

Innovazioni scientifiche e prevenzione.
PrEP, l'importanza del test HIV, Terapia: come si contrasta
l'infezione

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Disclosures

Cristina Mussini has served as a paid consultant to Gilead Sciences, Angelini, Abbvie, Janssen, MSD, ViiV Healthcare and received research fundings from Gilead Sciences, Janssen, MSD and ViiV Healthcare.

Come era vista una persona che vive con l'infezione da HIV



Ho detto persona che vive con l'infezione da HIV e non sieropositivo o infetto da HIV perché anche le parole sono stigmatizzanti.



AIDS

SE LO CONOSCI LO EVITI
SE LO CONOSCI NON TI UCCIDE



COMMISSIONE NAZIONALE PER LA LOTTA CONTRO L'AIDS
Ministero della Sanità



UNITED COLORS
OF BENETTON.

Il nostro pensiero non può non andare alle tantissime persone che non ci sono più e che si sono battute per avere farmaci efficaci



1996: l'anno della svolta



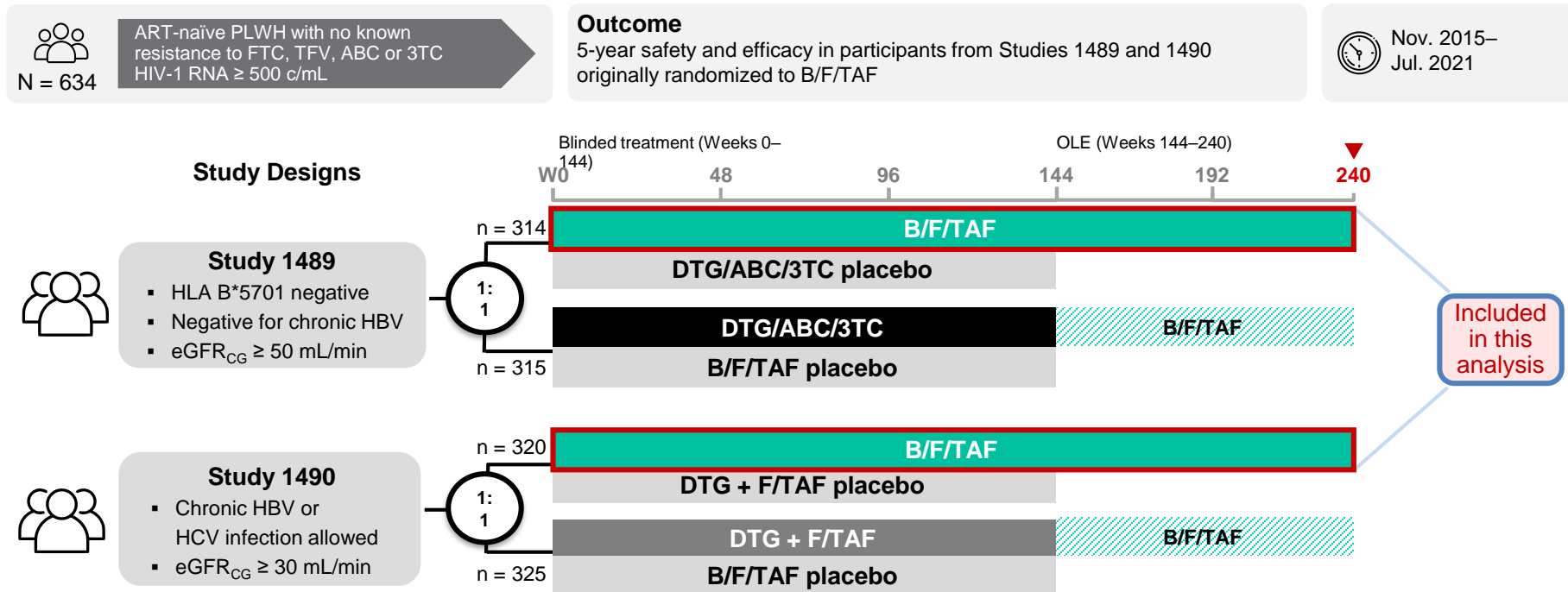
- ✓ Introdotta HAART con risposta clinica "drammatica" ("*Lazarus Syndrome*").
- ✓ Identificati i corecettori di HIV CXCR4 e CCR5
- ✓ 23 milioni di infetti nel mondo, in Italia 34.430 casi cumulativi di AIDS

Terapia antiretrovirale

| Regimen | Main requirements | Additional guidance (see footnotes) |
|---|--|---|
| Recommended regimens | | |
| 2 NRTIs + INSTI | | |
| ABC/3TC + DTG ABC/3TC/DTG | HLA-B*57:01 negative HBsAg negative | I (ABC: HLA-B*57:01, cardiovascular risk) II (Weight increase (DTG)) |
| TAF/FTC/BIC | | II (Weight increase (BIC, TAF)) |
| TAF/FTC or TDF/XTC + DTG | | II (Weight increase (DTG, TAF)) III (TDF: prodrug types. Renal and bone toxicity. TAF dosing) |
| TAF/FTC or TDF/XTC + RAL qd or bid | | II (Weight increase (RAL, TAF)) III (TDF: prodrug types. Renal and bone toxicity. TAF dosing) IV (RAL: dosing) |
| 1 NRTI + INSTI | | |
| XTC + DTG or 3TC/DTG | HBsAg negative HIV-VL < 500,000 copies/mL Not recommended after PrEP failure | II (Weight increase (DTG)) V (3TC/DTG not after PrEP failure) |
| 2 NRTIs + NNRTI | | |
| TAF/FTC or TDF/XTC + DOR or TDF/3TC/DOR | | II (Weight increase (TAF)) III (TDF: prodrug types. Renal and bone toxicity. TAF dosing) VI (DOR: caveats, HIV-2) |
| Alternative regimens | | |
| 2 NRTIs + NNRTI | | |
| TAF/FTC or TDF/XTC + EFV or TDF/FTC/EFV | At bedtime or 2 hours before dinner | II (Weight increase (TAF)) III (TDF: prodrug types. Renal and bone toxicity. TAF dosing) VII (EFV: neuro-psychiatric adverse events. HIV-2 or HIV-1 group 0, dosing) |
| TAF/FTC or TDF/XTC + RPV or TAF/FTC/RPV or TDF/FTC/RPV | CD4 count > 200 cells/ μ L HIV-VL < 100,000 copies/mL Not on gastric pH increasing agents With food | II (Weight increase (TAF)) III (TDF: prodrug types. Renal and bone toxicity. TAF dosing) VIII (RPV: HIV-2) |
| 2 NRTIs + PI/r or PI/c | | |
| TAF/FTC or TDF/XTC + DRV/c or DRV/r or TAF/FTC/DRV/c | With food | II (Weight increase (TAF)) III (TDF: prodrug types. Renal and bone toxicity. TAF dosing) IX (DRV/r: cardiovascular risk) X (Boosted regimens and drug-drug interactions) |

B/F/TAF DATI A 5 ANNI

Studies 1489 & 1490: B/F/TAF at 5 years



HLA, human leukocyte antigen; OLE, open-label extension

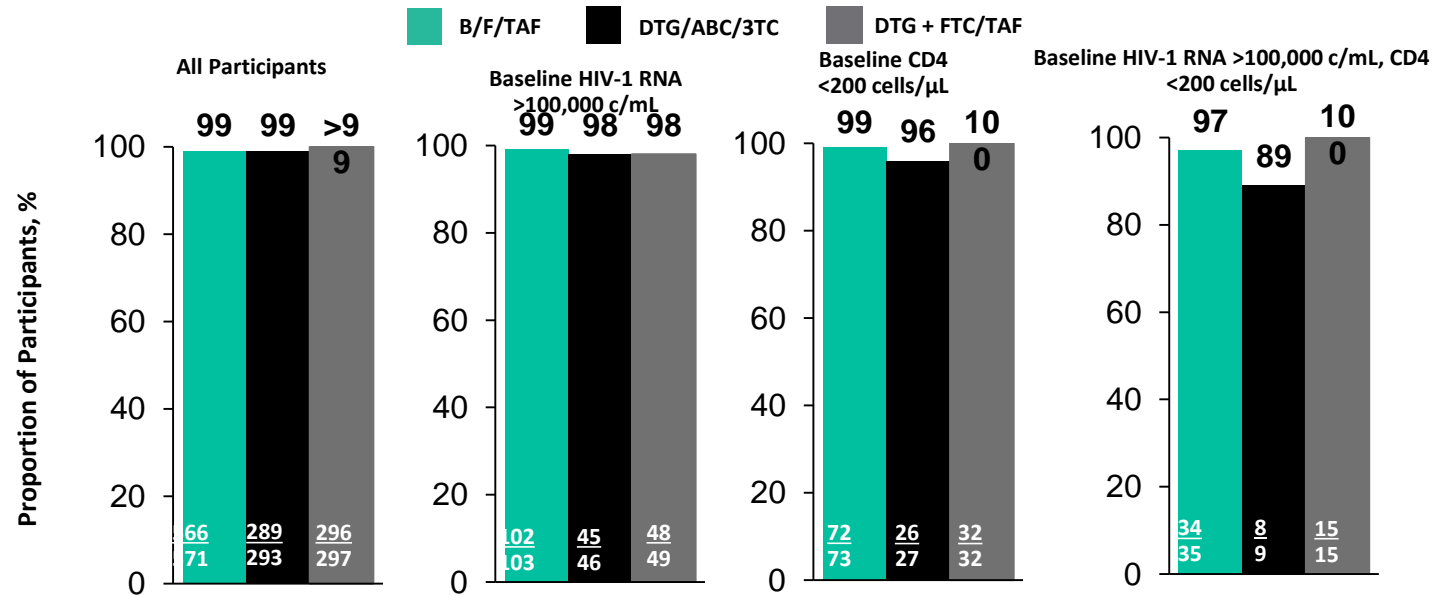
Wohl D, et al. CROI 2022, Poster 494



Pooled 1489 & 1490 Studies: B/F/TAF vs DTG-containing Regimens in ART-Naïve Adults

HIV-1 RNA <50 copies/mL at Week 48

Pooled Per-Protocol Analysis

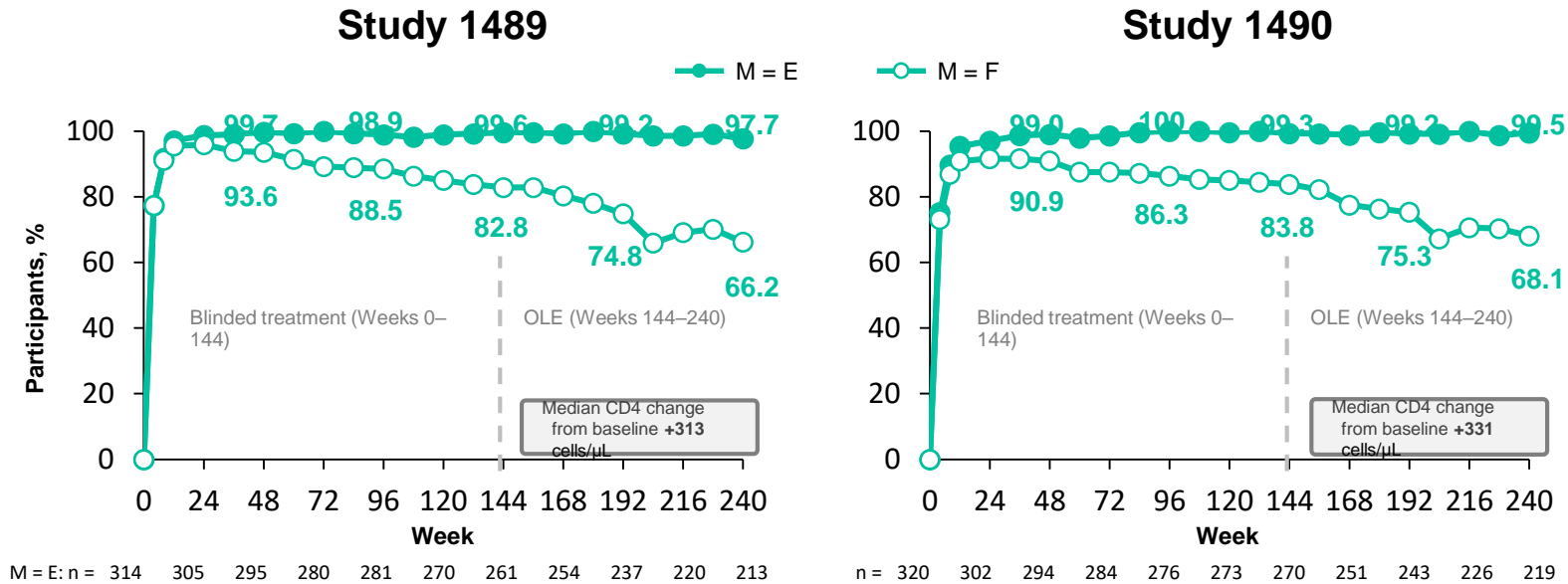


No participants discontinued due to lack of efficacy and developed emergent resistance

Virologic suppression rates were similarly high for B/F/TAF and DTG-containing regimens regardless of high viral load, low CD4 counts, or both

Virologic Outcomes Through Week 240 (HIV-1 RNA < 50 c/mL)

Studies 1489 & 1490: B/F/TAF at 5 years



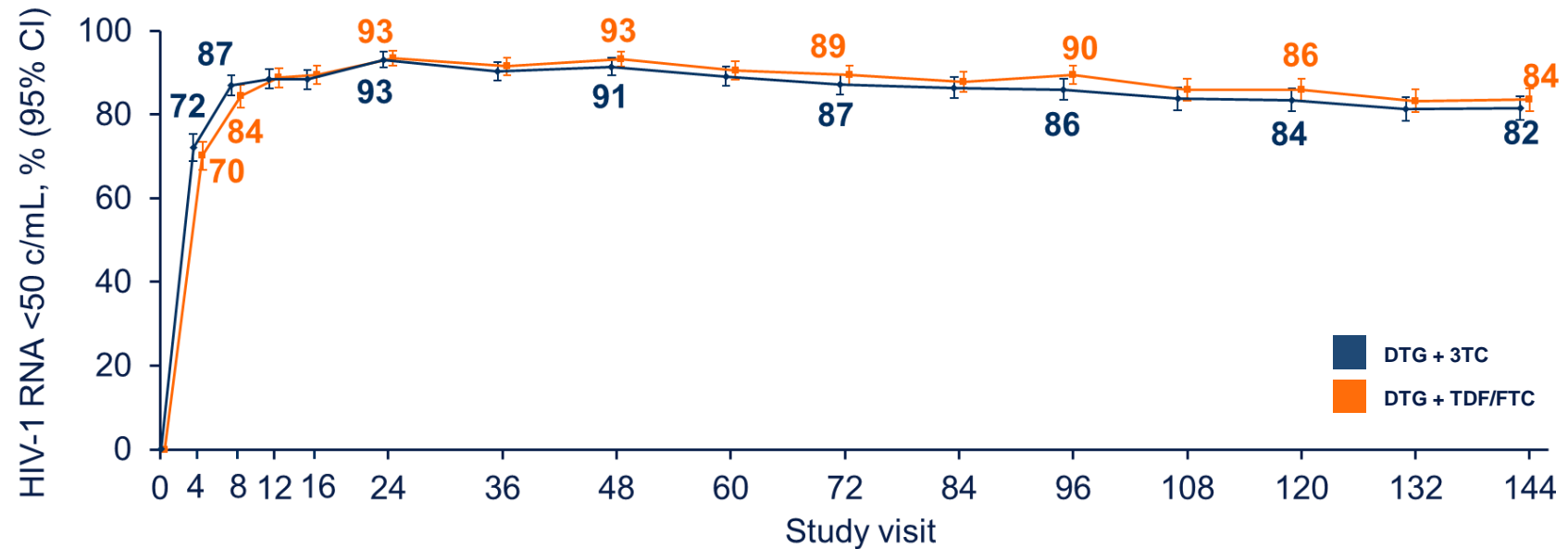
High rates of virologic suppression with B/F/TAF were maintained through Week 240

M = E, missing equals excluded; M = F, missing equals failure

Wohl D, et al. CROI 2022, Poster 494



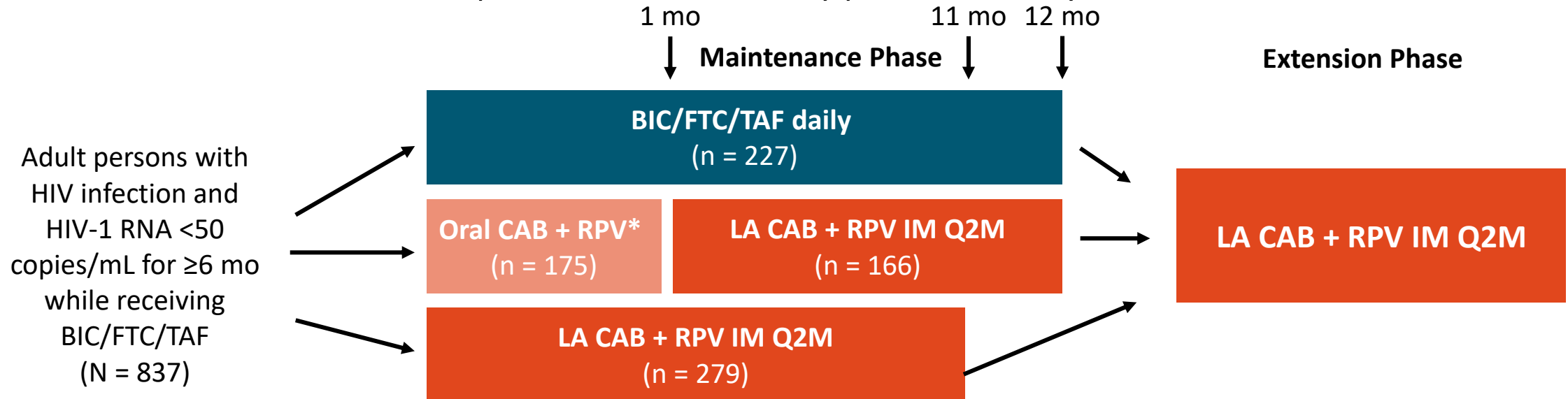
Snapshot Analysis of the Proportion of Participants with Plasma HIV-1 RNA <50 c/mL through Week 144 by Visit in the Pooled ITT-E Population



- DTG + 3TC was non-inferior to DTG + TDF/FTC in snapshot analysis HIV-1 RNA <50 c/mL for GEMINI-1, GEMINI-2, and the pooled ITT-E population at Week 144

SOLAR: Study Design

- Multicenter, randomized, open-label noninferiority phase IIIb study



*Patients randomized to LA arm chose between 1 mo OLI or starting with injections.

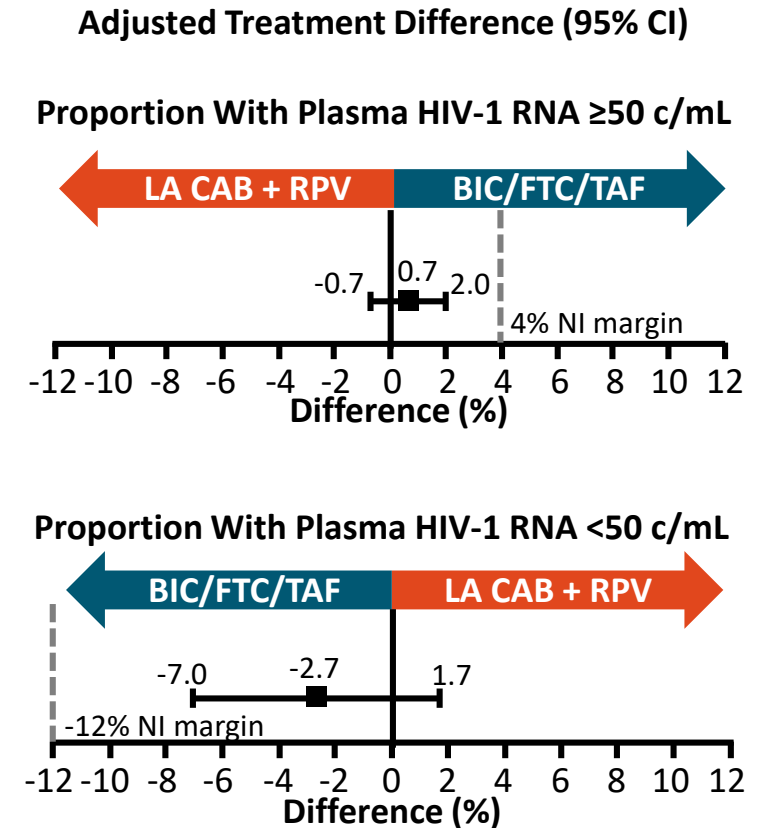
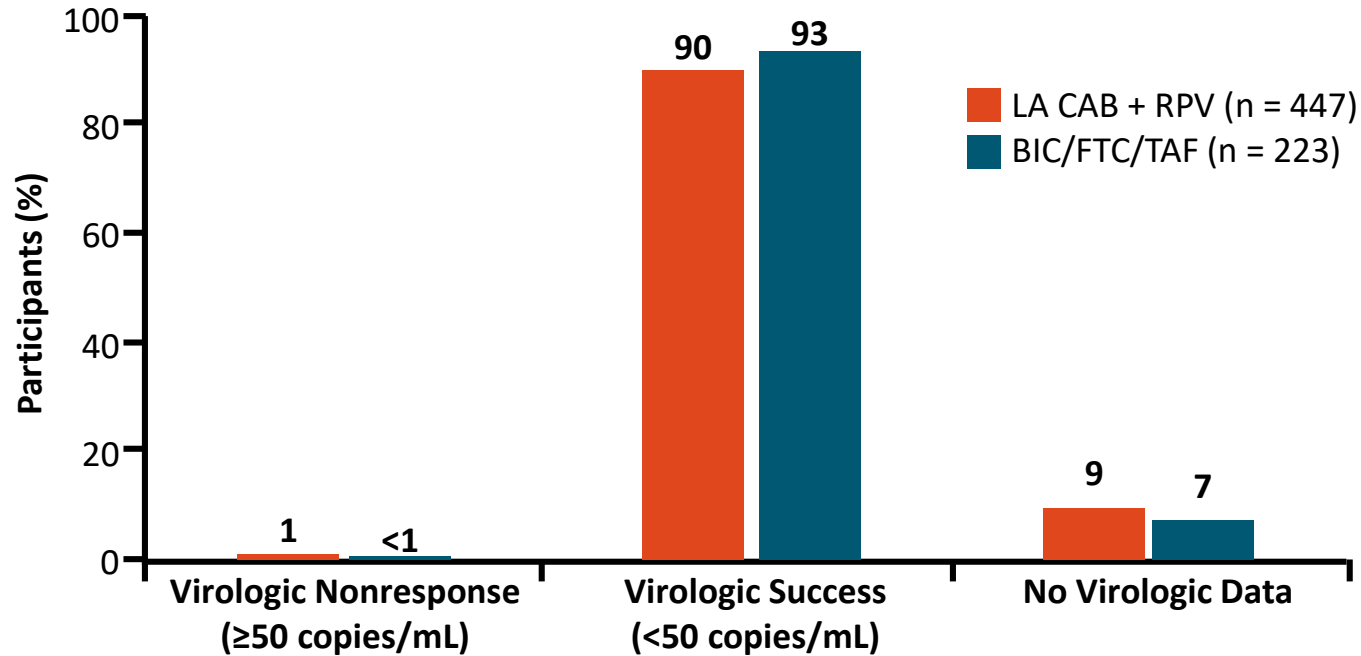
- **Primary endpoint:** proportion of patients with HIV-1 RNA ≥ 50 copies/mL by FDA snapshot analysis in mITT-E population at 12 mo; 4% noninferiority analysis
 - For those who started with injections, study outcomes were assessed at Mo 11

SOLAR: Baseline Characteristics of mITT-E Population

| Characteristic | LA CAB + RPV (n = 447) | BIC/FTC/TAF (n = 223) |
|---------------------------------------|---------------------------|--------------------------|
| Median age, yr (range) | 37 (18-74) | 37 (18-66) |
| ▪ ≥50 yr of age, n (%) | 86 (19) | 42 (19) |
| Female sex at birth, n (%) | 77 (17) | 41 (18) |
| Race, n (%) | | |
| ▪ Black | 95 (21) | 49 (22) |
| ▪ White | 307 (69) | 156 (70) |
| ▪ Asian | 23 (5) | 11 (5) |
| ▪ Other | 22 (5) | 7 (3) |
| Median BMI, kg/m ² (range) | 26.01 (16.63-65.21) | 25.43 (16.48-68.35) |

- At baseline, 47% of mITT-E population reported worrying about ≥1 psychosocial challenge related to daily oral therapy including medication adherence, fear of HIV disclosure, and reminder of HIV status

SOLAR: Primary Outcome at Mo 12 in mITT-E Population



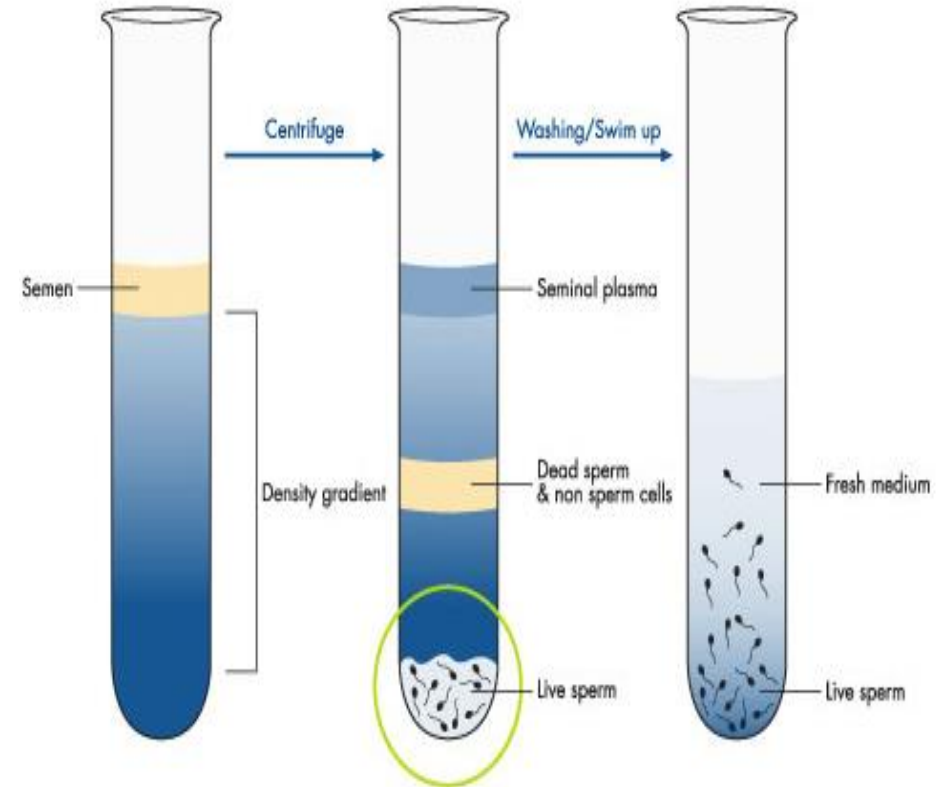
- LA CAB + RPV noninferior virologic efficacy to BIC/FTC/TAF at 12 mo



Undetectable = Untransmittable

Sperm washing

- HIV cannot attach to or infect spermatozoa due to lack of receptors
- Centrifugation of 'sperm' performed in specialist units to remove HIV



ART, mode of delivery and MTCT rates

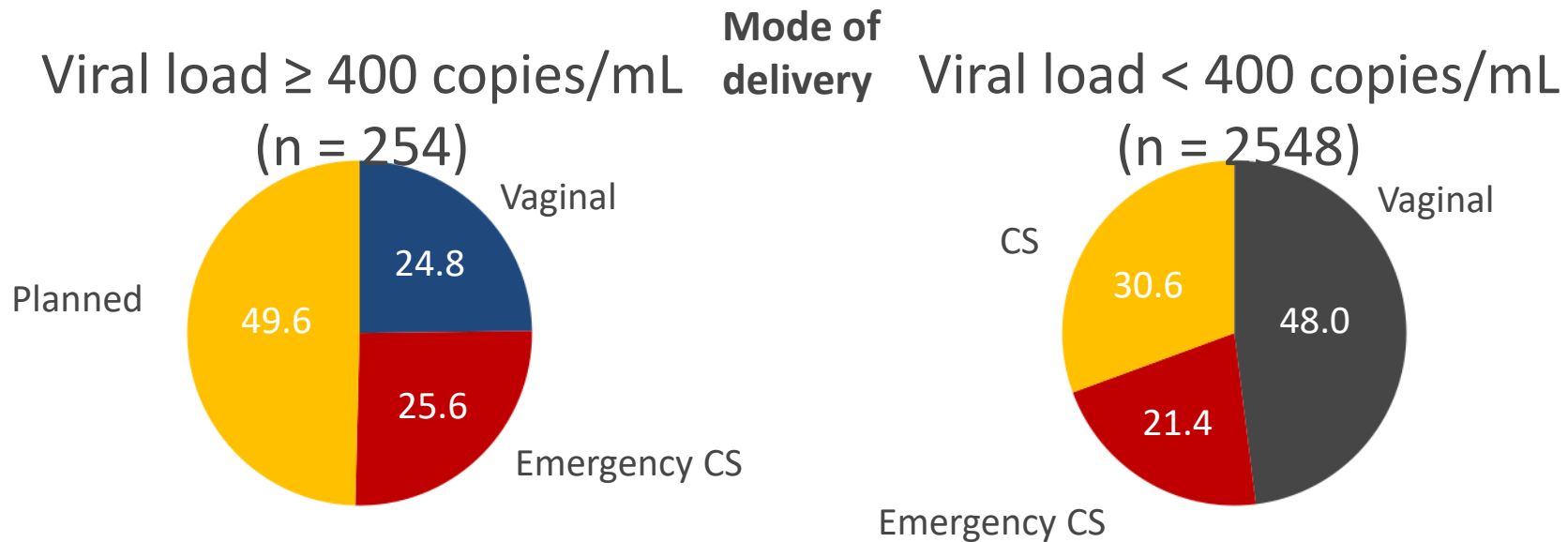
| Townsend, 2008 ² | MTCT rate (%) | n infected | Total |
|--------------------------------------|---------------|------------|-------|
| ART + elective caesarean section | 0.7 | 17 | 2286 |
| ART + planned vaginal delivery | 0.7 | 4 | 559 |
| ART + emergency caesarean section | 1.7 | 15 | 877 |
| Untreated elective caesarean section | 5.8 | 3 | 52 |
| Untreated planned vaginal delivery | 25.0 | 2 | 8 |

- Prematurity was a risk factor for MTCT¹
- Early and sustained control of viral load is associated with a decreasing residual risk of MTCT²

ARVs used during pregnancy should be selected only if potential benefit justifies the potential risk³

France: Mode of delivery in the French Perinatal Cohort

- Mode of delivery recorded for 2,802 pregnant women with HIV enrolled between 2005 and 2009 in the French Perinatal Cohort (EPF/ANRS CO1-11)



- Main indications of planned CS for viral load $<$ 400 copies/mL was
 - 42% for a repeat CS
 - 18% for HIV exclusively

CS = caesarean section

Ma adesso uccide ancora?

Global estimates for adults and children | 2022

| | |
|-------------------------------|---|
| People living with HIV | 39.0 million [33.1 million–45.7 million] |
|-------------------------------|---|

| | |
|---------------------------|--|
| New HIV infections | 1.3 million [1.0 million–1.7 million] |
|---------------------------|--|

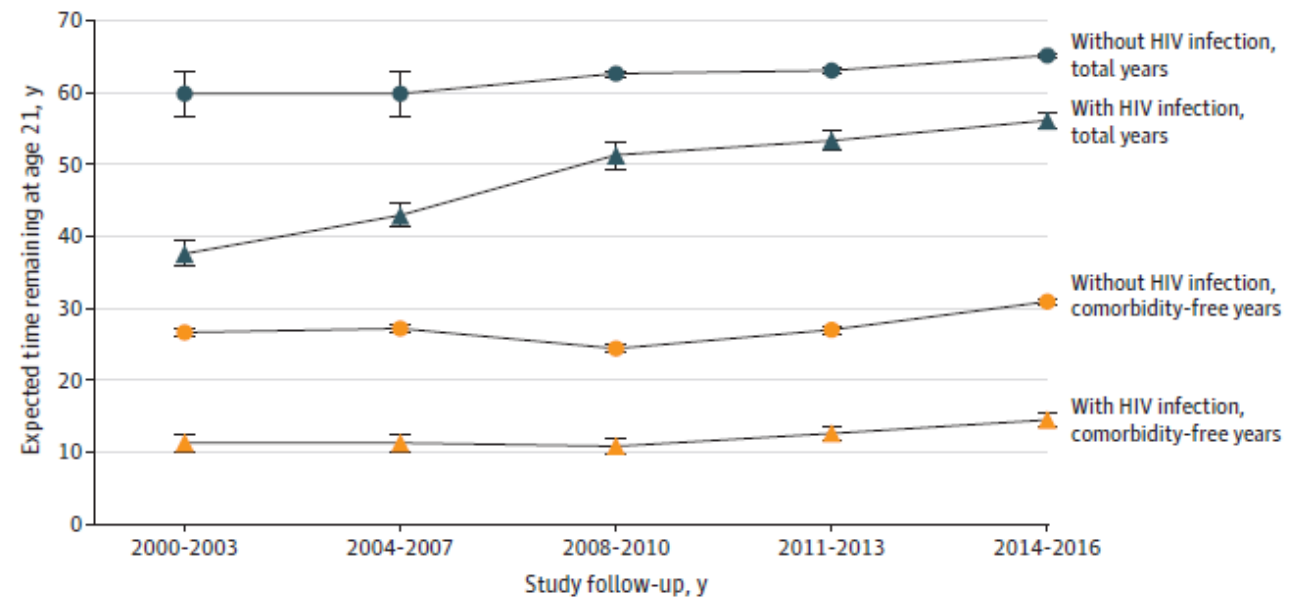
| | |
|---------------------------|----------------------------------|
| Deaths due to AIDS | 630 000 [480 000–880 000] |
|---------------------------|----------------------------------|

Comparison of overall and comorbidity-free life expectancy between adults with or without HIV in the United States, 2000–2016

Table 2. Mortality and Incidence of Common Comorbidities Among Individuals With and Without HIV Infection, Kaiser Permanente, 2000-2016

| Outcome | Individuals with HIV infection | | Individuals without HIV infection | |
|------------------------|--------------------------------|--|-----------------------------------|--|
| | Events | Incidence, per 100 person-years (95% CI) | Events | Incidence, per 100 person-years (95% CI) |
| Mortality | 2661 | 1.3 (1.3-1.4) | 9147 | 0.4 (0.4-0.4) |
| Any comorbidity | 11 366 | 10.0 (9.8-10.2) | 60 707 | 3.8 (3.7-3.8) |
| Chronic disease | | | | |
| Liver | 4768 | 2.7 (2.6-2.8) | 10 569 | 0.5 (0.5-0.5) |
| Kidney | 3146 | 1.7 (1.6-1.8) | 10 257 | 0.5 (0.4-0.5) |
| Lung | 5457 | 3.5 (3.4-3.6) | 35 776 | 1.9 (1.9-1.9) |
| Diabetes | 2456 | 1.3 (1.3-1.4) | 21 339 | 1.0 (1.0-1.0) |
| Cancer | 1922 | 1.0 (1.0-1.0) | 10 619 | 0.5 (0.5-0.5) |
| Cardiovascular disease | 813 | 0.4 (0.4-0.4) | 6296 | 0.3 (0.3-0.3) |

Figure 1. Overall and Comorbidity-Free Life Expectancy at Age 21 Years for Individuals With and Without HIV Infection, Kaiser Permanente, 2000-2016



Matched cohort study quantified the gap in life span and comorbidity-free years by HIV status among adults with access to care. This study used data from insured adults with and without HIV infection (aged ≥ 21 years) matched 1:10 (based on age [2-year groups], sex, race/ethnicity, medical center, and calendar year at the start of follow-up, with random selection from the uninfected subgroups defined by each matching factor) in northern and southern California and the mid-Atlantic states of Washington DC, Maryland, and Virginia from Jan 2000 through Dec 2016 (PLWH, $n=39,000$; people without HIV, $n=387,767$). Data were analyzed from Sep 2019 through Mar 2020.

CI, confidence interval; HIV, human immunodeficiency virus

Young women, 15-24 years are highly exposed

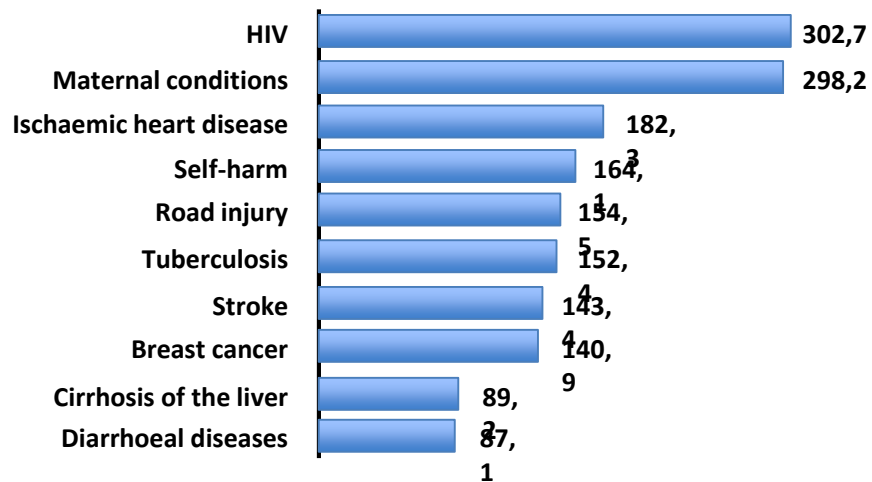
- Young women, aged 15-24 years
 - Make up 12% of the global HIV population
 - Make up 59% of new infections among their age group
 - In sub-saharan Africa, teenage girls and young women are 3 times as likely to acquire HIV as boys and young men
 - Every week, 5000 of them become infected with HIV (1 every 2 minutes)
- Worsening situation during COVID
 - Millions of girls out of school
 - Spikes in teenage pregnancies and gender-based violence
 - Disruption to key HIV treatment and prevention services



Ending AIDS by 2030 requires that we address girls' and women's diverse roles by putting them at the centre of the response.

AIDS = 1° cause of death in 15-49-year old females

AIDS-related illnesses are the leading cause of death among 15-49-year-old females globally (hundred thousands)



Source: Global health estimates 2016: deaths by cause, age, sex, by country and by region. 2000-2016 Geneva, World Health Organization; 2018.

21X
HIV INCIDENCE IS 21 TIMES HIGHER AMONG FEMALE SEX WORKERS THAN AMONG THE GENERAL POPULATION

Source: UNAIDS, 2019

AROUND

44

adolescent girls (10-19 years) died of AIDS-related illnesses every day in 2018.

Source: UNAIDS, 2019 estimates

Vulnerability of women in low-income countries

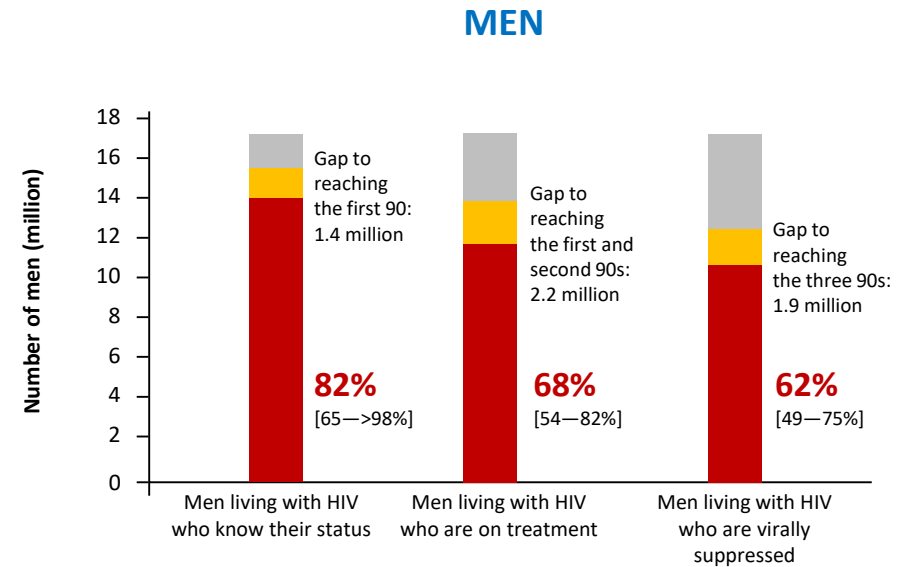
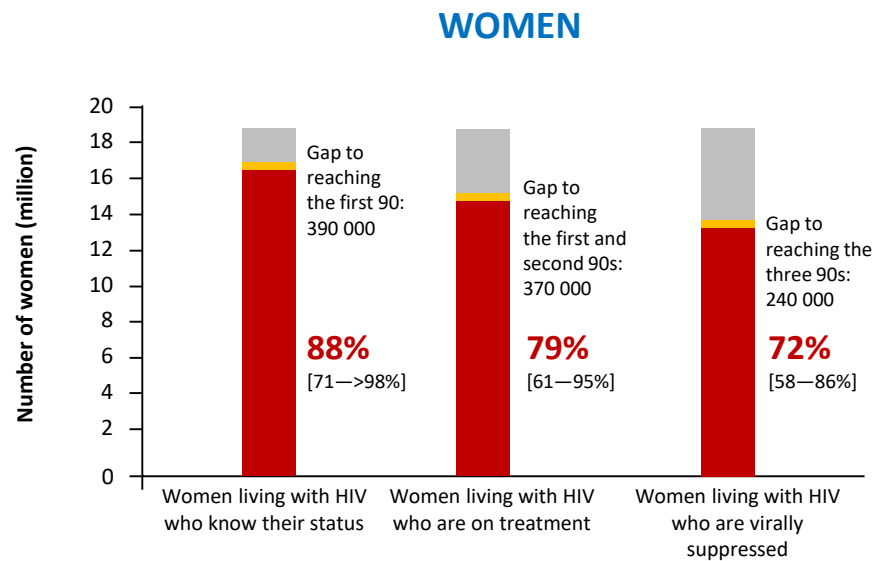
- **7 out of 10 women** in conflict setting and in refugee populations are exposed to gender-based and sexual violence.

www.unwomen.org/en/what-we-do/humanitarian-action/facts-and-figures

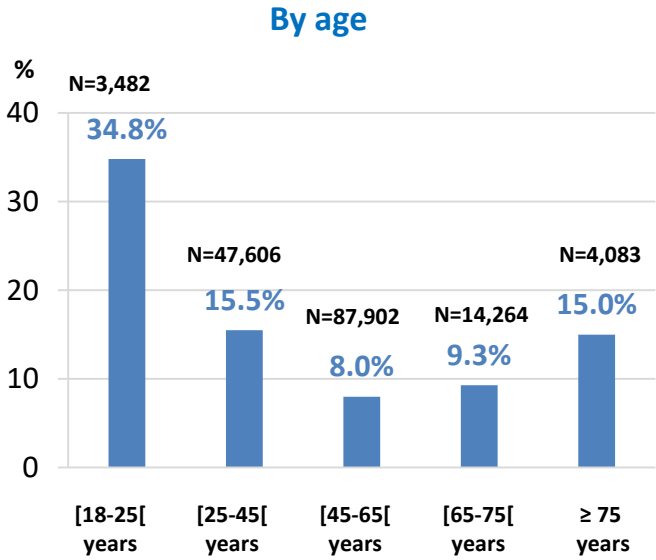
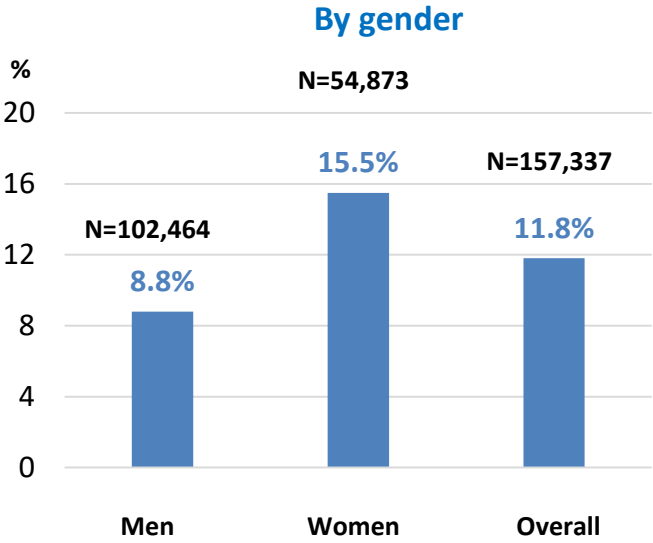
- Women who have experienced violence are **50%** more likely to be living with HIV.
- Women who have been physically or sexually abused by their partners report higher rates of mental health issues, including depression and anxiety, higher use of alcohol and less control over sexual decision-making.

Jewkes, R. et al (2010). Intimate partner violence, relationship power inequity, and incidence of HIV infection in young women in South Africa: a cohort study. The Lancet 210; 376(9734):41-48

HIV TESTING AND TREATMENT CASCADE, WOMEN (AGED 15+ YEARS) COMPARED TO MEN (AGED 15+ YEARS), GLOBAL, 2020



COCOVIH : Proportion of untreated Persons living with HIV in 2019 - FRANCE



Il problema maggiore in cui la comunicazione potrebbe davvero aiutare

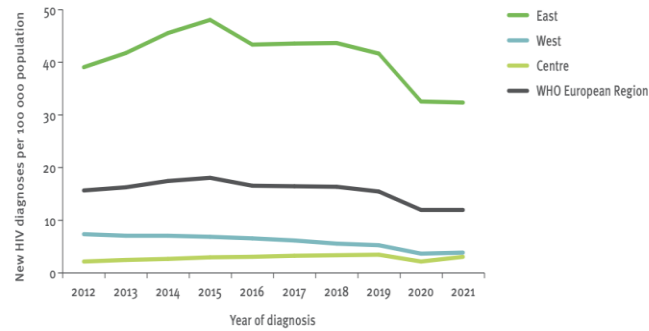
HIV/AIDS surveillance in Europe

2022

2021 data

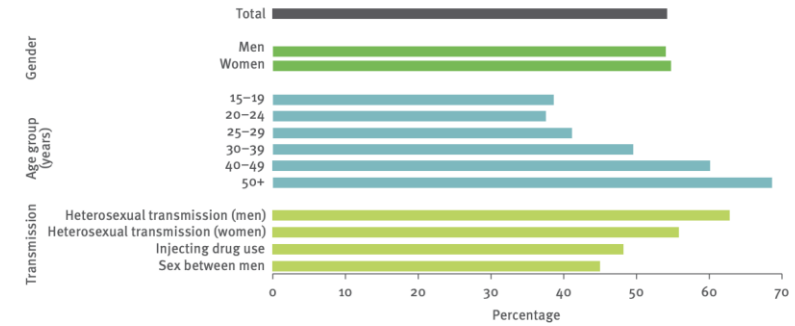


Fig. 2.2. New HIV diagnoses per 100 000 population, by year of diagnosis, WHO European Region, 2012–2021

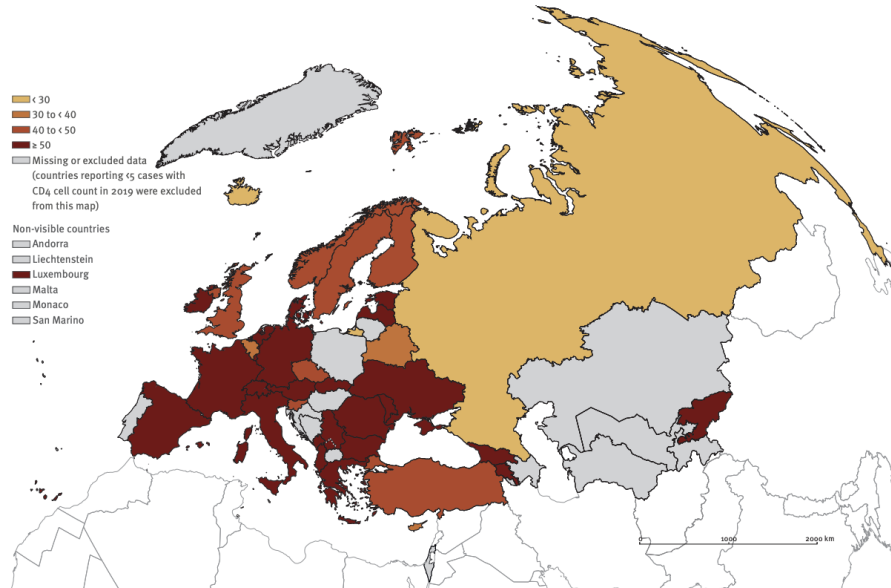


Notes: Includes data from 46 countries. Data from Andorra, Bosnia and Herzegovina, Monaco, North Macedonia, Turkmenistan and Uzbekistan excluded due to inconsistent reporting over the decade. Data from Portugal not published at country request.

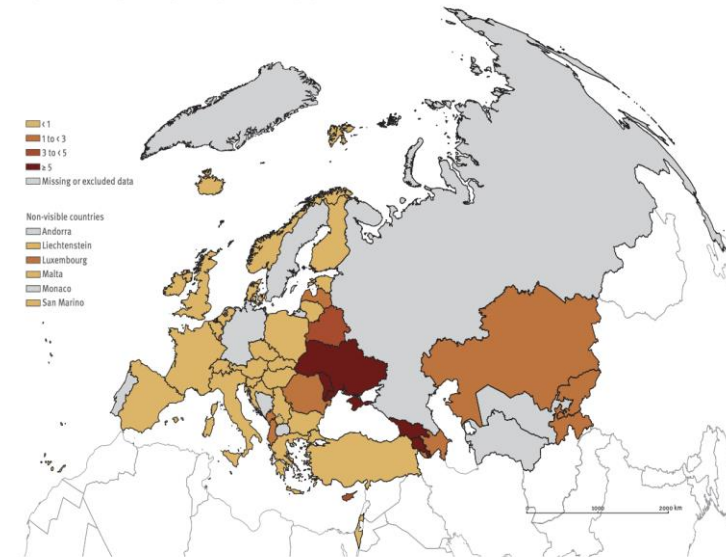
Fig. 8. Proportion of people diagnosed late (CD4 cell count < 350 per mm³) by gender, age and transmission, WHO European Region, 2021 (n = 28 742)



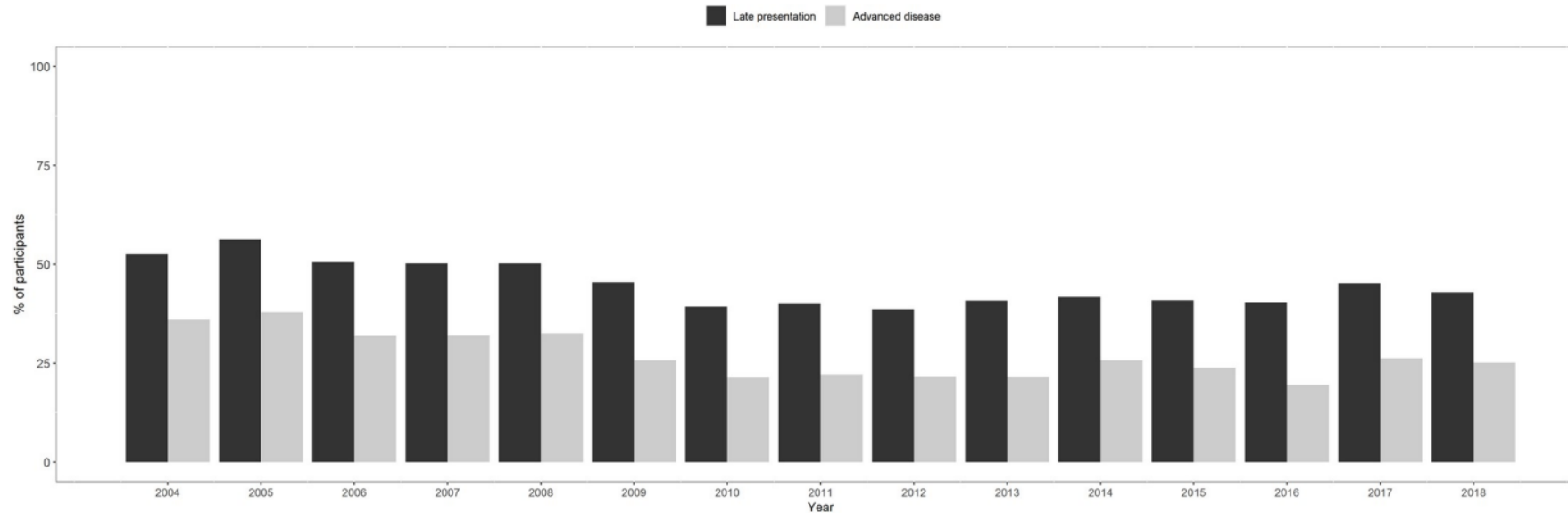
Map 7. Percentage of adult (> 14 years) HIV diagnoses with CD4 < 350 cells/mm³ at diagnosis, 2021



Map 8. AIDS diagnoses reported per 100 000 population, 2021



Stiamo migliorando negli anni?



| Group | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 |
|-------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| LP | 52.5 | 56.2 | 50.5 | 50.2 | 50.2 | 45.5 | 39.3 | 40.0 | 38.7 | 40.9 | 41.8 | 41.0 | 40.3 | 45.2 | 43.0 |
| LPAD | 36.0 | 37.9 | 31.9 | 32.0 | 32.5 | 25.8 | 21.3 | 22.2 | 21.5 | 21.5 | 25.7 | 23.9 | 19.5 | 26.3 | 25.1 |

Fig 1. Annual prevalence of LP and LPAD, 2004–2018.

Perchè I pazienti arrivano alla diagnosi tardivamente?

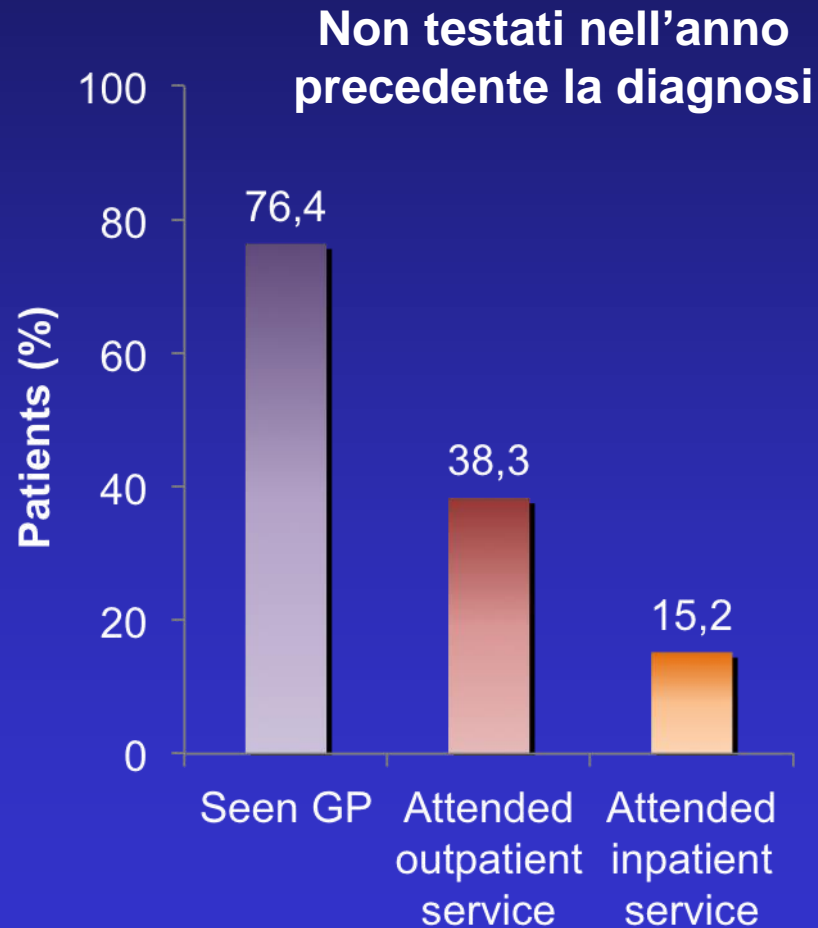
- Barriere nei confronti del test a livello del paziente
- Barriere nei confronti del test a livello del medico



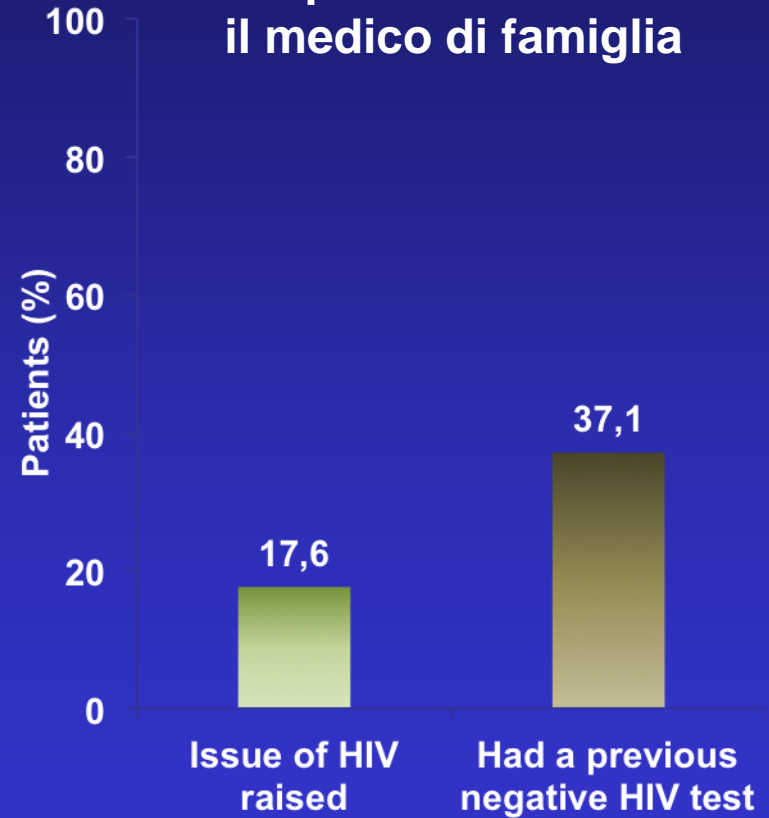
Perdita di opportunità

Occasioni perse per i medici

Survey population: 263 Africans in London diagnosed as HIV-positive



Del 76.4% dei pazienti che avevano visto il medico di famiglia



Perchè I medici non testano per HIV?

- Otto barriere sono state identificate :
 - Tempo insufficiente
 - Necessità di consenso informato
 - Mancanza di informazioni
 - Non accettazione da parte del paziente
 - Il colloquio pre-test
 - Altre priorità

Anche per lo stigma



COSA POSSIAMO FARE?

Condizioni Indice (IC)

Malattie Sessualmente Trasmesse (MST)

Epatitis B e C

Linfoma

Displasia anale o della cervice uterina

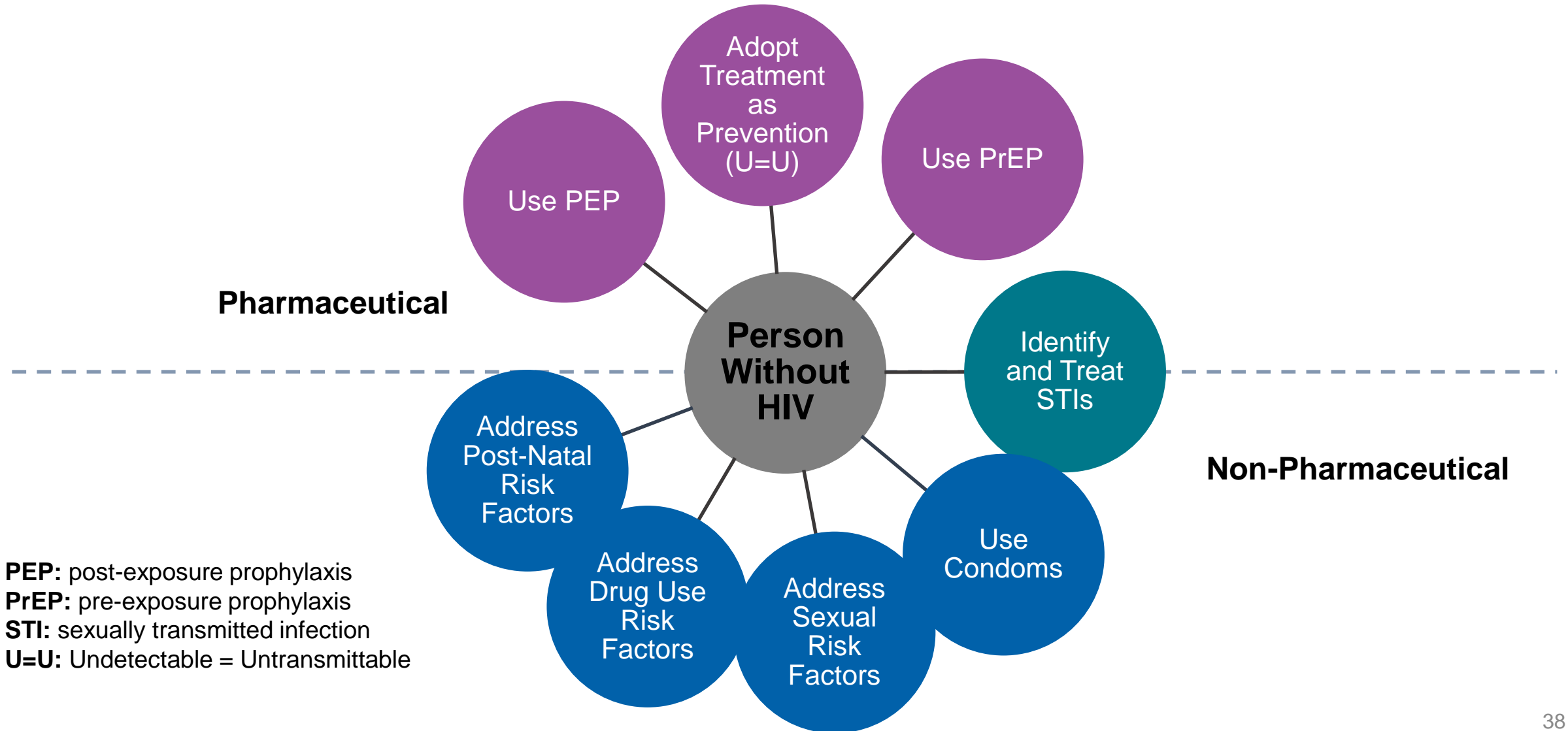
Piastrinopenia o neutropenia per >4 settimane

Herpes zoster <65 anni

Dermatite seborroica o esantema

Sindrome simil-mononucleosica

Current HIV Prevention Options



AIFA approva la rimborsabilità dei farmaci per la profilassi pre-esposizione a HIV-1 (PrEP)



Con Delibera CdA n. 15 del 26 aprile 2023

Once-Daily Oral TDF-Based PrEP Efficacy in Clinical Trials

| Population | Study | Phase | Patients | | Efficacy for Reducing HIV Incidence, % |
|------------------|----------------------------|--------|--------------------|--------------------|--|
| | | | Study Drug | Control | |
| MSM | iPrEx ¹ | III | FTC/TDF (n = 1251) | Placebo (n = 1248) | 44.0 (P = .005) |
| HS men/ women | Partners PrEP ² | III | FTC/TDF (n = 1583) | Placebo (n = 1586) | 75.0 (P <.001) |
| | TDF2 ³ | II/III | FTC/TDF (n = 611) | Placebo (n = 608) | 62.2 (P = .03) |
| PWID | BTS ⁴ | II/III | TDF (n = 1204) | Placebo (n = 1207) | 48.9 (P = .01) |
| | | | | | If detectable TDF: 73.5 (P = .03) |

▪ Effectiveness in open-label/extension/demonstration project studies (MSM)

- iPrEx OLE: 49% reduction with vs without PrEP after adjusting for sexual practices⁵
- PROUD: 86% reduction with immediate vs deferred (12 mo) PrEP initiation (P = .0001)⁶
- Demo Project: 557 initiated PrEP, 437 retained 48 wk; 2 HIV infections occurred, both with TFV-DP levels consistent with <2 doses/wk at seroconversion⁷

1. Grant. NEJM. 2010;363:2587. 2. Baeten. NEJM. 2012;367:399. 3. Thigpen. NEJM. 2012;367:423. 4. Choopanya. Lancet. 2013;381:2083.

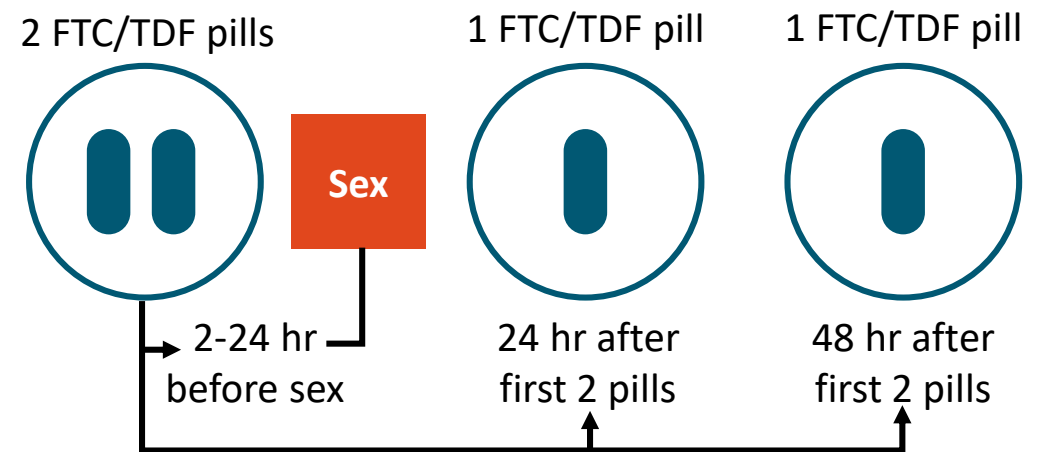
5. Grant. Lancet Infect Dis. 2014;14:820. 6. McCormack. Lancet. 2016;387:53. 7. Liu. JAMA Intern Med. 2016;176:75.

ANRS IPERGAY: On-Demand Oral FTC/TDF PrEP in MSM at High Risk for HIV Infection

- ANRS IPERGAY: double-blind, randomized study of on-demand FTC/TDF vs placebo as PrEP¹

| Study Phase | N | Follow-up, PY | Risk Reduction, % | P Value |
|---|-----|---------------|-------------------|---------|
| Placebo controlled, randomized ¹ | 400 | 431.3 | 86 | .002 |
| Open-label extension ² | 361 | 518 | 97 | NR |

- On-demand “2-1-1” PrEP regimen³:



- On-demand FTC/TDF should **not** be used for: MSM with HBV infection, MSM who may have difficulty adhering to complex dosing regimen (eg, adolescents, active SUD), populations other than adult MSM³

..Ma nel mondo reale?

Baseline Characteristics

| Characteristics (Median, IQR) or (n, %) | Daily N=1544 (50.5%) | On Demand N=1515 (49.5%) | P-value |
|--|----------------------------|--------------------------------|---------|
| Age (years) | 35 (28 – 43) | 36 (30 – 44) | <.0001 |
| MSM | 1511 (97.9) | 1503 (99.2) | 0.0002 |
| Heterosexual men or women | 20 (1.3) | 11 (0.7) | |
| Transgender | 13 (0.8) | 1 (0.1) | |
| 2-year university degree or more | 1086 (83.8) | 1126 (87.8) | 0.0033 |
| Employed | 1101 (85.2) | 1106 (86.4) | 0.3620 |
| History of PrEP use | 843 (54.6) | 868 (57.3) | 0.1333 |
| Use of Chemsex* | 223 (14.4) | 203 (13.4) | 0.4045 |
| No. condomless sex acts in prior 4 weeks | 2 (0 – 6) | 2 (0 – 4) | <.0001 |
| No. sexual partners in prior 3 months | 12 (6 - 25) | 10 (5 - 15) | <.0001 |

* at last sexual intercourse : cocaine, GHB, MDMA, mephedrone..

HIV Incidence

Global HIV Incidence: 0.11/100 PY (95% CI: 0.04-0.23) (6 cases)

Mean Follow-up of 22.1 months and 5633 Person-Years

Rate of study discontinuation: 14.4/100 PY

| Treatment | Follow-Up Pts-years | HIV Incidence per 100 Pts-years (95% CI) | IRR (95%CI) |
|-------------------|------------------------|--|----------------|
| TDF/FTC Daily | 2583.25 | 0.12 (0.02 – 0.34) | 0.99 |
| TDF/FTC On Demand | 2553.68 | 0.12 (0.02 – 0.34) | (0.13-7.38) |

361 HIV-infections averted*

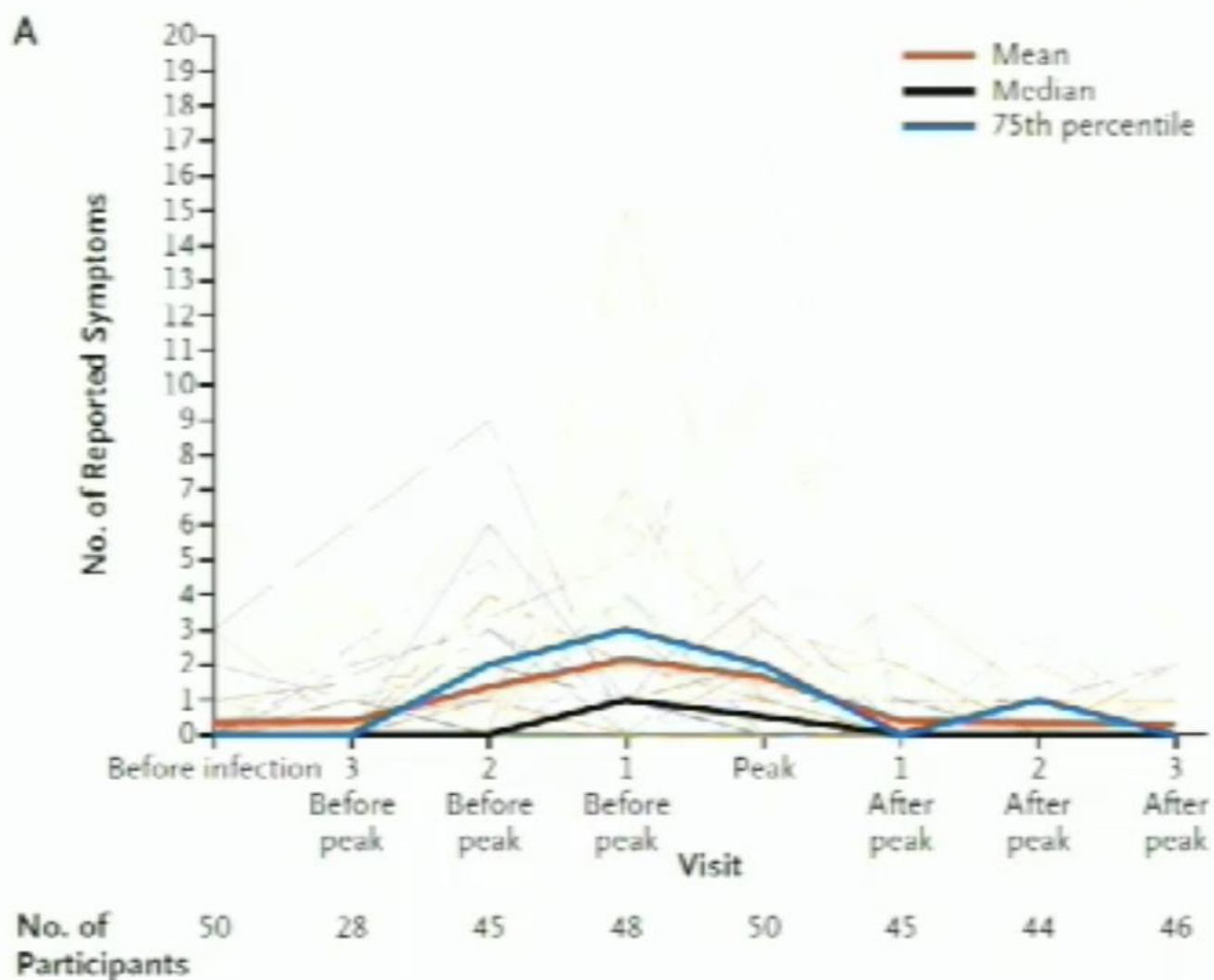
* assuming an incidence of 6.6/100 PY as observed in the Placebo group of the ANRS Ipergay study

Very Low Number of Signs and Symptoms During Acute HIV-Infection

ORIGINAL ARTICLE

Prospective Study of Acute HIV-1 Infection
in Adults in East Africa and Thailand

71% participants no symptoms
Median 1 symptom and/or sign



Robb et al, NEJM 2016

PrEP Eligibility by Regimen for Cisgender Women

| Risk Group | Daily FTC/TDF ¹⁻⁵ | On-Demand (2:1:1) FTC/TDF ²⁻⁵ | Daily FTC/TAF ^{5,6} | DPV Ring ^{7,8} | Injectable CAB ^{5,9,10} |
|------------------------------|-------------------------------------|--|--|---|---|
| Heterosexual/cisgender women | FDA approved, guideline recommended | Off label, not recommended | Off label, not recommended, studies underway | Unavailable in US, EMA positive opinion in high-burden settings outside EU, WHO recommended | FDA approved, guideline recommended (except in pregnancy) |



“Call for advocacy to protect US women’s access to user-controlled HIV prevention technologies, consistent with both global regulatory decisions to date and with a reproductive justice framework.”¹¹

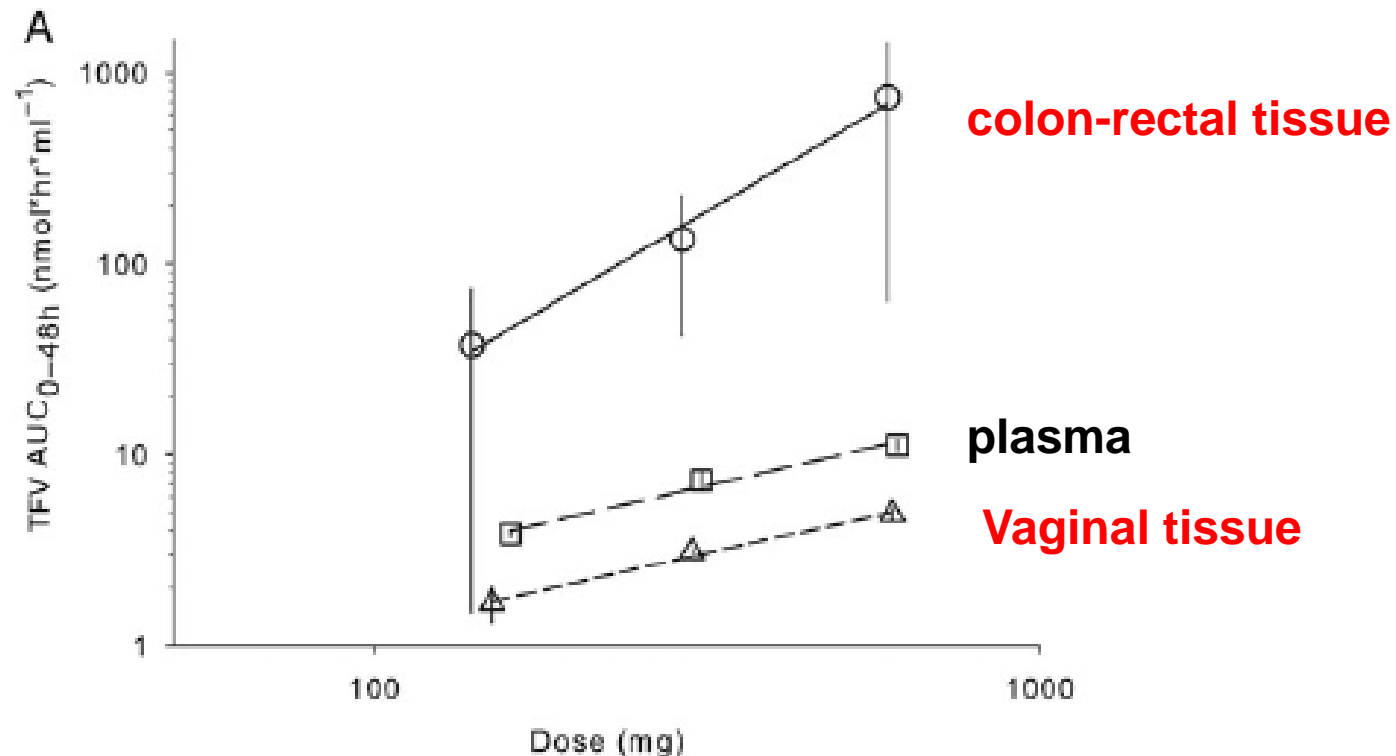
1. FTC/TDF PI. 2. Saag. JAMA. 2020;324:1651. 3. Tan. CMAJ. 2017;189:E1448. 4. apps.who.int/iris/bitstream/handle/10665/325955/WHO-CDS-HIV-19.8-eng.pdf. 5. cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. 6. FTC/TAF PI. 7. ema.europa.eu/en/opinion-medicine-use-outside-EU/human/dapivirine-vaginal-ring-25-mg. 8. who.int/news/item/26-01-2021-who-recommends-the-dapivirine-vaginal-ring-as-a-new-choice-for-hiv-prevention-for-women-at-substantial-risk-of-hiv-infection. 9. who.int/news/item/28-07-2022-who-recommends-long-acting-cabotegravir-for-hiv-prevention. 10. CAB extended-release injectable suspension PI. 11. Gollub. AIDS Educ Prev. 2022;34:311.

A Translational Pharmacology Approach to Predicting Outcomes of Preexposure Prophylaxis Against HIV in Men and Women Using Tenofovir Disoproxil Fumarate With or Without Emtricitabine

Mackenzie L. Cottrell,¹

JID April 2016

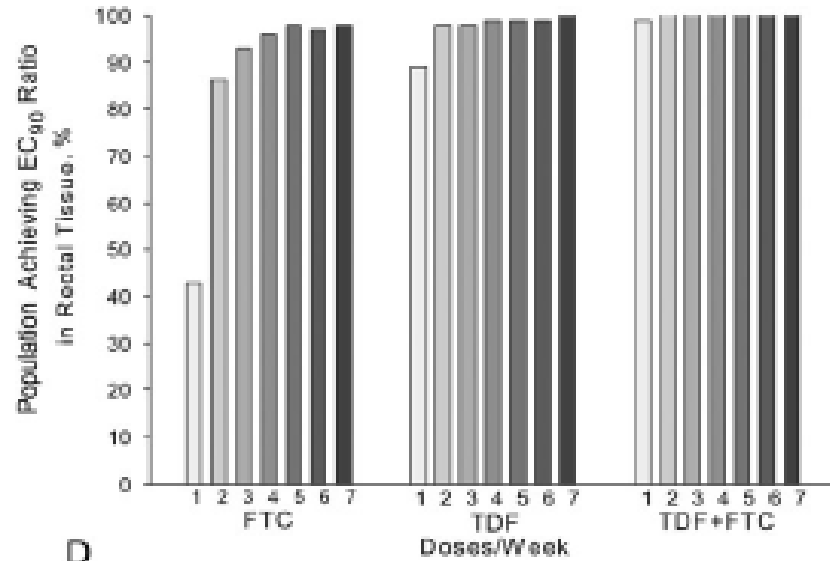
TDF 10 times more concentrated in colon-rectal tissue.



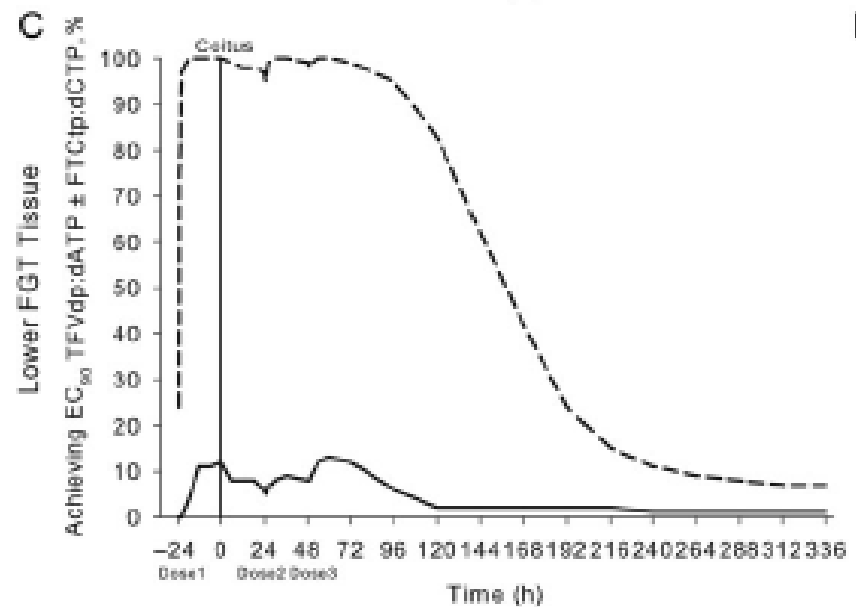
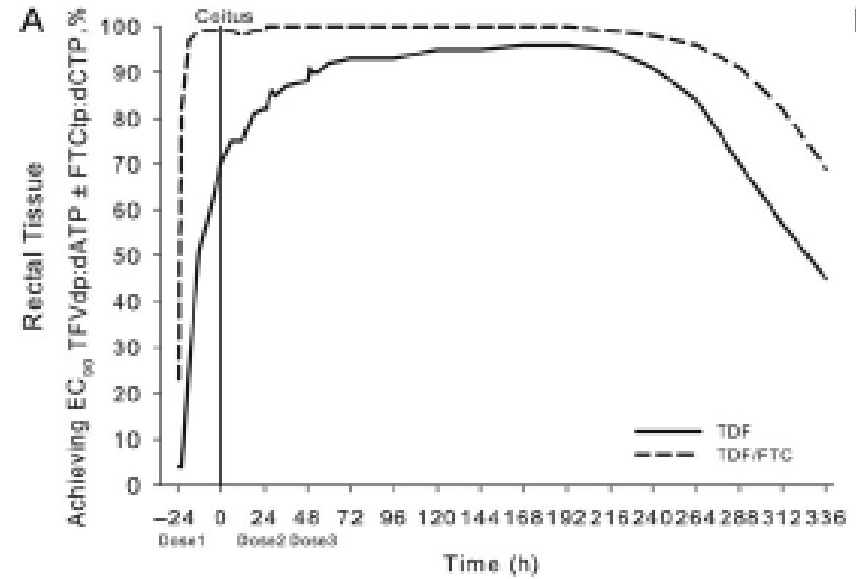
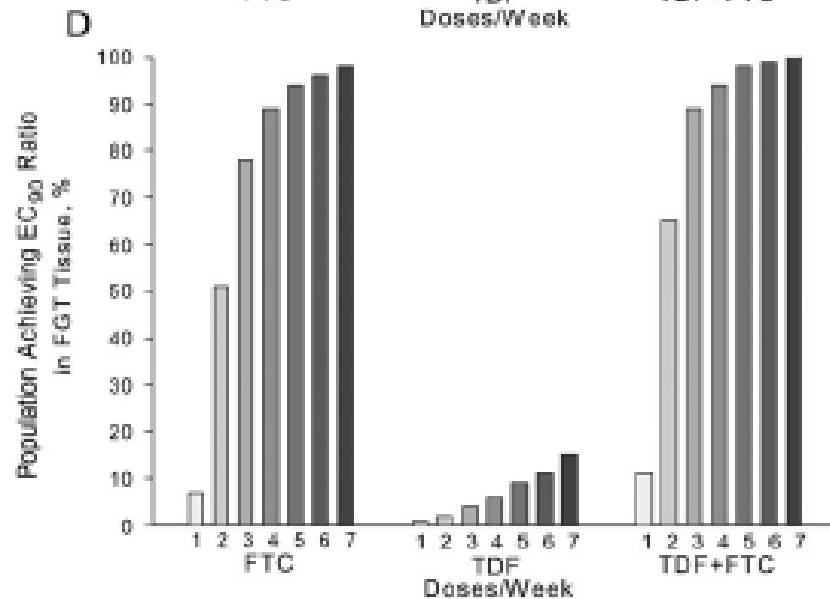
M: protection with 2 doses/week – Ipergay model: protection 240 hours

F: protection 5-6 doses/week – Ipergay model: protection 120 hours

M

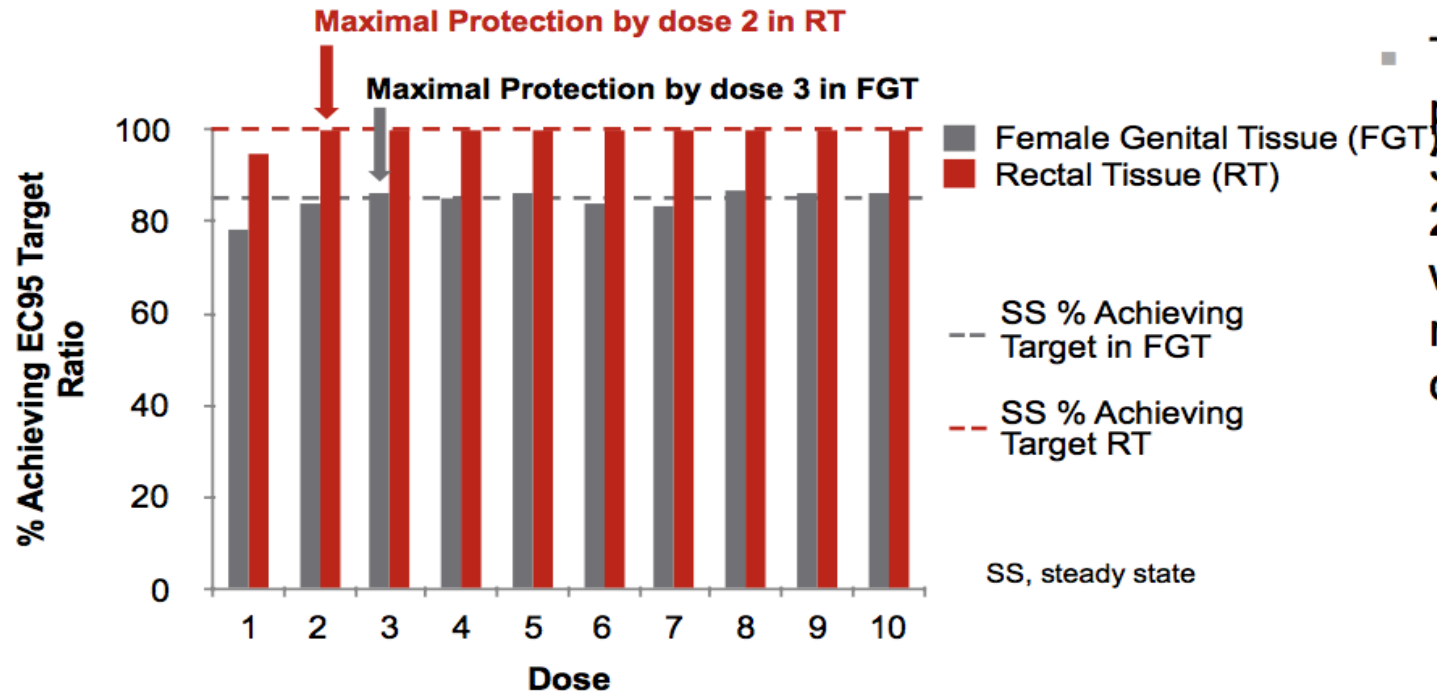


F



Time to Protection with Daily Dosing of Truvada® for PrEP

- WHO recommends additional HIV prevention measures should be used for 7 days after starting daily PrEP¹
- Target ratios have been defined for TFV and FTC for adequate cellular protection in genital tissue²



- Time to maximal protection is achieved by 3rd dose in FGT and by 2nd dose in RT³, well within the WHO recommendation of 7 days post-PrEP initiation

1. WHO Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection. Module 1: Clinical. Geneva: World Health Organization; 2017 (WHO/HIV/2017.17)
 2. Cottrell M, et al J Infect Dis. 2016 Jul 1;214(1):55
 3. Kashuba A, IAS 2017, France, Paris. Symposium #MOSY0803

HPTN 083 and 084: LA IM CAB Q2M vs Daily Oral FTC/TDF for PrEP

- International, randomized, double-blind phase IIb/III (083) and phase III (084) trials
- LA IM CAB met criteria for **superiority** vs daily oral FTC/TDF in both trials

HPTN 083¹

- N = 4566 MSM and TGW
- 12 incident infections on LA CAB
 - **4 with on-time injections**
 - Additional 3 identified after initial analysis (**7 reported with on-time injections to date**)²
- HR for CAB vs FTC/TDF:
0.34 (95% CI: 0.18-0.62)

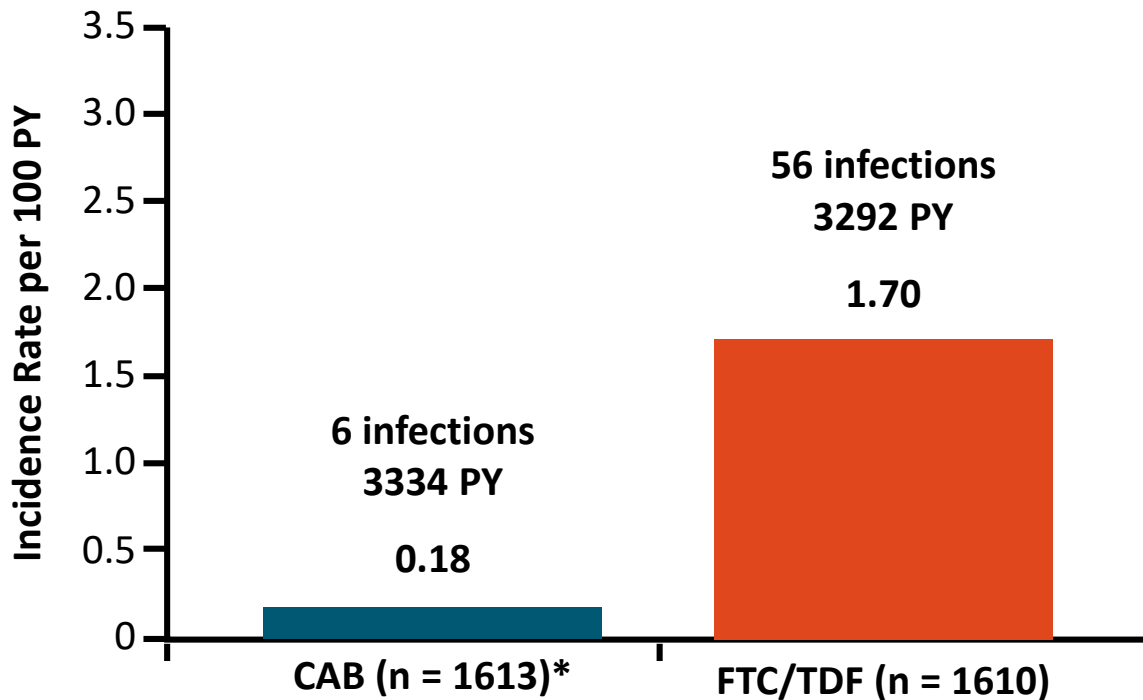
HPTN 084³

- N = 3224 cisgender women
- 4 incident infections on LA CAB
 - **1 with on-time injections**
 - 1 later determined to be infected at baseline
- HR for CAB vs FTC/TDF:
0.12 (95% CI: 0.05-0.31)

HPTN 084: 1-Yr Follow-up After Unblinding

HIV Incidence in Blinded + 1-Yr Unblinded Periods

HR: 0.11; 95% CI: 0.05-0.24

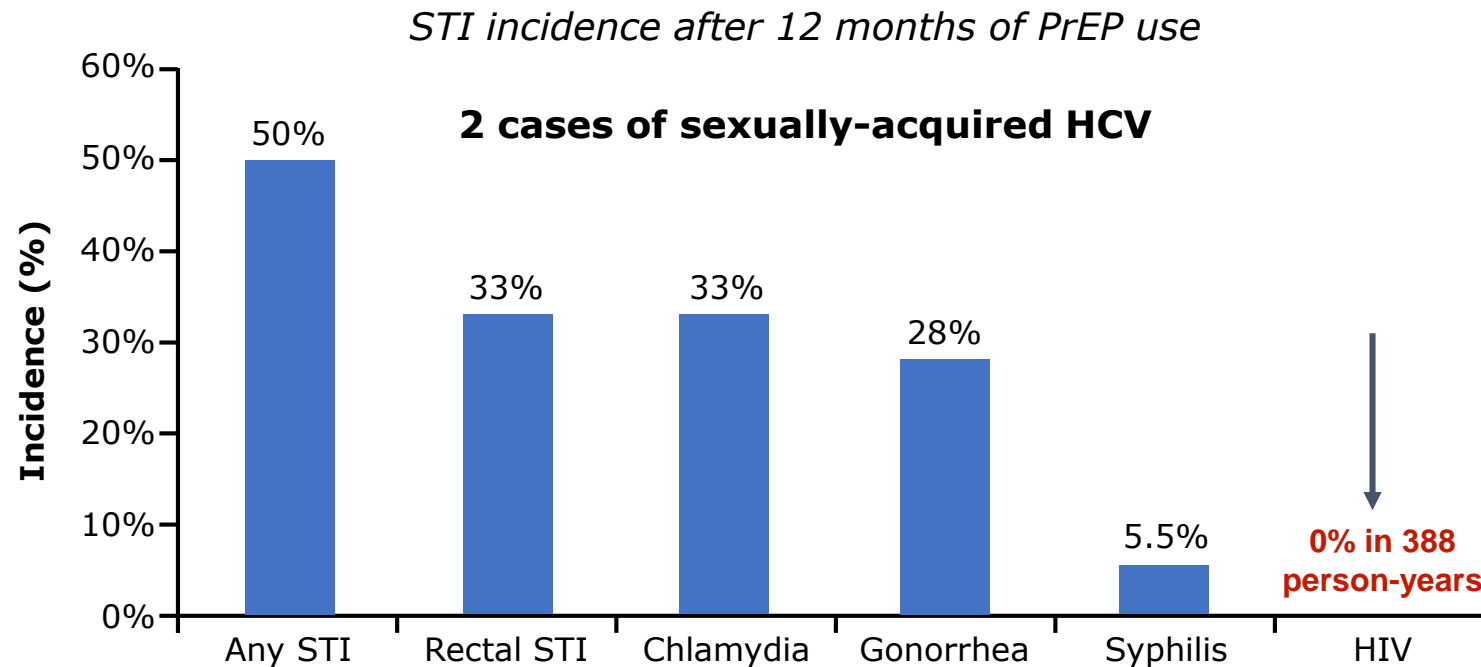


*Excludes 1 baseline infection from blinded period.

- 3 additional infections identified in CAB group during 1-yr unblinded period
 - 2 without recent CAB injections
 - 1 with no quantifiable CAB during oral lead-in
 - Received first injection at first positive visit
 - Identified 28 days later
- 7 HIV infections out of 1614 participants in CAB arm to date
 - **None with injections within 2 wk of target dose**

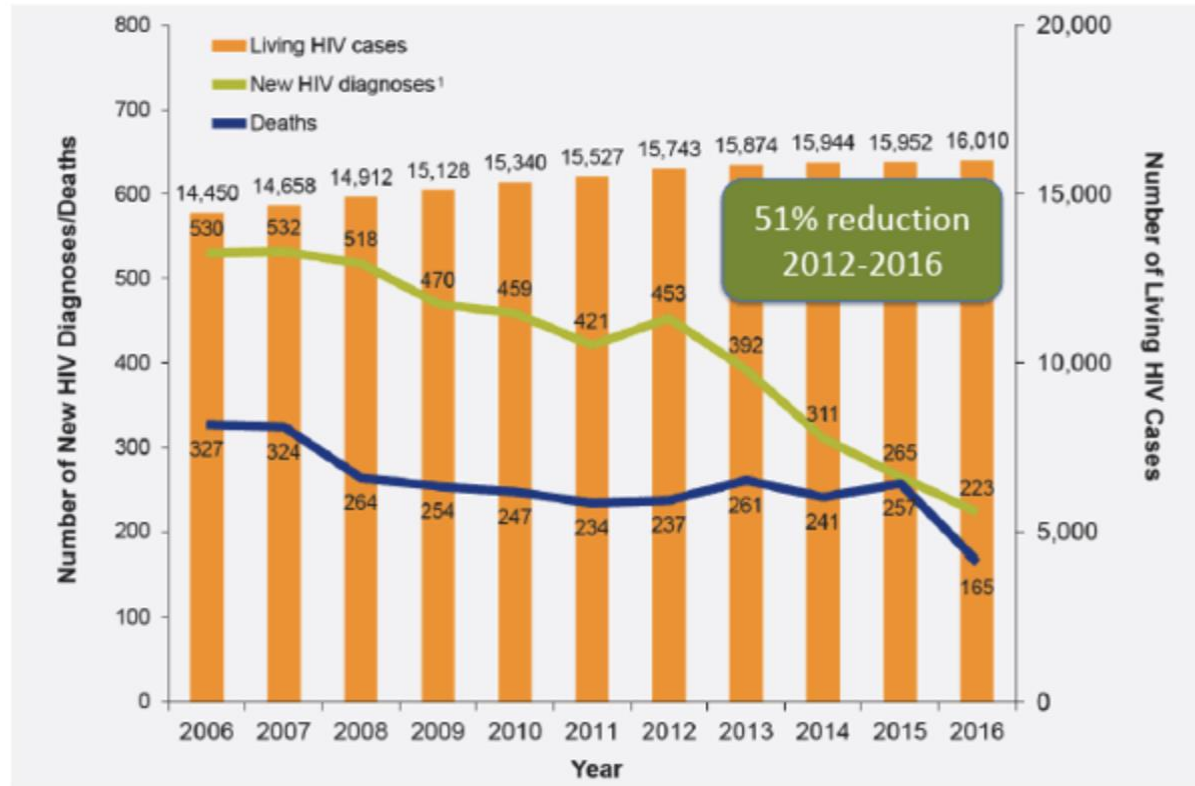
Kaiser Permanente cohort

A study of 657 PrEP users (mostly MSM) from 2012–2015 within the Kaiser Permanente integrated healthcare system, San Francisco



Of those taking part in the study, 187 were diagnosed with at least 1 STI during follow-up, and 78 individuals were diagnosed with multiple STIs

HIV Diagnoses, Persons Living with HIV and Deaths San Francisco, 2006-2016





Il lato positivo

Amo la mia vita **anche con l'HIV**.
Grazie al test, sono in **terapia**
e **non trasmetto l'infezione**.

Se hai una vita sessualmente attiva,
fai il test periodicamente anche tu.
È **semplice, anonimo e gratuito**.



Per informazioni
helpaids.it
Numero verde AIDS
800 856 080