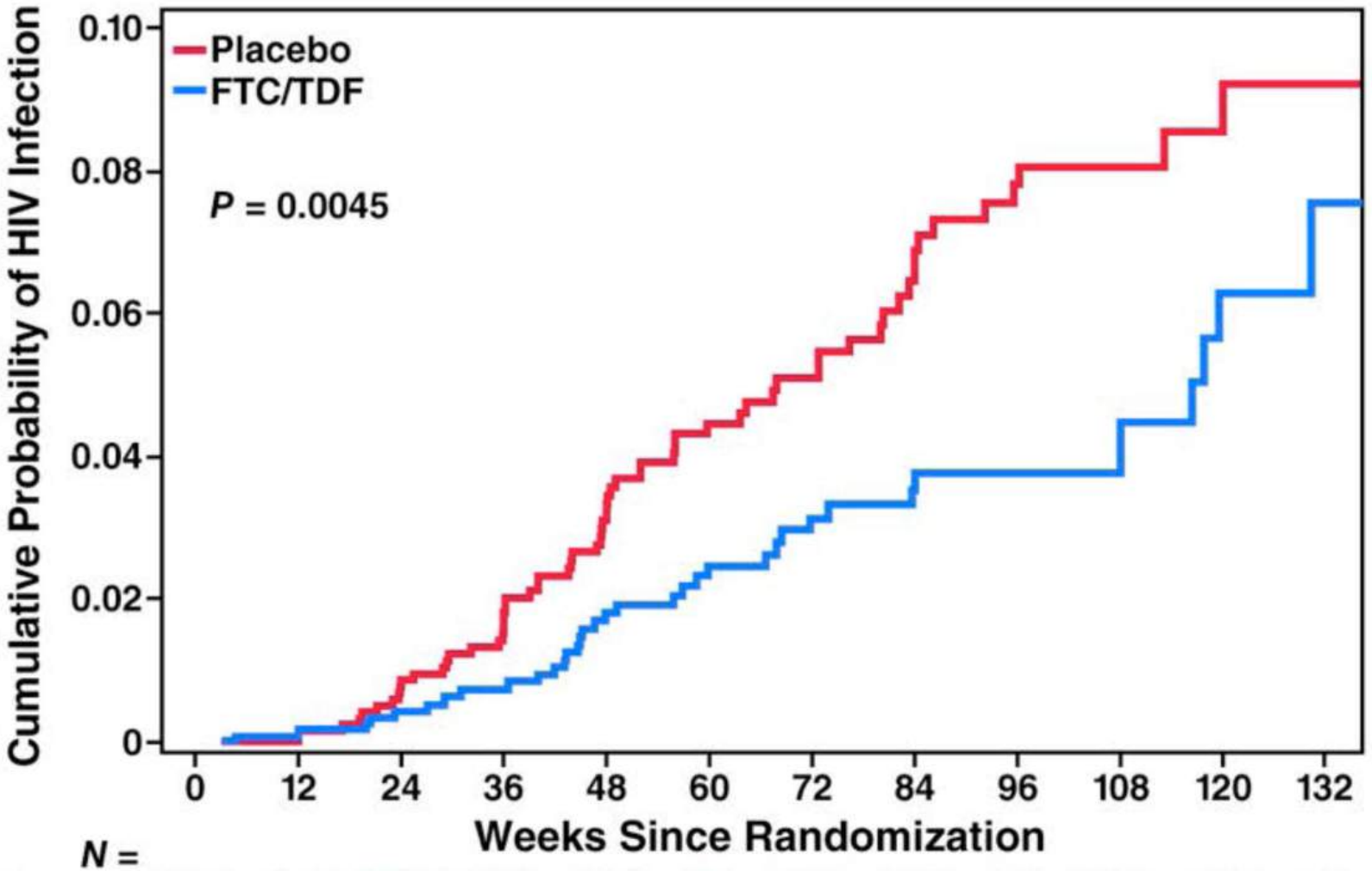
“Sì, ma non sappiamo se funziona…”

- dati affiadbili dicono che funziona se la prendi



www.prepwatch.org

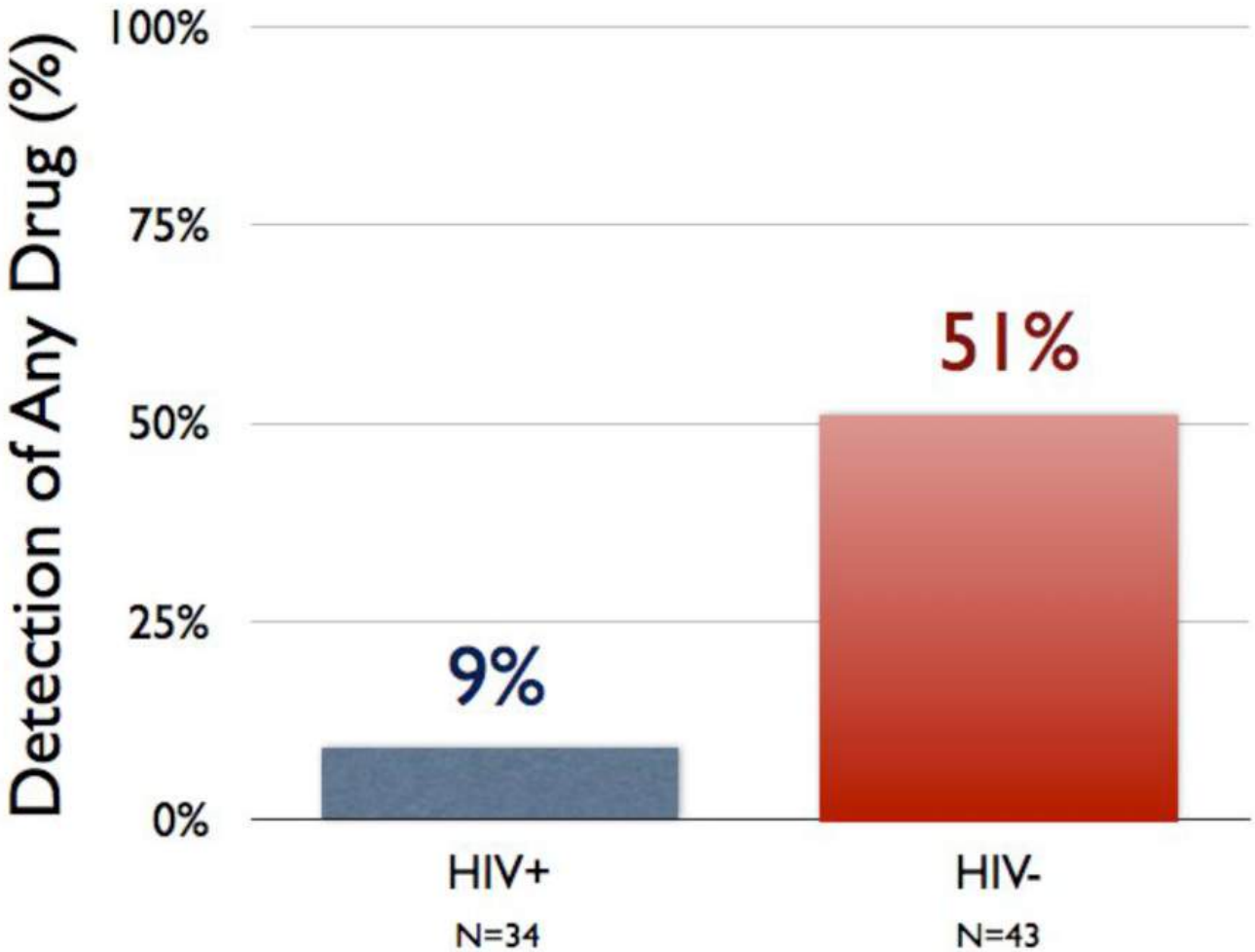
Efficacy (MITT) 44% (15-63%) Through May 1, 2010
Infection Numbers: 64 – 36 = 28 averted



N =												
Placebo:	1248	1194	1108	1005	852	674	546	444	370	258	137	60
FTC/TDF:	1251	1188	1097	988	848	693	558	447	367	267	147	65

10.200B2

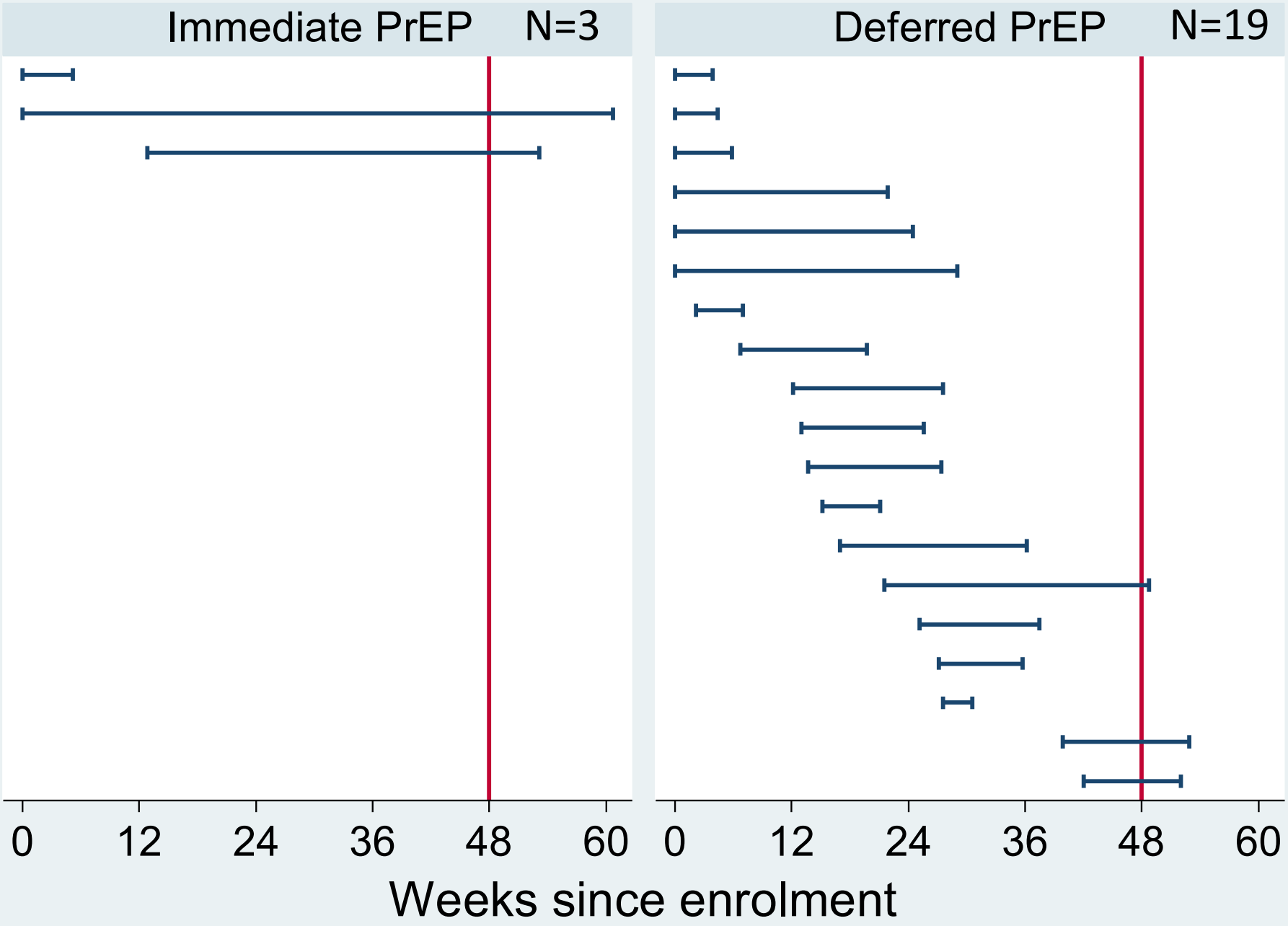
Drug Detection by HIV Status in the FTC/TDF Group



New England Journal of Medicine, online Nov 23, 2010

Results:
HIV endpoint

Individual incident HIV infections



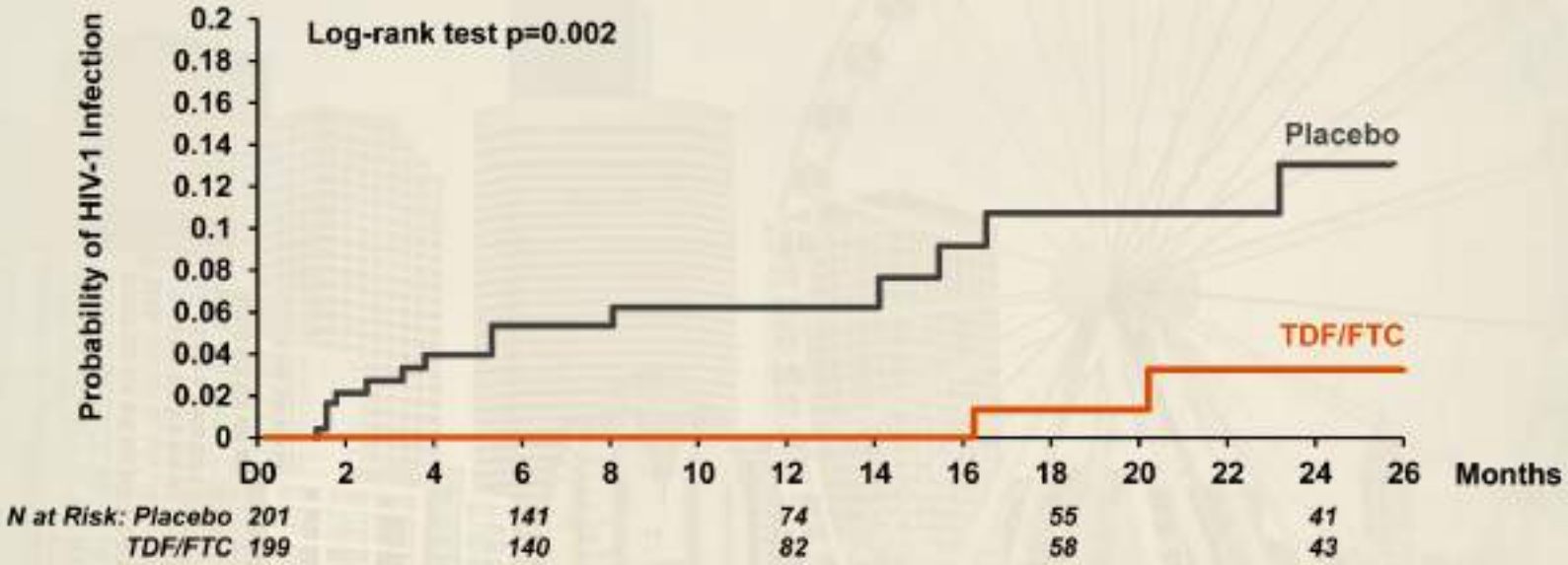
HIV Incidence

Group	No. of infections	Follow-up (PY)	Incidence (per 100 PY)	90% CI
Overall	22	453	4.9	3.4–6.8
Immediate	3	239	1.3	0.4–3.0
Deferred	19	214	8.9	6.0–12.7

Efficacy =86% (90% CI: 58 – 96%)
P value =0.0002

Rate Difference =7.6 (90% CI: 4.1 – 11.2)
Number Needed to Treat =13 (90% CI: 9 – 25)

Ipergay: Time to HIV Infection



- Infections: Placebo: 14 (incidence: 6.6 per 100 PY)
  TDF/FTC: 2 (incidence: 0.94 per 100 PY)
- Relative Reduction: 86% (95% CI: 40–99%, p=0.002)
- Number needed to treat for one year to prevent one infection: 18

Molina JM, et al. 22nd CROI; Seattle, WA; February 23-26, 2015. Abst. 23LB.

La profilassi pre-esposizione - PrEP

"Non è sicura. I farmaci comportano effetti collaterali"

Safety in Partners PrEP [1]

	FTC/TDF	TDF	Placebo
Neutropenia			
Grade 1 or 2	15%	2%	2%
Grade 3 or 4	4%	2%	2%
Serum creatinine	NS		
phosphorus abnormalities	NS		
SAEs	NS		
Deaths	NS		

Modest GI and fatigue in active arms during month 1.

1. Baeten JR et al, NEJM, 2012.

Simon Collins, Glasgow 2014

PrEP interruptions for medical event

- **PrEP interrupted** by 28 participants (**both groups**) but only **13** had events considered related to drug:
  - nausea alone or with diarrhoea/abdominal pain/aches and fatigue (n=5)
  - decline in creatinine clearance (n=2)
  - headache (n=2)
  - joint pain, with fatigue in one case (n=2)
  - sleep disturbance (n=1)
  - flu-like illness (n=1)
- **PrEP re-started** by 11 of 13 participants above

Ipergay: Adverse Events

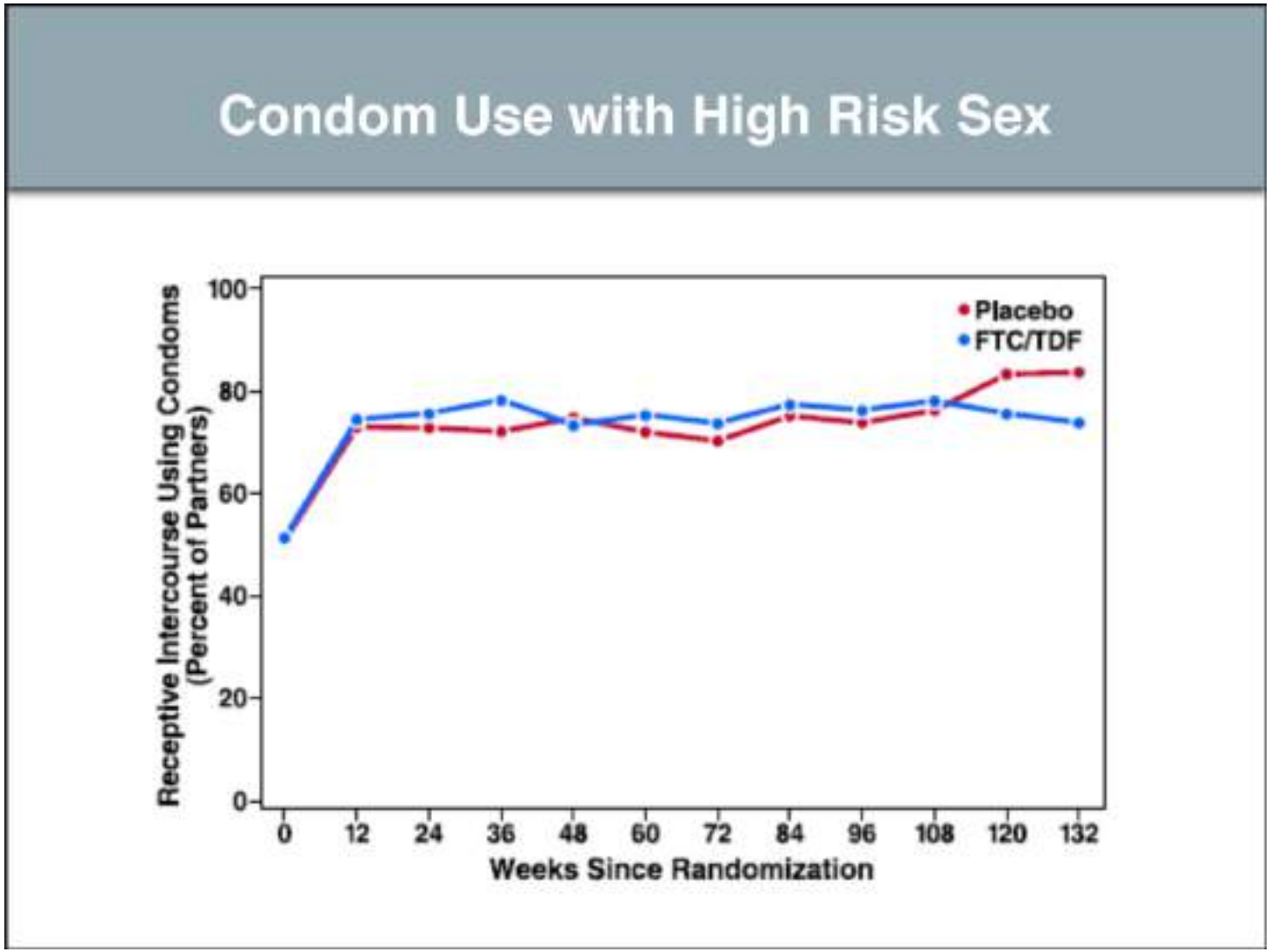
Nb of Participants (%)	TDF/FTC n=199	Placebo n=201	P-value
Any AE	184 (92)	178 (89)	0.18
Any Serious AE	18 (9)	16 (8)	0.70
Any Grade 3 or 4 AE	17 (9)	14 (7)	0.56
Treatment D/C Due to AE	1*	0	
Drug-Related GI AEs	25 (13)	11 (6)	0.013
Nausea/Vomiting	15	2	
Abdominal Pain	11	4	
Diarrhea	7	5	

*Deep veinous thrombosis with suspected DDI with dabigatran

Molina JM, et al. 22nd CROI; Seattle, WA; February 23-26, 2015. Abst. 23LB

La profilassi pre-esposizione - PrEP

"Porta ad abbandonare il preservativo"

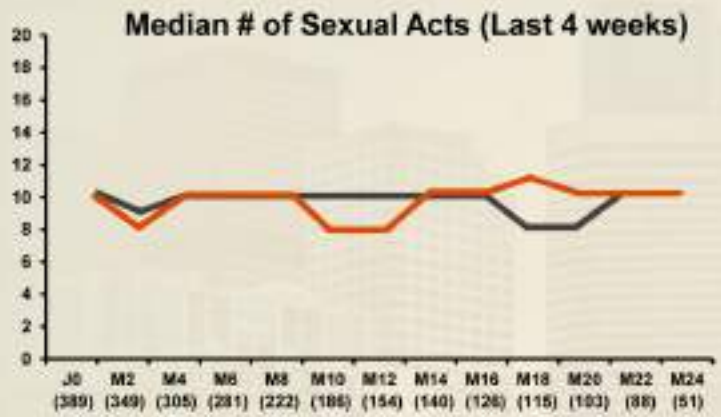


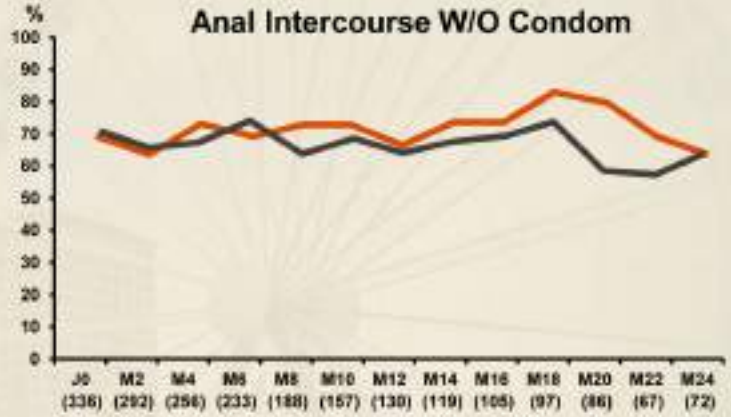
Reported sexual behaviour (preliminary)

Anal sex partners in last 90 days BASELINE n=539	**Immediate** Median (IQR)	**Deferred** Median (IQR)
Total number of partners	10.5 (5-20)	10 (4-20)
Condomless partners, participant receptive	3 (1-5)	2 (1-5)
Condomless partners, participant insertive	2.5 (1-6)	3 (1-7)

Anal sex partners in last 90 days MONTH 12 n=349	**Immediate** Median (IQR)	**Deferred** Median (IQR)
Total number of partners	10 (3-24)	8 (3-15)
Condomless partners, participant receptive	3 (1-8)	2 (1-5)
Condomless partners, participant insertive	3 (1-8)	3 (1-6)

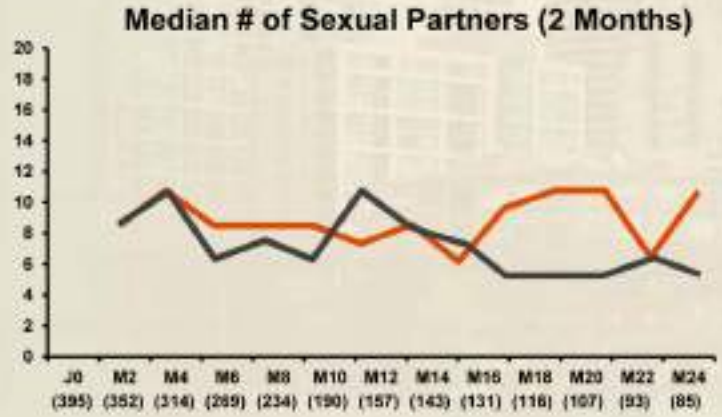
Ipergay: Risk Behavior

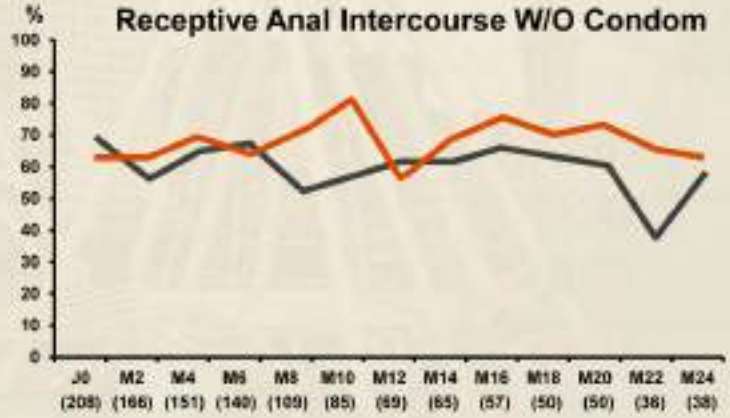




TDF/FTC

Placebo

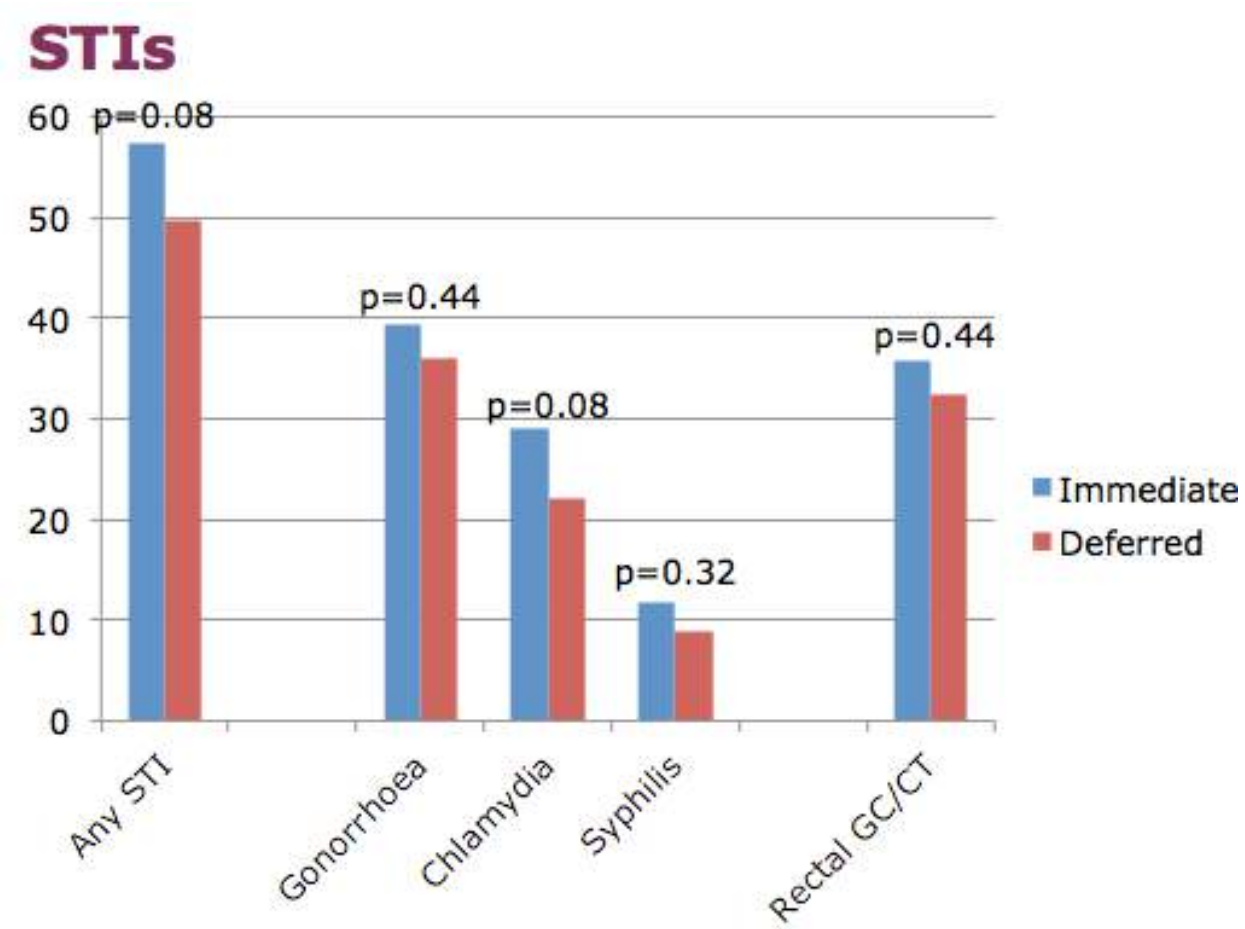




Molina JM, et al. 22nd CROI; Seattle, WA; February 23-26, 2015. Abst. 23LB.

La profilassi pre-esposizione - PrEP

"Le altre infezioni a trasmissione sessuale esploderanno!"



Caveat
Number of screens differed between the groups: e.g. Rectal gonorrhoea/chlamydia, 974 in the IMM group and 749 in the DEF

Sheena McCormack, PROUD study, CROI 2015

La profilassi pre-esposizione - PrEP

"Se ci si infetta, si rischia che il virus diventi resistente"

Drug Resistance

- **3** of **6** individuals who were seroconverting around baseline (immediate group) or month 12 (deferred group) developed **M184V/I** mutations (as a mixture with wild type)

- **K65R** was not detected

La profilassi pre-esposizione - PrEP

"È creata dall'industria farmaceutica per fare soldi"

- Gli studi non sono stati voluti dall'industria: in genere ha solo donato il farmaco
- Il beneficio commerciale sarà limitato
- La casa farmaceutica che produce il farmaco non fa programmi di promozione della PrEP negli USA
- La maggior parte degli utenti hanno la PrEP grazie a programmi assistenziali
- Improbabile che ci sia un uso diffuso fino a quando non ci sarà il generico.
- Il prezzo da ottenere è vicino a quello di condoms + lube o contraccettivi orali o Viagra ecc

Simon Collins, Glasgow 2014

La profilassi pre-esposizione - PrEP

"Non dovremmo medicalizzare il sesso!"

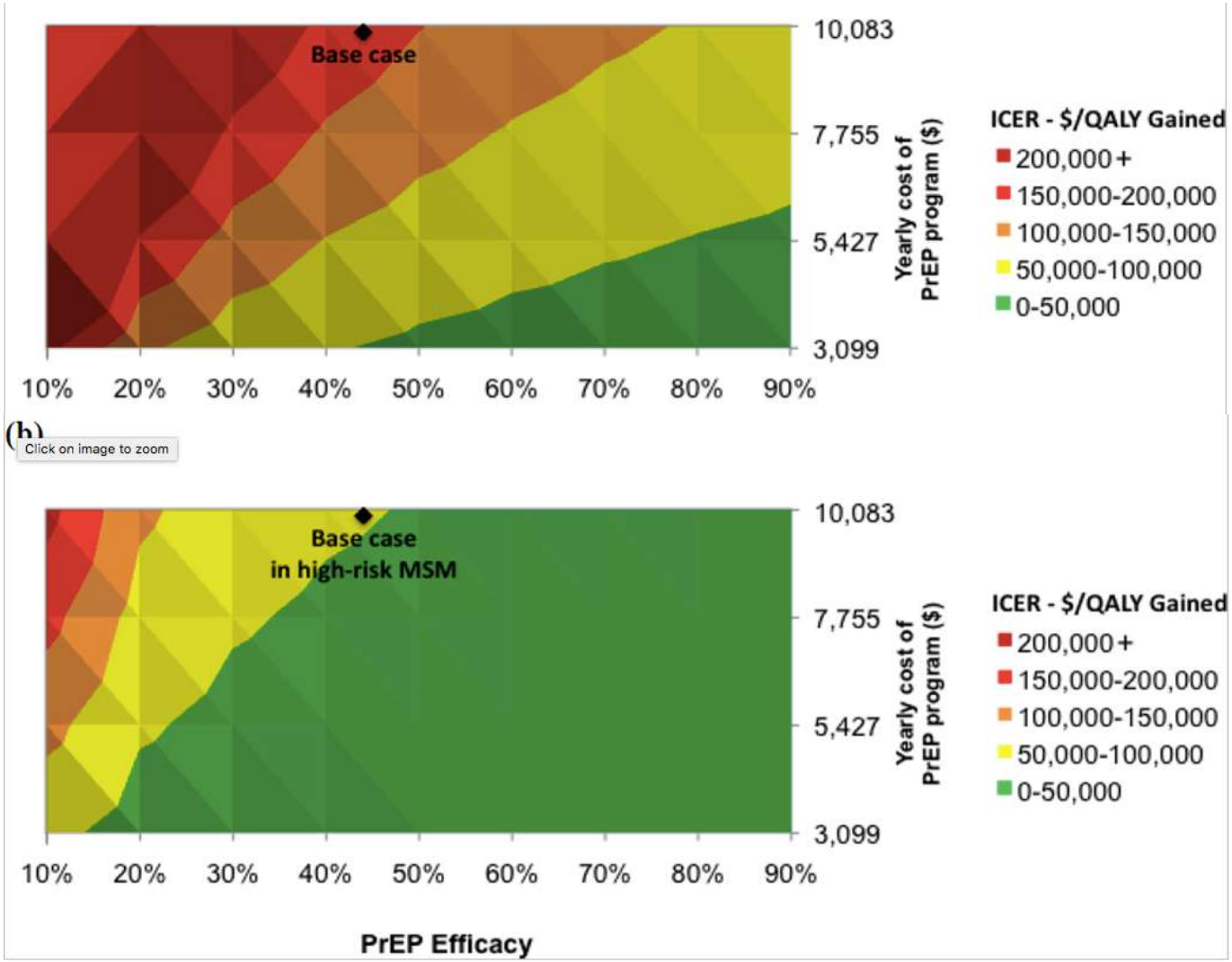
- La PrEP non è per tutti: probabile interesse dal 50% dei possibili utenti [1,2]
- Non deve "sostituire" i condom
- Non dura per tutta la vita
- Disponibilità significa poter scegliere
- Lo scopo è "affrontare un periodo a più alto rischio senza che l'infezione da HIV arrivi a complicare il resto della vita"

1.Aghaizu A , BHIVA 2012. 2. Thng C, BHIVA 2012.

Simon Collins, Glasgow 2014

La profilassi pre-esposizione - PrEP

"È troppo cara, dovremmo usare meglio i soldi"



1. Jessie L. Juusola, The Cost-Effectiveness of Preexposure Prophylaxis for HIV Prevention in Men Who Have Sex with Men in the United States, Ann Intern Med. 2012 Apr 17; 156(8): 541–550

La profilassi pre-esposizione - PrEP

“Perché dovremmo permettere alle persone di fare sesso come vogliono?”

La profilassi pre-esposizione - PrEP

"Perché dovremmo permettere alle persone di fare sesso come vogliono?"

prepineurope.org
Un manifesto per la prevenzione dell'HIV

prepineurope.org

269 Supporters Sign now Share

The HIV Prevention Manifesto: we need PrEP now!

Read
the Manifesto

Sign
and add your support

The manifesto

OPEN LETTER FROM HIV & LGBT EUROPEAN COMMUNITY ORGANISATIONS AND OTHER CONCERNED EUROPEANS TO PHARMACEUTICAL INDUSTRIES, EUROPEAN AND NATIONAL INSTITUTIONS

Background

In recent years, there has been considerable debate about the role that antiretroviral drugs (ARVs) could play in combined HIV prevention strategies. One way of using them is as pre-exposure prophylaxis (PrEP); this involves the use of specific ARVs to reduce

Download PDFs of the statement

- The HIV Prevention Manifesto – English
- The HIV Prevention Manifesto – German
- The HIV Prevention

prepineurope.org
Un manifesto per la prevenzione dell'HIV

I contenuti:

- Gilead deve presentare richiesta di autorizzazione a EMA;
- EMA deve chiarire il percorso regolatorio per la PrEP;
- Migliorare la ricerca sulla PrEP insieme a ricercatori indipendenti;
- Linee guida di implementazione lanciate da ECDC con la collaborazione della società civile e le società cliniche;
- I governi devono individuare forme di copertura della PrEP;
- Adottare strategie combinate di prevenzione dell'HIV in cui nessun metodo sia posto in competizione con altri.

prepineurope.org
Un manifesto per la prevenzione dell'HIV

I firmatari italiani:

Anlaids

Associazione Radicale Certi Diritti

Circolo di cultura omosessuale Mario Mieli

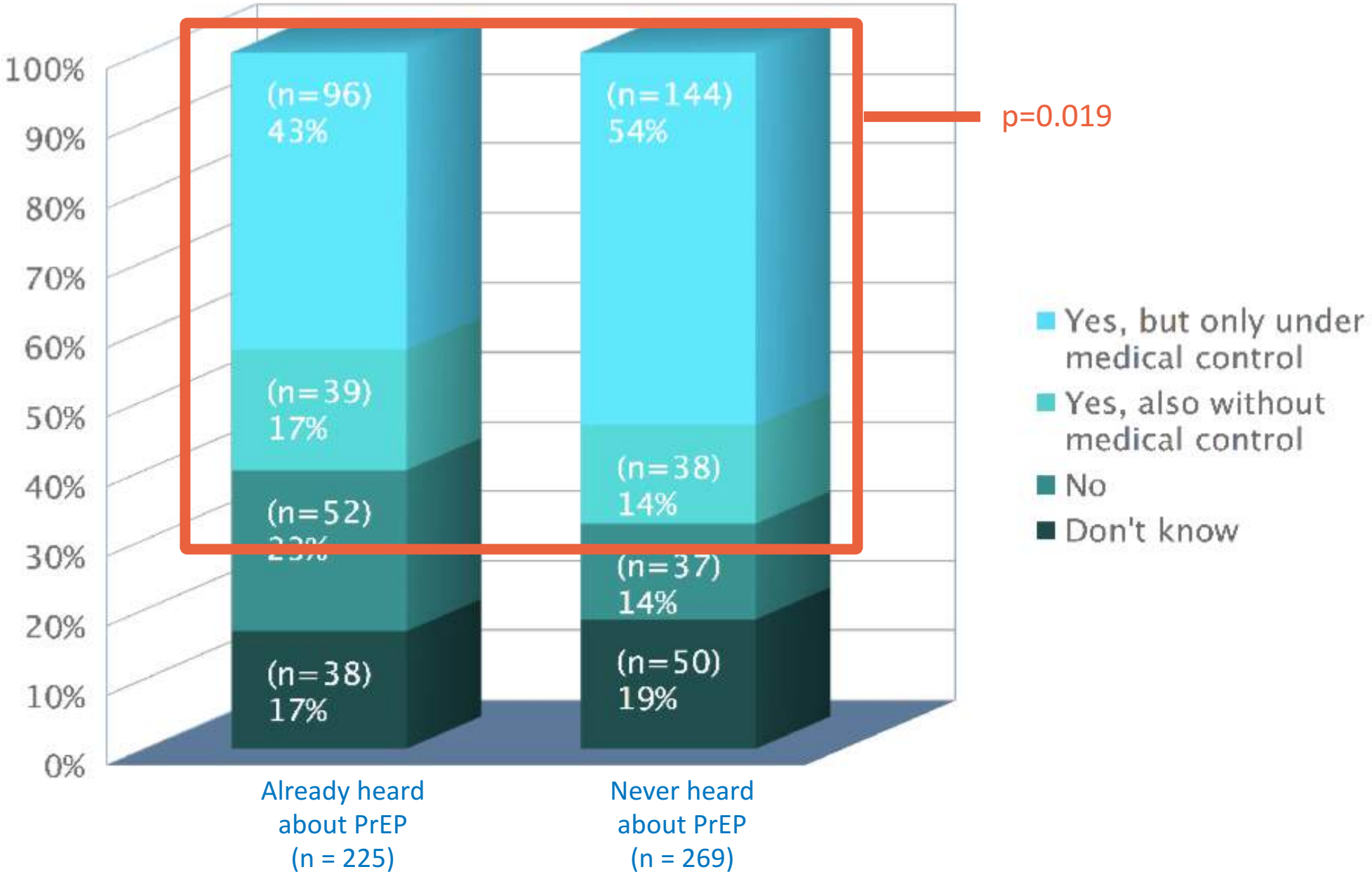
Lila

Nadir

Plus

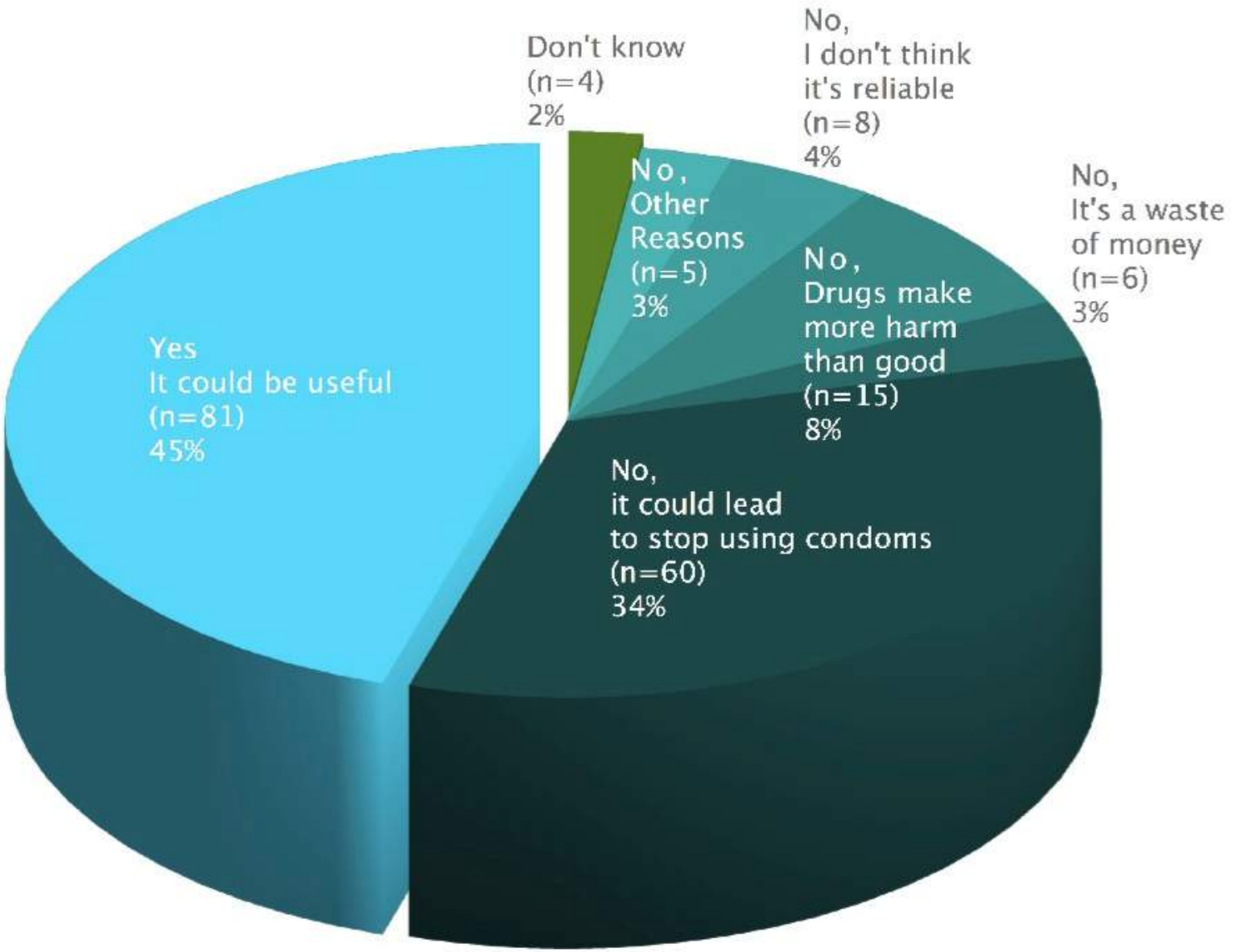
3 – Will to take PrEP

Q4 – Should a clinician offer to you this opportunity, would you use it?
n = 503



4b – PrEP for others

Q6a – Again, if you answered “No” or “Don't know”, do you think this opportunity should be offered to other people, even if you would not take it?
n = 179



Qualità della vita

- Per tre decenni l'impatto della paura dell'infezione ha avuto effetti pesanti: prima, durante e dopo il sesso.
- PrEP e TasP possono cambiare questo scenario
- Potenzialmente normalizzare HIV: lo stigma resta alto in gruppi ad alto rischio
- Assumere il controllo del rischio HIV è una motivazione
- L'intimità è una motivazione

Riduce l'ansia

- "I'm a physician and I've started PrEP" [1]

"I am a 60-year-old gay man who has spent those same three decades trying to keep myself from becoming infected with HIV. I am tired of being scared, so I am starting on PrEP".

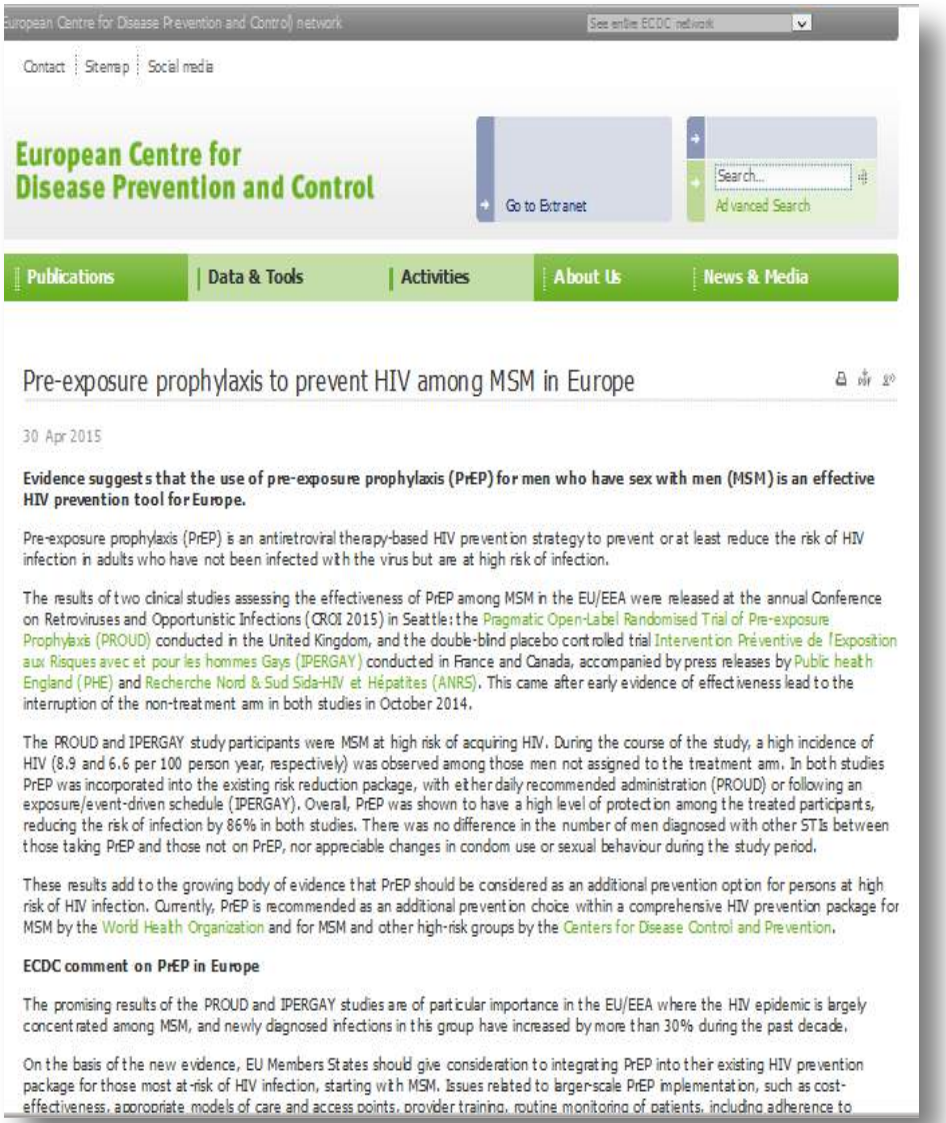
"If there is something out there that can reduce my risk of getting HIV by 95%, I will use it. I'm tired of being scared of HIV." — Dr Howard Grossman, July 2014

1. Grossman H, I'm an HIV Physician. And I'm Starting PrEP. TheBody.com. July 2014.

Name a common side effect from taking PrEP.
Peace of mind.
Learn about PrEP – www.myprepexperience.blogspot.com

ECDC opinion on PrEP April 2015

- Countries should give consideration to integrating PrEP into their existing HIV prevention package for those most at-risk, starting with MSM
- Issues related to PrEP implementation will need to be addressed in the context of each Member State's health system
- ECDC will provide support to Member States and the European Commission with regards to PrEP implementation



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Pre-exposure prophylaxis to prevent HIV among MSM in Europe

30 Apr 2015

Evidence suggests that the use of pre-exposure prophylaxis (PrEP) for men who have sex with men (MSM) is an effective HIV prevention tool for Europe.

Pre-exposure prophylaxis (PrEP) is an antiretroviral therapy-based HIV prevention strategy to prevent or at least reduce the risk of HIV infection in adults who have not been infected with the virus but are at high risk of infection.

The results of two clinical studies assessing the effectiveness of PrEP among MSM in the EU/EEA were released at the annual Conference on Retroviruses and Opportunistic Infections (CROI 2015) in Seattle: the Pragmatic Open-Label Randomised Trial of Pre-exposure Prophylaxis (PROUD) conducted in the United Kingdom, and the double-blind placebo controlled trial Intervention Préventive de l'Exposition aux Risques avec et pour les hommes Gays (IPERGAY) conducted in France and Canada, accompanied by press releases by Public health England (PHE) and Recherche Nord & Sud Sida-HIV et Hépatites (ANRS). This came after early evidence of effectiveness lead to the interruption of the non-treatment arm in both studies in October 2014.

The PROUD and IPERGAY study participants were MSM at high risk of acquiring HIV. During the course of the study, a high incidence of HIV (8.9 and 6.6 per 100 person year, respectively) was observed among those men not assigned to the treatment arm. In both studies PrEP was incorporated into the existing risk reduction package, with either daily recommended administration (PROUD) or following an exposure/event-driven schedule (IPERGAY). Overall, PrEP was shown to have a high level of protection among the treated participants, reducing the risk of infection by 86% in both studies. There was no difference in the number of men diagnosed with other STIs between those taking PrEP and those not on PrEP, nor appreciable changes in condom use or sexual behaviour during the study period.

These results add to the growing body of evidence that PrEP should be considered as an additional prevention option for persons at high risk of HIV infection. Currently, PrEP is recommended as an additional prevention choice within a comprehensive HIV prevention package for MSM by the World Health Organization and for MSM and other high-risk groups by the Centers for Disease Control and Prevention.

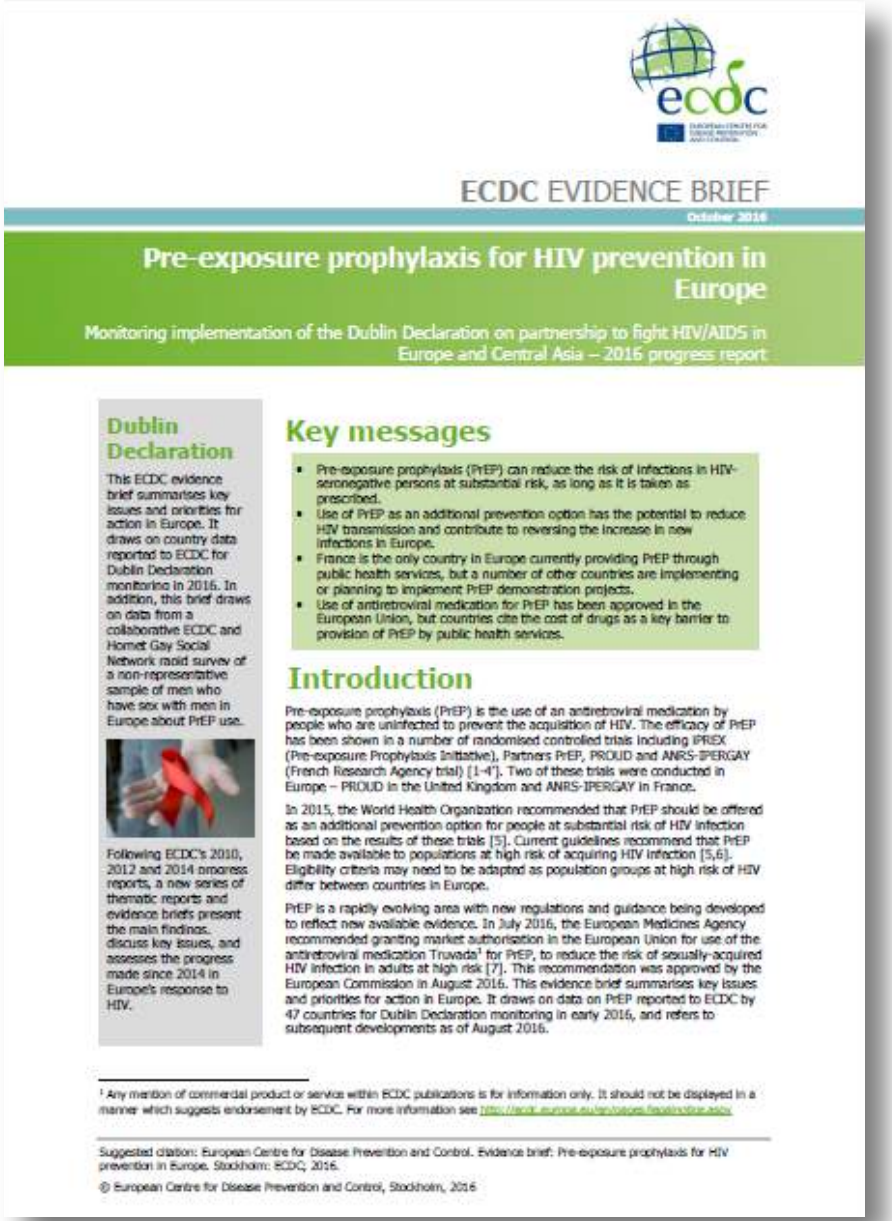
ECDC comment on PrEP in Europe

The promising results of the PROUD and IPERGAY studies are of particular importance in the EU/EEA where the HIV epidemic is largely concentrated among MSM, and newly diagnosed infections in this group have increased by more than 30% during the past decade.

On the basis of the new evidence, EU Members States should give consideration to integrating PrEP into their existing HIV prevention package for those most at-risk of HIV infection, starting with MSM. Issues related to larger-scale PrEP implementation, such as cost-effectiveness, appropriate models of care and access points, provider training, routine monitoring of patients, including adherence to

Status of PrEP implementation in Europe

(Published 16 October)



ECDC EVIDENCE BRIEF

October 2016

Pre-exposure prophylaxis for HIV prevention in Europe

Monitoring implementation of the Dublin Declaration on partnership to fight HIV/AIDS in Europe and Central Asia – 2016 progress report

Dublin Declaration

This ECDC evidence brief summarises key issues and priorities for action in Europe. It draws on country data reported to ECDC for Dublin Declaration monitoring in 2016. In addition, this brief draws on data from a collaborative ECDC and Hornet Gay Social Network rapid survey of a non-representative sample of men who have sex with men in Europe about PrEP use.

Following ECDC's 2010, 2012 and 2014 progress reports, a new series of thematic reports and evidence briefs present the main findings, discuss key issues, and assesses the progress made since 2014 in Europe's response to HIV.

Key messages

- Pre-exposure prophylaxis (PrEP) can reduce the risk of infections in HIV-seronegative persons at substantial risk, as long as it is taken as prescribed.
- Use of PrEP as an additional prevention option has the potential to reduce HIV transmission and contribute to reversing the increase in new infections in Europe.
- France is the only country in Europe currently providing PrEP through public health services, but a number of other countries are implementing or planning to implement PrEP demonstration projects.
- Use of antiretroviral medication for PrEP has been approved in the European Union, but countries cite the cost of drugs as a key barrier to provision of PrEP by public health services.

Introduction

Pre-exposure prophylaxis (PrEP) is the use of an antiretroviral medication by people who are uninfected to prevent the acquisition of HIV. The efficacy of PrEP has been shown in a number of randomised controlled trials including iPREX (Pre-exposure Prophylaxis Initiative), Partners PrEP, PROUD and ANRS-IPERGAY (French Research Agency trial) [1-4]. Two of these trials were conducted in Europe – PROUD in the United Kingdom and ANRS-IPERGAY in France.

In 2015, the World Health Organization recommended that PrEP should be offered as an additional prevention option for people at substantial risk of HIV infection based on the results of these trials [5]. Current guidelines recommend that PrEP be made available to populations at high risk of acquiring HIV infection [5,6]. Eligibility criteria may need to be adapted as population groups at high risk of HIV differ between countries in Europe.

PrEP is a rapidly evolving area with new regulations and guidance being developed to reflect new available evidence. In July 2016, the European Medicines Agency recommended granting market authorisation in the European Union for use of the antiretroviral medication Truvada[1] for PrEP, to reduce the risk of sexually-acquired HIV infection in adults at high risk [7]. This recommendation was approved by the European Commission in August 2016. This evidence brief summarises key issues and priorities for action in Europe. It draws on data on PrEP reported to ECDC by 47 countries for Dublin Declaration monitoring in early 2016, and refers to subsequent developments as of August 2016.

[1] Any mention of commercial product or service within ECDC publications is for information only. It should not be displayed in a manner which suggests endorsement by ECDC. For more information see http://ecdc.europa.eu/en/about/legal/intellectual.aspx

Suggested citation: European Centre for Disease Prevention and Control. Evidence brief: Pre-exposure prophylaxis for HIV prevention in Europe. Stockholm: ECDC; 2016.

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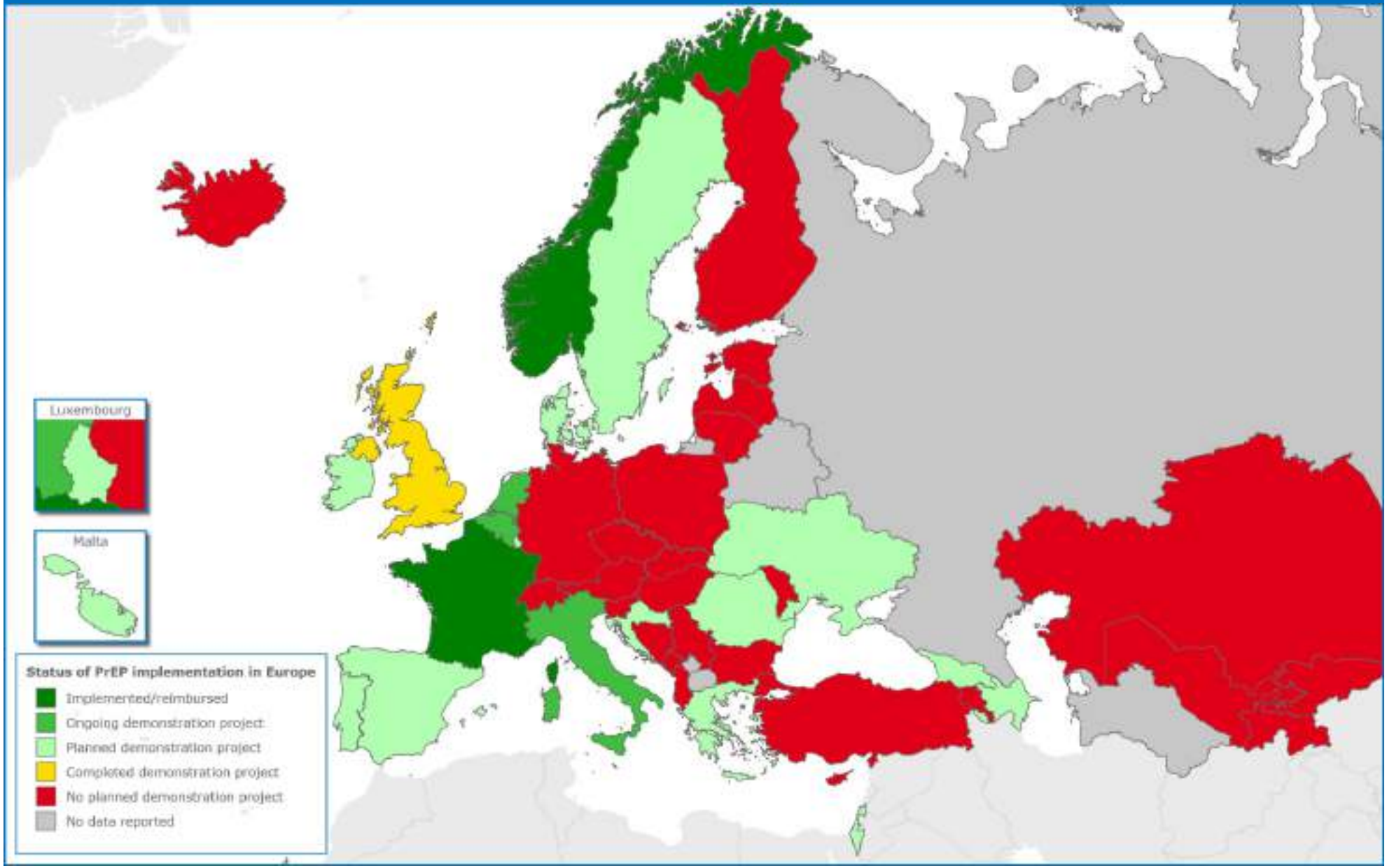
ECDC. Evidence brief: Pre-exposure prophylaxis for HIV prevention in Europe. Stockholm: ECDC; 2016.

Status of PrEP implementation in Europe



ECDC. Evidence brief: Pre-exposure prophylaxis for HIV prevention in Europe. Stockholm: ECDC; 2016. (updated)

Timeframe and setting of PrEP implementation

COUNTRY	STATUS OF PrEP	TIMEFRAME	SETTING
FRANCE	Implemented/reimbursed	2016	Health care setting
NORWAY	Implemented/reimbursed	2016	Health care setting
BELGIUM	Ongoing demonstration project	(2015-2018)	Health care setting
NETHERLANDS	Ongoing demonstration project	(2015-2018)	Health care setting
ITALY	Ongoing demonstration project		Health care setting
UNITED KINGDOM	Completed demonstration project	(2012-2016)	Health care setting
CROATIA	Planned demonstration project	(2016-?)	Health care setting
DENMARK	Planned demonstration project	(2017-2018)	Community-based setting
GREECE	Planned demonstration project	(2016-2017)	Health care setting
IRELAND	Planned demonstration project	(2016-2017)	Health care & community setting
LUXEMBOURG	Planned demonstration project	(2016-2017)	Health care setting
MALTA	Planned demonstration project	--	TBD
PORTUGAL	Planned demonstration project	(2016-2017)	Community-based setting
ROMANIA	Planned demonstration project	--	TBD
SPAIN	Planned demonstration project	(2016-2017)	Community-based setting/STI clinic
SWEDEN	Planned demonstration project	(2016-2017)	Health care setting
AZERBAIJAN	Planned demonstration project	(TBD)	TBD
GEORGIA	Planned demonstration project	(2017-2018)	TBD
ISRAEL	Planned demonstration project	(2017-2018)	Health care setting
UKRAINE	Planned demonstration project	(2017-2018)	Community-based setting

PrEP in Francia

Libération — Sida : Touraine donne son feu vert au Truvada en prévent... — 100

À CHAUD

Sida : Touraine donne son feu vert au Truvada en prévention

Par Eric Favereau — 23 novembre 2015 à 17:23

Le Truvada réduit considérablement le risque de transmission du VIH. Photo Justin Sullivan. AFP

PARTAGER TWEETER

VintageSynth for sale

A lot of vintage analog synths FiveG is a vintage gears specialist

fiveg.net

PrEP in Francia

Disponibile dal 1° gennaio 2016 per:

- **Adulti maggiorenni**
- **Test HIV sierologico negativo (ELISA 4a generazione)**
- **Nessun sintomo di infezione primaria**
- **Nessuna esposizione all'HIV recente (< 1 mese)**
- **Alto rischio di acquisizione di HIV per via sessuale**

High Risk of Sexual HIV Acquisition

MSM or transgender individuals with:

- Condomless anal sex with > 2 different partners over the last 6 months
- STIs (syphilis, chlamydiae, gonorrhea, HBV, HCV) over the last 12 months
- Multiple PEP treatments in the last 12 months
- Use of drugs during sexual intercourse (cocaine, GHB, MDMA, etc…)

Other persons at high risk on **a case by case basis**:

- Sex workers exposed to condomless sex
- Vulnerable persons exposed to condomless sex with people from a group with a high prevalence of HIV
  - Person from areas/countries of high HIV prevalence
  - Person with multiple sexual partners
  - IVDU

Other high risk situations of HIV acquisition

Who is Not Eligible for Truvada

HIV Serologic assay positive or unknown

Signs or symptoms of primary HIV-infection

Creatinine clairance < 50 ml/mn

Chronic HBV infection if PrEP used On Demand

Breast-feeding

Hypersensitivity to TDF or FTC or excipients

Dosing Regimens and Follow-up

Dosing Regimen

Daily (1 pill a day) or **On demand** (only for MSM)

Patients follow-up

Doctor visits at baseline, month 1 and every 3 months

Baseline tests: HIV/HBV/HCV, tests for STIs (PCR 3 sites and syphilis), creatinine and ALT

Tests at Month 1 and every 3 months: HIV test (4th generation ELISA), ALT and creatinine

Tests for STIs as needed (at least once a year)

Global Sexual Health

Referrals for psychiatry, addictology, anuscopy, sex therapy…

Requirements for the Truvada RTU

Doctors should tell their patients that Truvada is prescribed through an RTU

At ANSM's request Gilead has opened a **website** (https://www.rtutruvada.fr) to collect information on PrEP

Doctors should **report anonymous data on this website**

- patients characteristics at treatment initiation,
- modalities of PrEP use (daily or on demand),
- incident HIV-infections,
- drug-related adverse events,
- pregnancies,

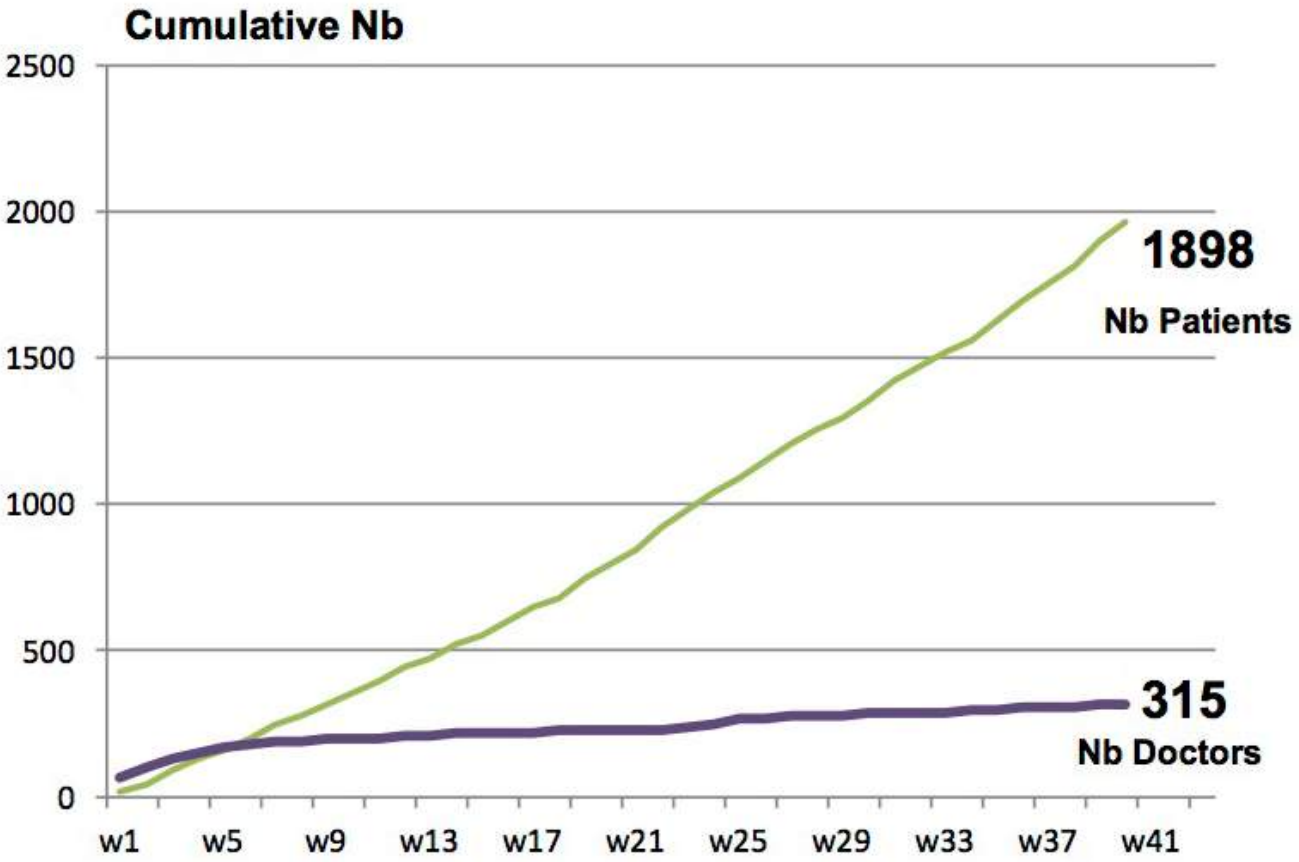
Data analyzed by Gilead and reported to ANSM **every 3 months.**

PrEP Implementation in France in 2016

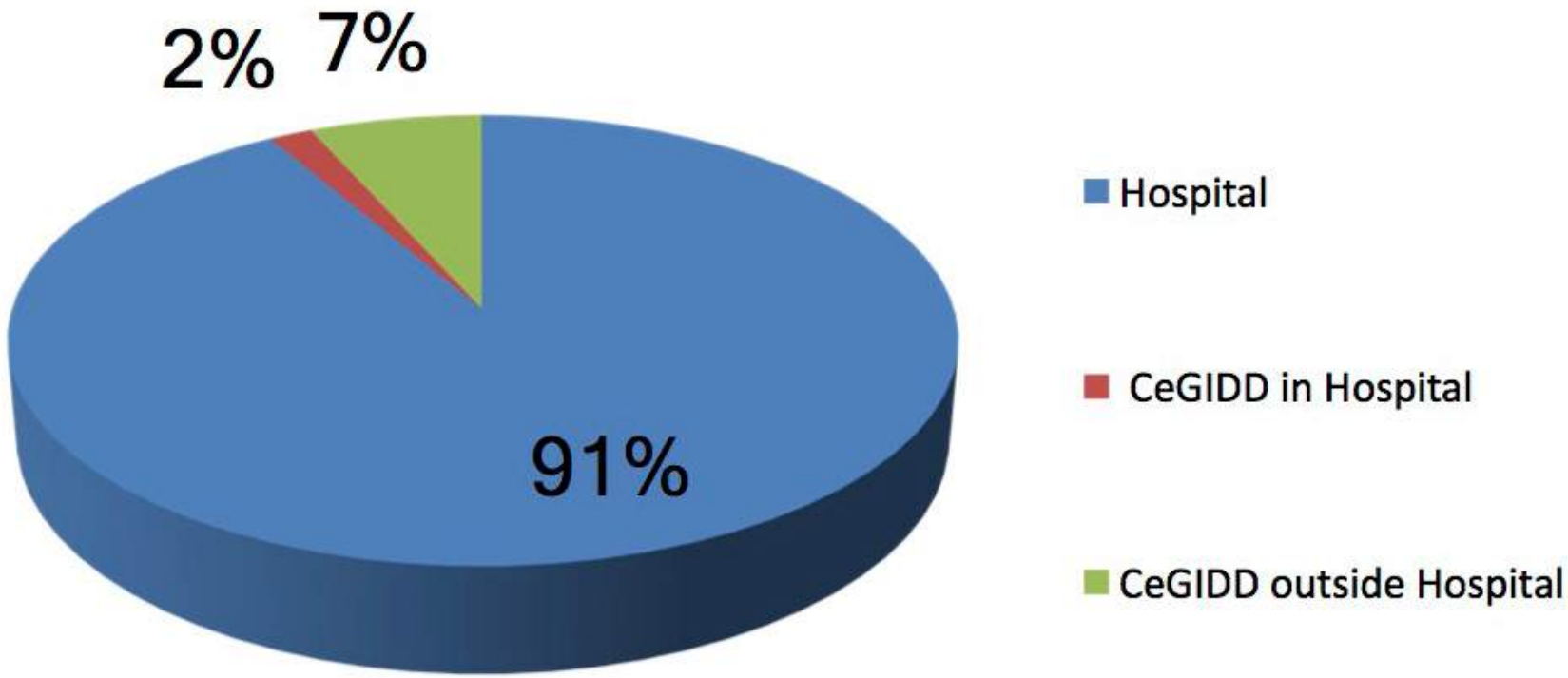
> 120 PrEP clinics have opened, initially in ANRS Ipergay sites (Paris, Lyon, Nice, Lille, Nantes)

AIDES Website: http://www.aides.org/info-sante/prep

TDF/FTC can be obtained at private and hospital pharmacies



Where is PrEP Delivered ?
France 01 to 09/2016



TDF/FTC can be prescribed by hospital-based HIV specialists and CeGIDD (STI clinics) since June 2016

Number of Users Registered per Region

Baseline Characteristics (Jan 2016- Sep 2016)

Pts Characteristics (Median, IQR) or (%)	N= 1526
Age, years	38 (30-44)
French	88.9%
Male	97.4%
Female	0.8% (n=12)
Transgender	0.4% (n=6)
MSM	97.5%
Use of psychoactive drugs	19.9%
STIs in prior 12 months	30.6%
PEP use in last 12 months	10.9%
On Demand PrEP	**61.1%**

PrEP "On Demand"

Three HIV Breakthrough Infections

Patient 1:

- Negative HIV serologic assay (4th Generation ELISA) at PrEP initiation
- HIV seroconversion at the next visit one month later
- HIV PCR retrospectively found positive at baseline
- Acute HIV-infection at PrEP initiation

Patient 2:

- Negative HIV serologic assay (4th Generation ELISA) at PrEP initiation
- HIV seroconversion at the next visit one month later
- HIV RNA: 500 cp/ml with M184I RAM

Patient 3:

- On PrEP for the last 2 years (on demand) but missed the August 2016 visit
- Comes back October 5 with a negative HIV test done on Sep15
- Run out of PrEP (last intake Sep 15) and had unprotected anal intercourse with multiple partners on Sep 29
- PrEP not delivered at the October 5 visit and he was asked to perform a HIV RNA test 2 weeks later: HIV RNA level: 6.7 log

Lessons Learned in France

- Close **partnership with the community** and strong political support have led to PrEP approval
- Increase **PrEP awareness** among doctors and people at risk (MSM, transgender, and heterosexual migrants)
- Adapt available resources to provide **comprehensive sexual health care including PrEP**
- Define best models of care and access points (hospitals, sexual health clinics, GP)
- **Monitor** and evaluate PrEP implementation
- High risk people self-select for PrEP: HIV-infection detected at screening or soon after PrEP initiation
- Demonstrate the **public health benefit** of PrEP implementation ANRS « PREVENIR » project

PrEP in Italia

La PrEP dovrebbe essere inserita nelle Linee guida nazionali che usciranno a dicembre 2016; sono stati proposti i seguenti criteri di inclusione:
Analizzare i comportamenti o l'esistenza di fattori recenti (ultimi 3 mesi) che comportino un rischio di acquisizione dell'infezione da HIV:
a) MSM:

- Almeno un rapporto anale senza l'uso del preservativo con partner occasionale HIV-positivo o di sierostato ignoto (storia di uso inconsistente o non uso del condom)
- Trattamento di una IST
- Precedente PEP

b) Eterosessuali

- Uso inconsistente del profilattico e rapporti occasionali o con partner a rischio per HIV e
- Almeno un rapporto anale senza l'uso del preservativo
- Trattamento di una IST
- Precedente PEP

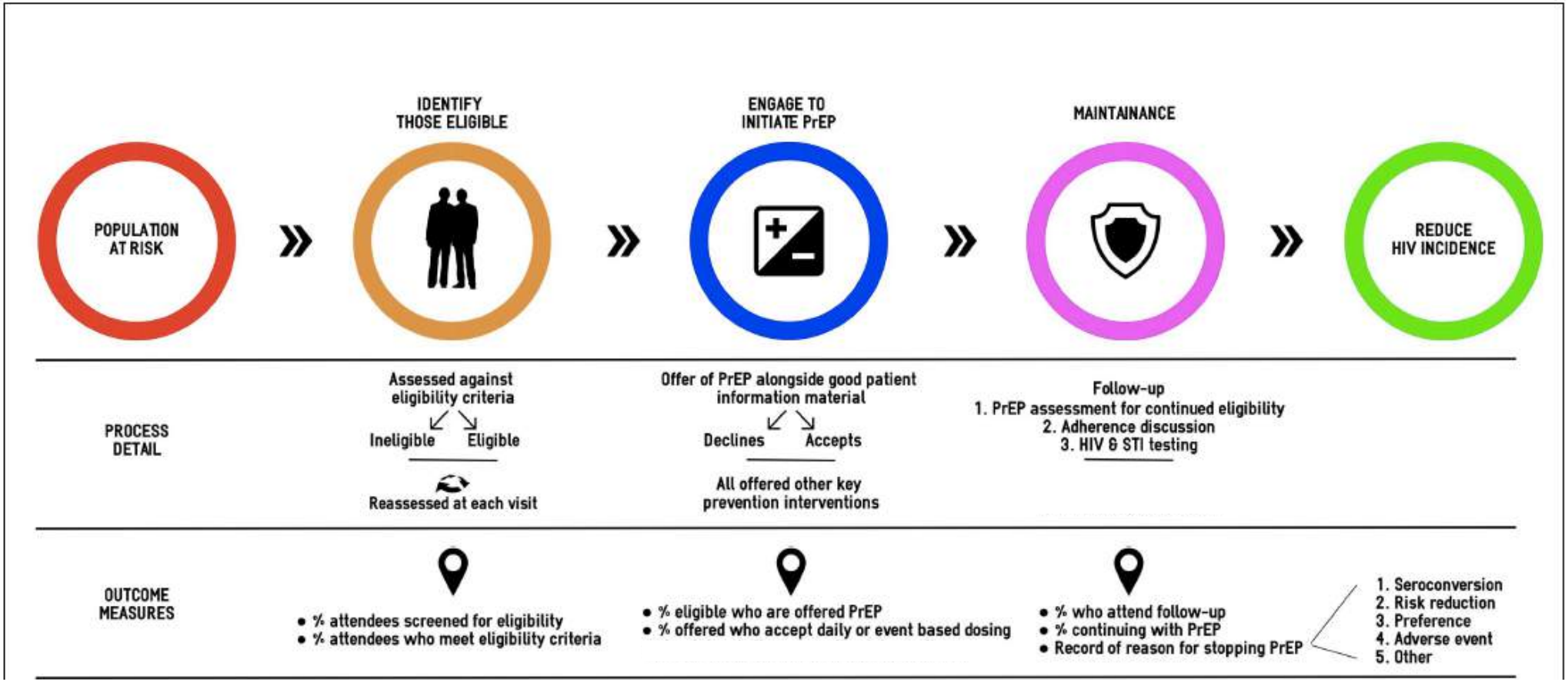
c) Tossicodipendenti per via iniettiva con scambio siringhe negli ultimi 6 mesi e in trattamento presso centri specializzati
d) Sex workers
e) Partner sessuali o iniettivi di persona HIV-positiva viremica:
- Non in terapia (rifiuto, scarsa aderenza);
- Inizio terapia, fino a soppressione virologica.
f) Casi particolari: concepimento in coppie siero discordanti
In coppie siero discordanti in cui l'uomo HIV positivo assume la cART ed è in soppressione virologica stabile, nei casi in cui uno o entrambi i partner non riescano ad affrontare con serenità un concepimento per via naturale, la PrEP alla donna può offrire un ulteriore beneficio nel ridurre al minimo il rischio di trasmissione.

PrEP in Italia

E nel frattempo?...

C’è chi la fa per conto proprio!

Monitorare i risultati di un programma PrEP



Grazie

www.plus-onlus.it

ChemSex: knowledge and behaviours among Italian MSM

Giulio Maria Corbelli

Plus onlus,
European AIDS Treatment Group

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What is Chemsex?

ChemSex is a common term used by gay men on sexual networking sites and smartphone Apps.

ChemSex is NOT the same as recreational drug use.

It is a specific form of recreational drug use.

ChemSex is defined by the use of any combination of drugs that includes three specific drugs ("chems") before or during sex by MSM (Men who have Sex with Men).

These three drugs are meth, meph and G.

- Methamphetamine (crystal/crystal meth/ Tina/meth).
- Mephedrone (meph/drone).
- GHB/GBL* (G, Gina).

Source: http://www.chemsexsupport.com/for-professionals

Reasons for ChemSex are similar to using other drugs

- To feel more sexually free and to overcome intimacy issues.
- To overcome fear of rejection, sexual shame.
- To cope with stigma over HIV/hepatitis C (HCV).
- To overcome problems in the past, including sexual abuse.
- To overcome internalised homophobia.
- Wanting 'better' sex, that lasts longer.
- Loneliness.
- Wanting intimacy, to connect to others, to feel part of a community.
- Wanting sexual affirmation.
- Because "everyone's doing it".
- Because it is an online hook-up 'norm'.
- Peer pressure.

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Source: David Stuart, 56 Dean Street and Simon Collins, HIV i-Base. *Methmephangee – ChemSex vs recreational drug use: a proposed definition for health workers*. HIV Treatment Bulletin, June 2015

However, side effects from ChemSex are more severe than other commonly used recreational drugs

ChemSex is associated with more extreme behaviour and risk:

- Extended sex for many hours.
- Sometimes multiple partners, multiple times.
- Extreme sexual disinhibition.
- Side effects include overdose (fatal), paranoia, psychosis and black-outs.
- Drug interactions can be serious and difficult to predict (i.e. between alcohol and GBL/GHB).
- Meth and meph are often injected ("slamming").
- Serious short and long term impact includes chronic depression, anxiety, weight-loss, paranoia, psychosis.

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Source: David Stuart, 56 Dean Street and Simon Collins, HIV i-Base. *Methmephangee – ChemSex vs recreational drug use: a proposed definition for health workers*. HIV Treatment Bulletin, June 2015

Possibili danni del Chemsex

Danni dovuti alla salute fisica

- Immediati (overdose accidentale o esposizione a IST); a medio termine (affaticamento, astinenza); a lungo termine (deterioramento dei muscoli)
- overdose: confusione, aggressività con possibili danni fisici a sé o altri, atti sessuali non voluti, perdita di coscienza

Danni alla salute mentale

- Attacchi di ira, ansia o aggressività, paranoia estrema che può richiedere l'intervento medico

Perdita di tempo

- Molti riferiscono che le sessioni di chemsex, che durano dalle 4 ore ai 4 giorni, vengono poi vissute come perdita di tempo

Danni relativi al lavoro e finanze

- Spesso non si riesce ad andare al lavoro per i postumi, si perdono opportunità di carriera e si spendono molti soldi per le droghe

Danni sociali e relazionali

- Le relazioni nelle sessioni sono spesso egocentriche incentrate sul piacere sessuale

Danni relativi alla comunità gay

- Grande diffusione delle IST, perdita delle relazioni, dinamica di normalizzazione delle droghe facilitata dalle app

Source:Sigmaresaerch: The Chemsex Study, 2014

Le sostanze

Nome	Gergo	Descrizione	Assunzione	Effetti	Possibili danni
Mefedrone	Mef, miao miao	droga stimolante nella forma di una polverina bianca	sniffare, ingoiare, iniettare in vena (slamming) o nel retto con una siringa senz'ago (booty bump)	Per circa un'ora dopo aver assunto mefedrone ti puoi sentire particolarmente allerta, vicino a chi ti circonda, sicuro di te ed eccitato. L'iniezione via slamming porta a una botta più rapida, intensa e duratura.	Ansia e paranoia, iperstimolazione del cuore, della circolazione e del sistema nervoso con possibili convulsioni

Le sostanze

Nome	Gergo	Descrizione	Assunzione	Effetti	Possibili danni
Crystal meth	Crystal, tina, meth, ice, T	Stimolante, forma più pura delle metamfetamine polvere, o cristalli bianchi o trasparenti	Inalato mediante una pipa di vetro, sniffato o iniettato per via intravenosa (slamming) o nel retto (booty bump)	Dà la carica, ti fa sentire vigile e sicuro di te, impulsivo e molto eccitato, senza freni inibitori	Aumenta anche la temperatura corporea, il battito cardiaco e la pressione sanguigna, con possibili rischi di infarto, ischemia, coma o morte – soprattutto se mischiato ad altri farmaci, compresi alcuni antidepressivi e antiretrovirali (in particolare, gli inibitori della proteasi).

Le sostanze

Nome	Gergo	Descrizione	Assunzione	Effetti	Possibili danni
GHB/ GBL	G, Gina, ecstasy liquida	GHB (acido gamma-idrossibutirrico) e GBL (lattone dell'acido gamma-idrossibutirrico) si presentano come un liquido identico all'acqua	Viene dosato con pipette o piccole siringhe in acqua o altra bevanda analcolica oppure iniettato nel retto con una siringa senz'ago (booty bumping)	Rilassa e fa sentire eccitato. Spesso si usa per aumentare l'effetto di altre droghe	Attacchi di panico, sudorazione e convulsioni, in caso di overdone perdita di coscienza. Pericolosissima con alcol e/o amfetamine

Le sostanze

Nome	Gergo	Descrizione	Assunzione	Effetti	Possibili danni
Ketamina	K, special K, vitamina K	Sedativo che si presenta in forma di polvere	Solitamente inalata, effetti durano tra i 45 e i 90 minuti. Se iniettata in forma liquida o ingoiata, i suoi effetti durano anche tre ore.	Ha il potere di eccitarti e di far perdere sensibilità al corpo, per cui il sesso può durare anche molto a lungo senza accorgersi di lesioni al glande o al retto. È una droga molto diffusa nell'ambito del fisting.	Ansia, depressione, istinti suicidi, perdita di memoria. Se eccedi col dosaggio puoi finire nel «K-hole»

Our research: Background

The first European Chemsex Forum (London, 6-8 April) launched a brief survey throughout Europe to understand knowledge and behaviour about Chemsex among MSM. Plus onlus translated the survey and launched it on the internet to assess knowledge and behaviour related to chemsex among Italian MSMs.

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The survey

European ChemSex Forum
6-8 April 2016
Congress Centre London

ChemSex: parlaci di sesso gay e droghe

Ti è mai capitato di fare sesso sotto effetto di droghe? Aiutaci a capire meglio! Partecipa a questo semplice e veloce questionario anonimo. Presenteremo i risultati al 1^ European ChemSex Forum che si tiene a Londra il 6-8 aprile

- online survey: promoted on Facebook, Twitter and mailing lists
- 23 February – 23 March, 2016
- 14 questions
- 312 respondents; 282 included in final analysis

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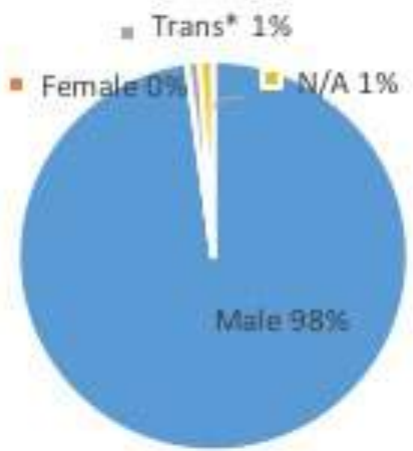
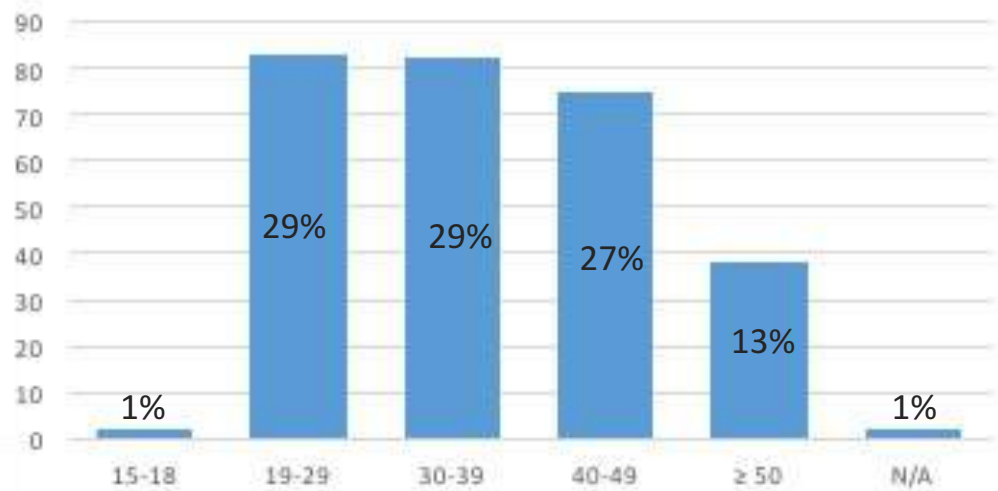
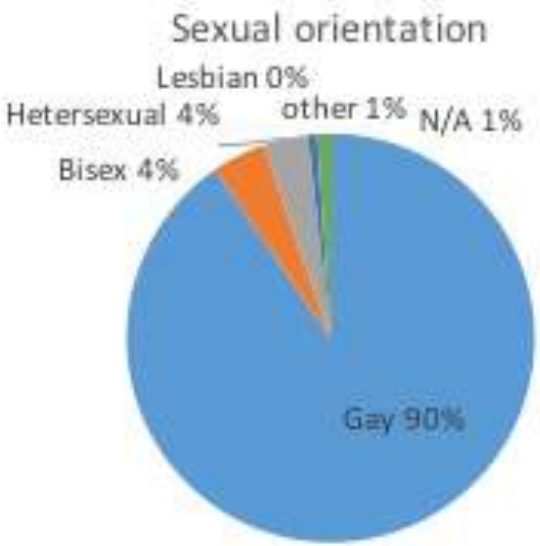
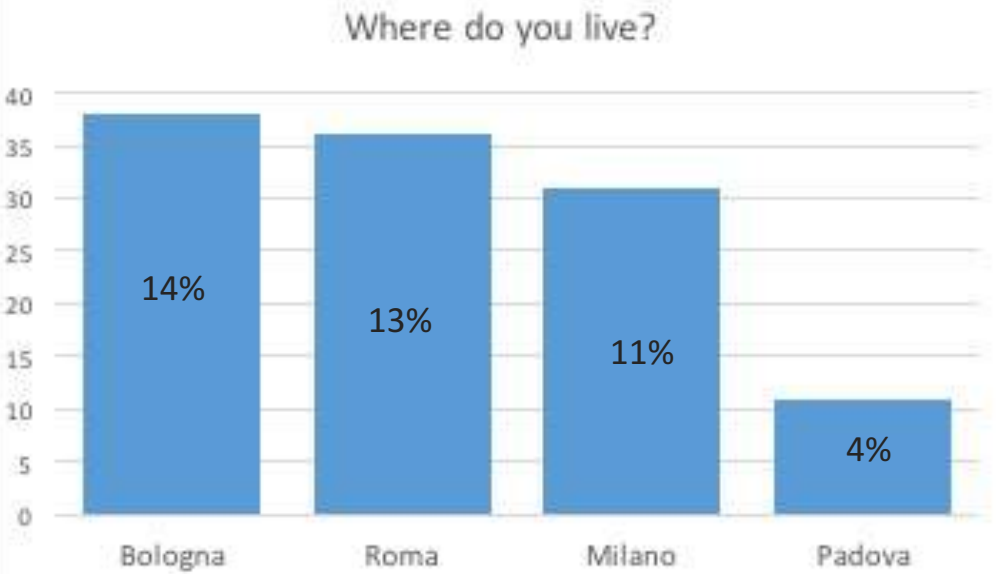
Characteristics of respondents









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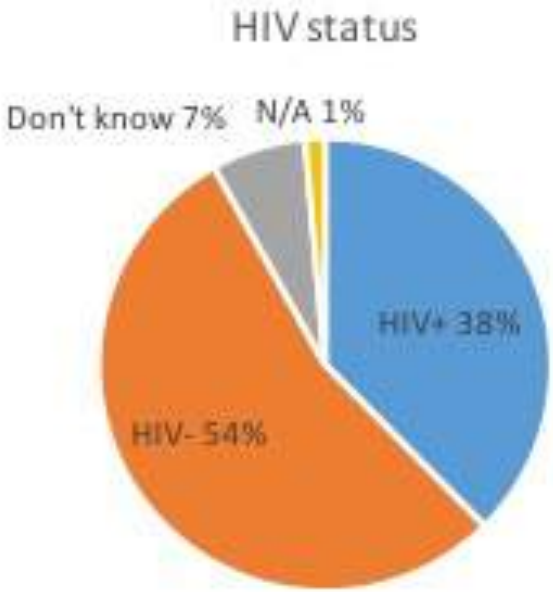
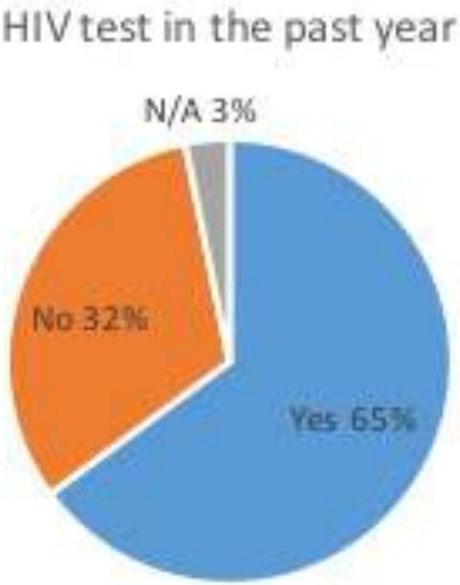
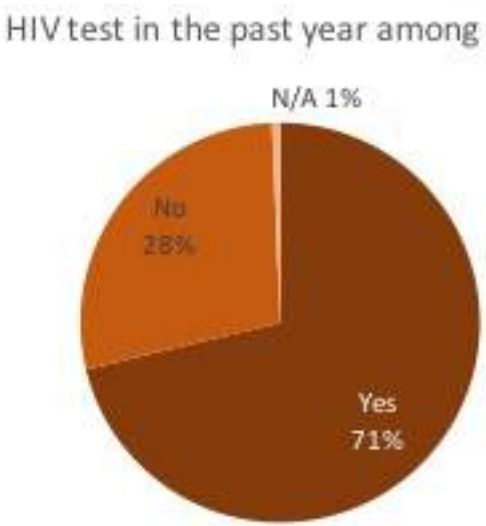
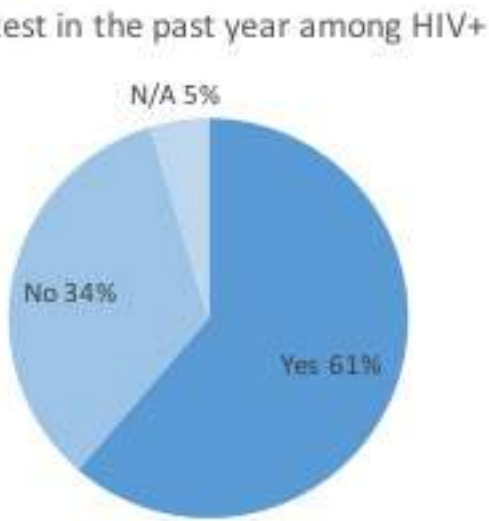
HIV status of respondents









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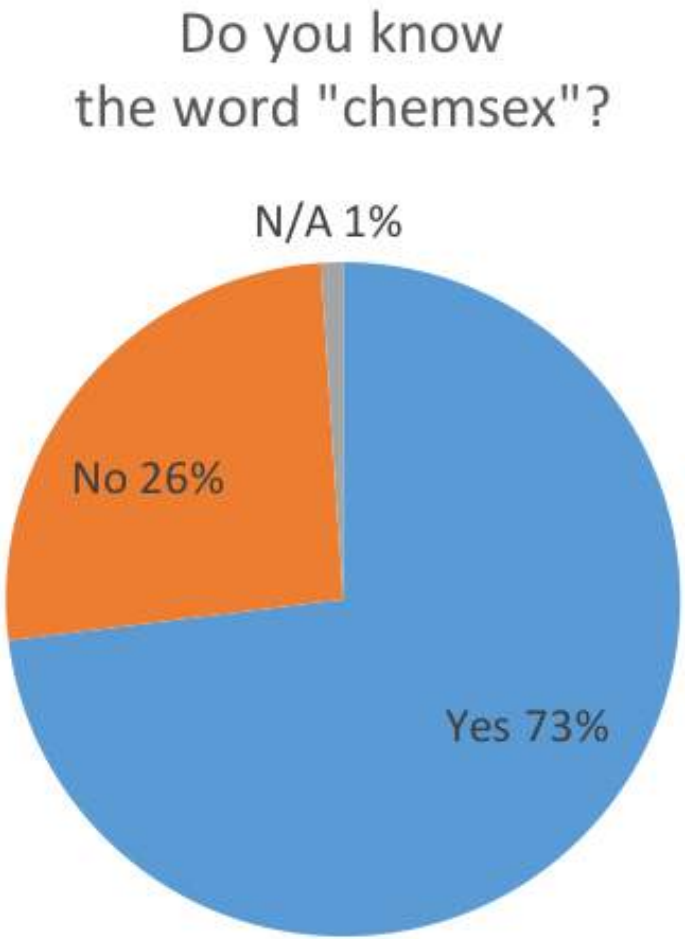
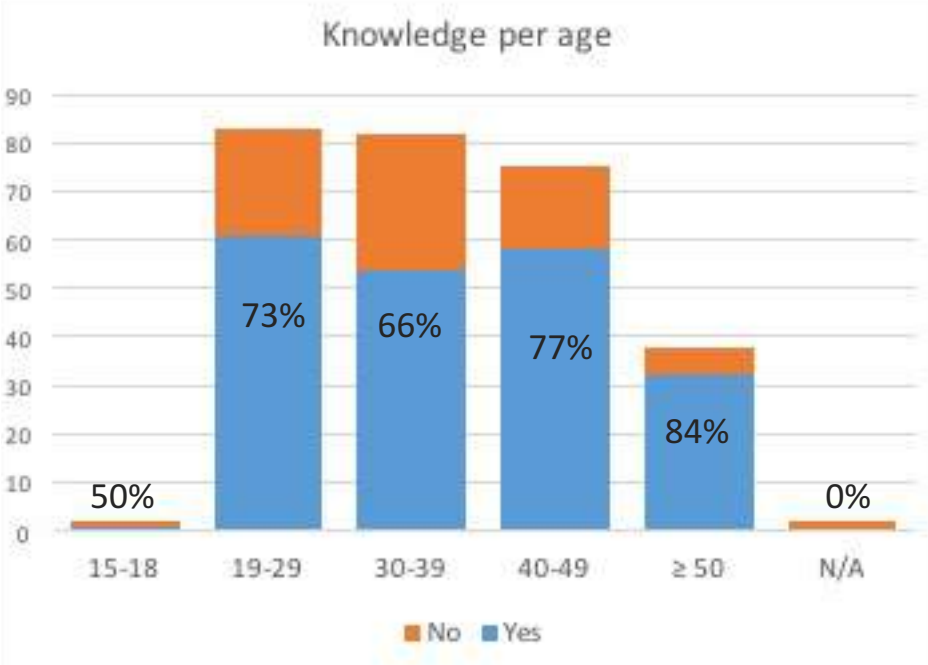
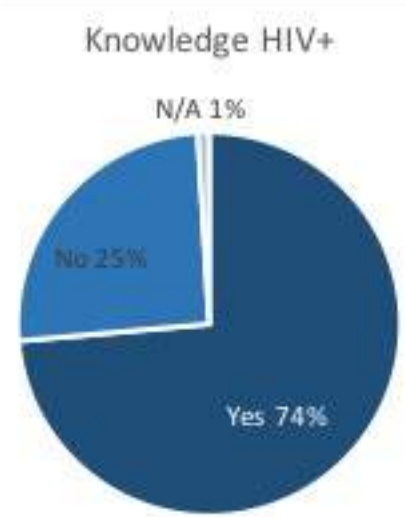
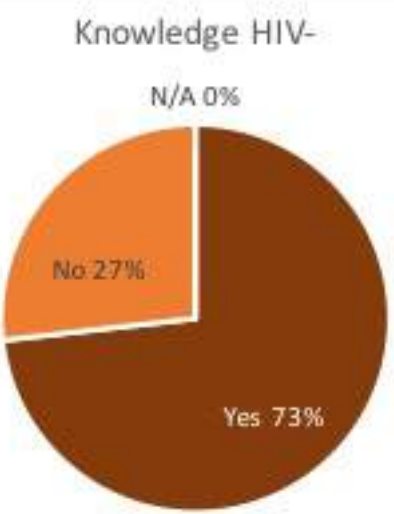
Knowledge of ChemSex









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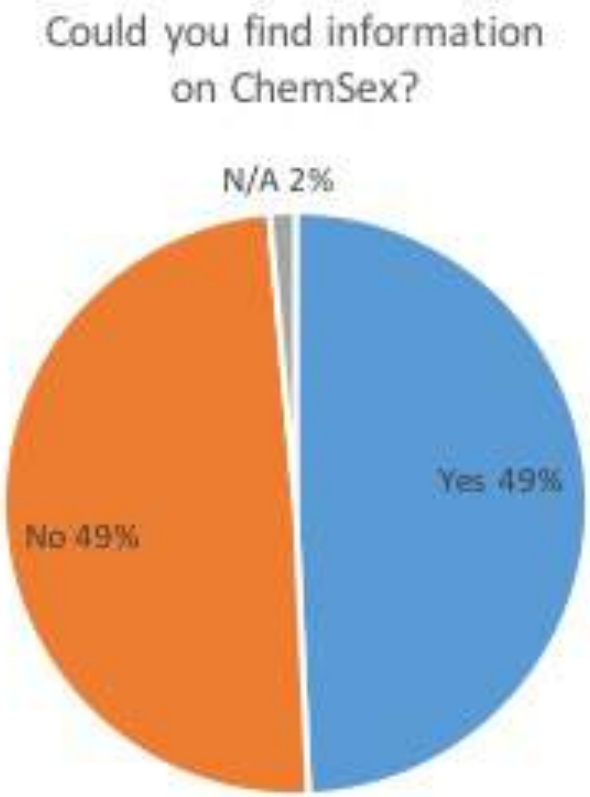
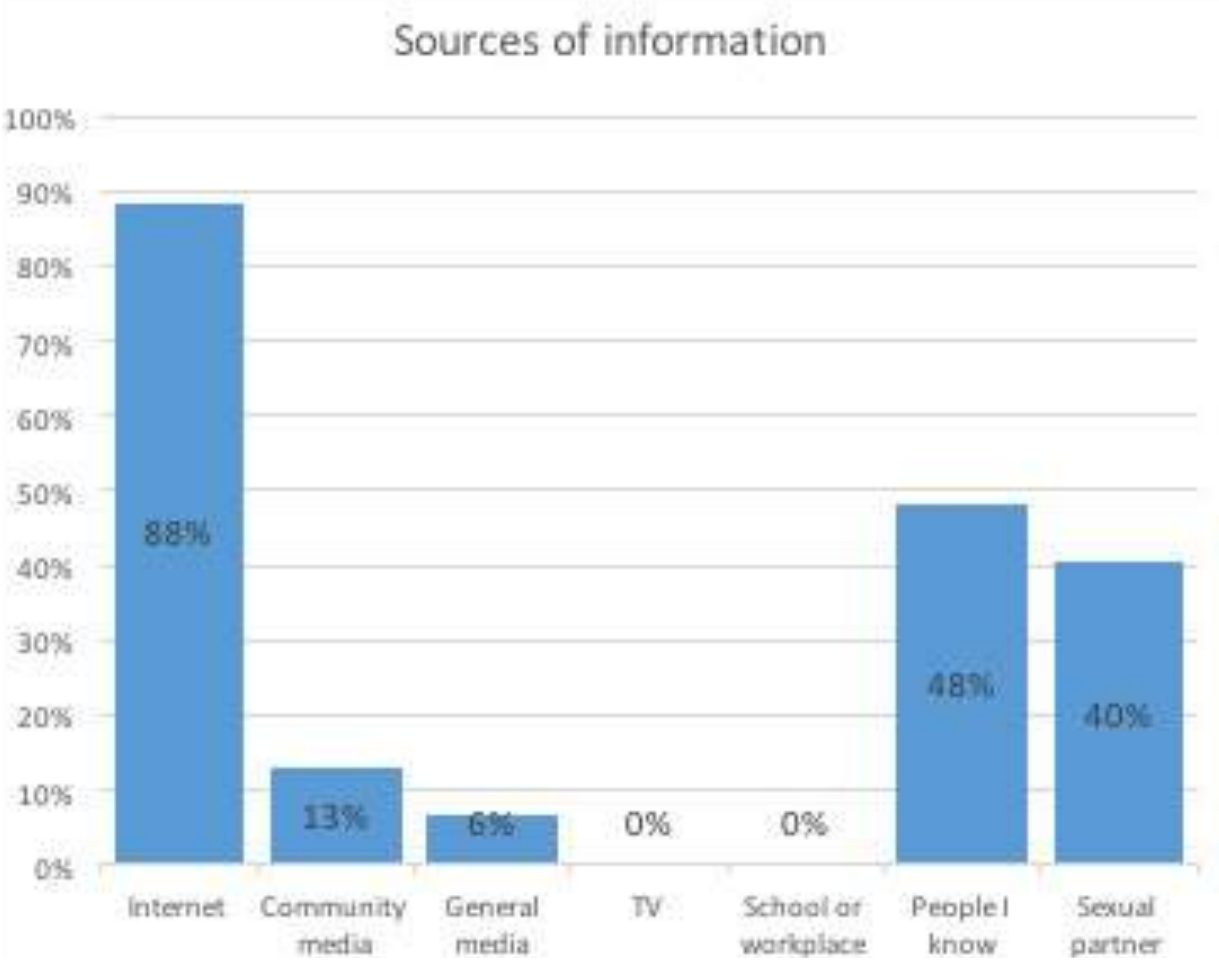
Information about ChemSex





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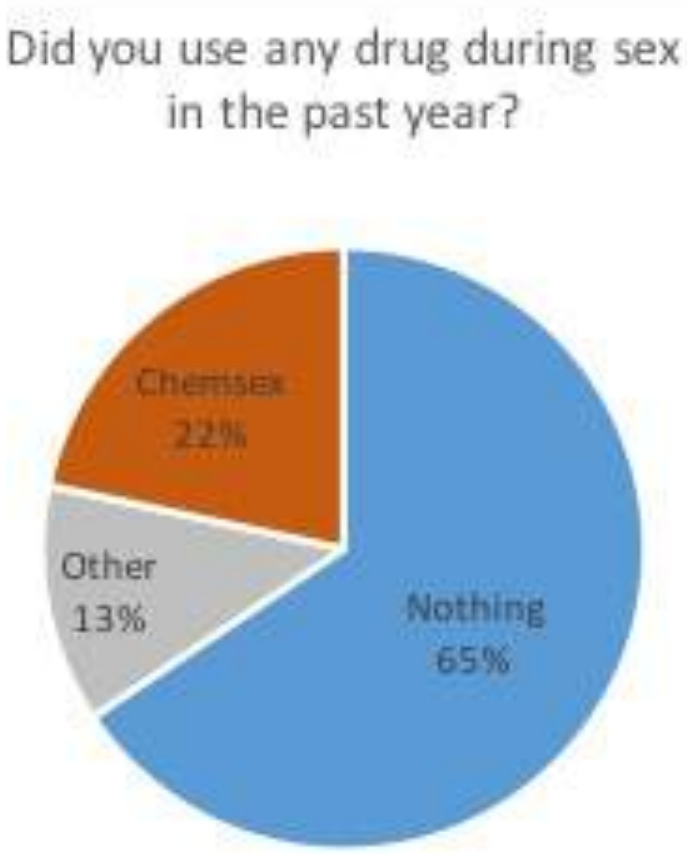
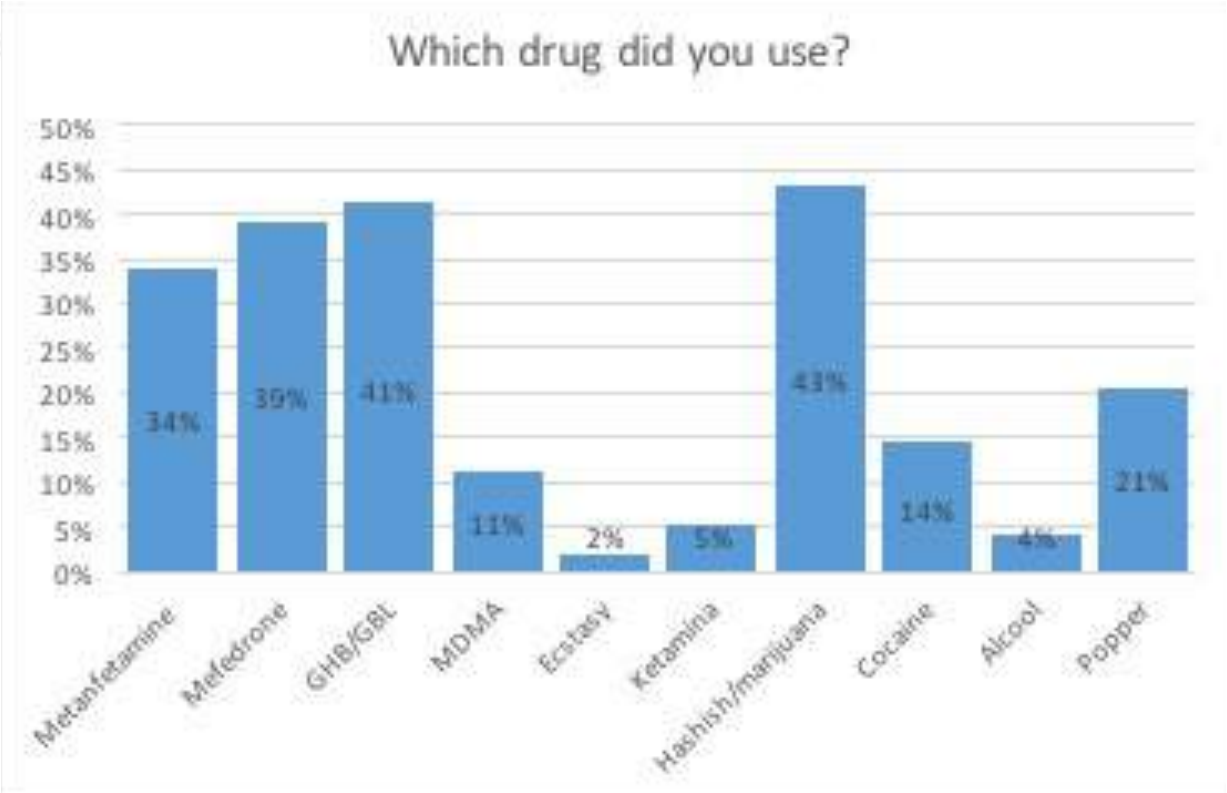
ChemSex use





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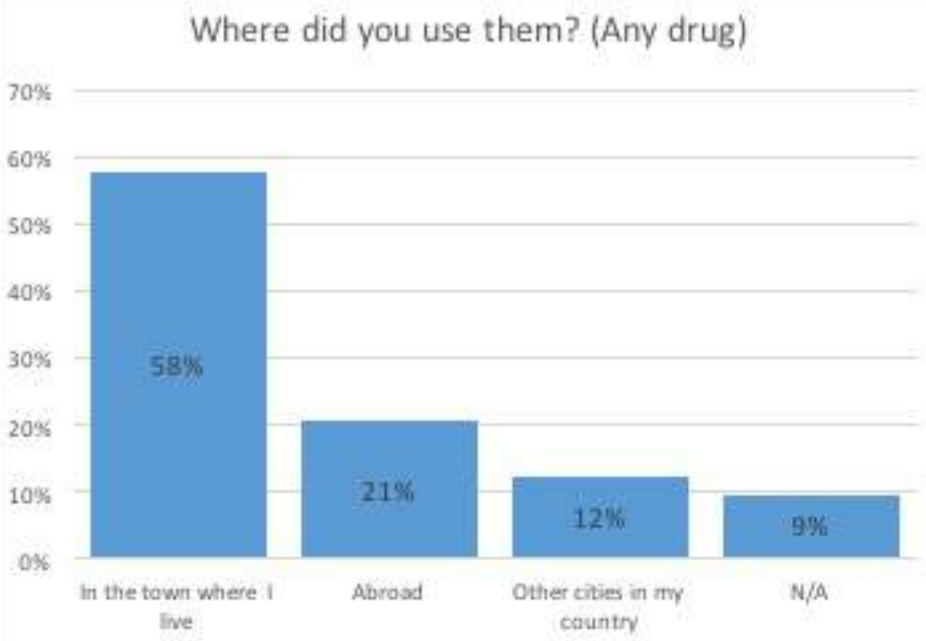
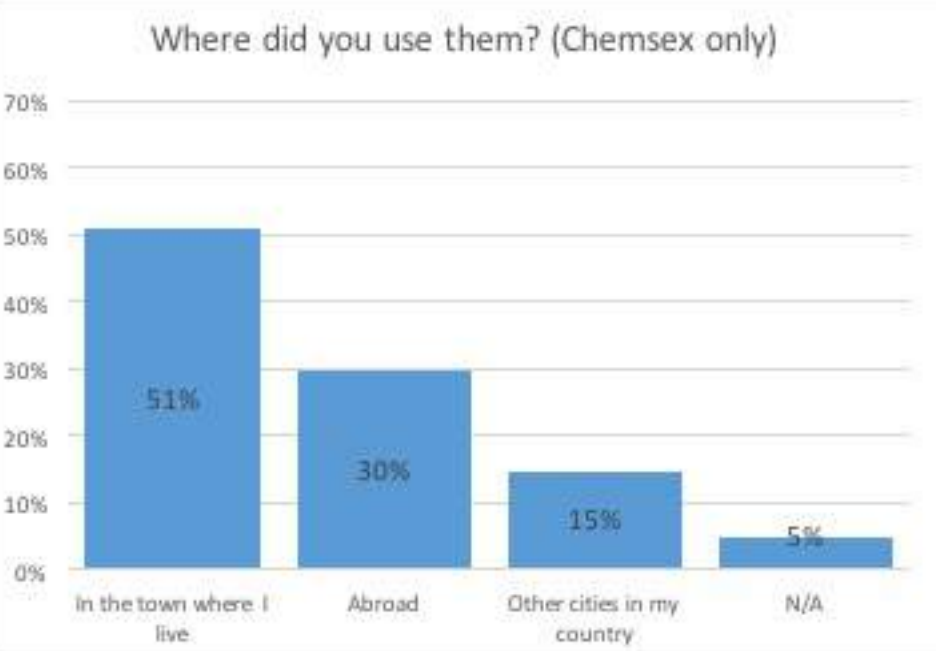
ChemSex habits





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Conclusions

Study limitations:

- Small sample
- Online recruitment
- Geographical limits
- Few demographic data

Despite these limitations:

- Many MSM in Italy know about Chemsex
- A significant proportion of MSM in Italy use Chemsex
- Little is known about health consequences of Chemsex
- There is a big need for harm reduction interventions and more information

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Thank you for your attention

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