

# PrEP for HIV Prevention

## The 4-1-1 on 2-1-1

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**February 10, 2022**

Last Updated: February 4, 2022

# Disclosures



As oral PrEP, only FTC/TDF and FTC/TAF are approved by the U.S. FDA and only for use as daily PrEP in some, but not all, populations. This talk will include discussion of other options for PrEP.

# Outline

- Review of RCT data
- Real world data - effectiveness and adherence
- Why do people choose 2-1-1?
- Prescribing

# Why talk about 2-1-1 (event-based, on demand) PrEP?

## HHS/CDC (2021)

Clinicians may choose to prescribe F/TDF off label using 2-1-1 dosing for adult MSM who have sex less than once per week and can anticipate sex.

## IAS/USA (2020)

2-1-1 dosing is recommended only for MSM (Ala). There are no data supporting 2-1-1 dosing using FTC/TAF.

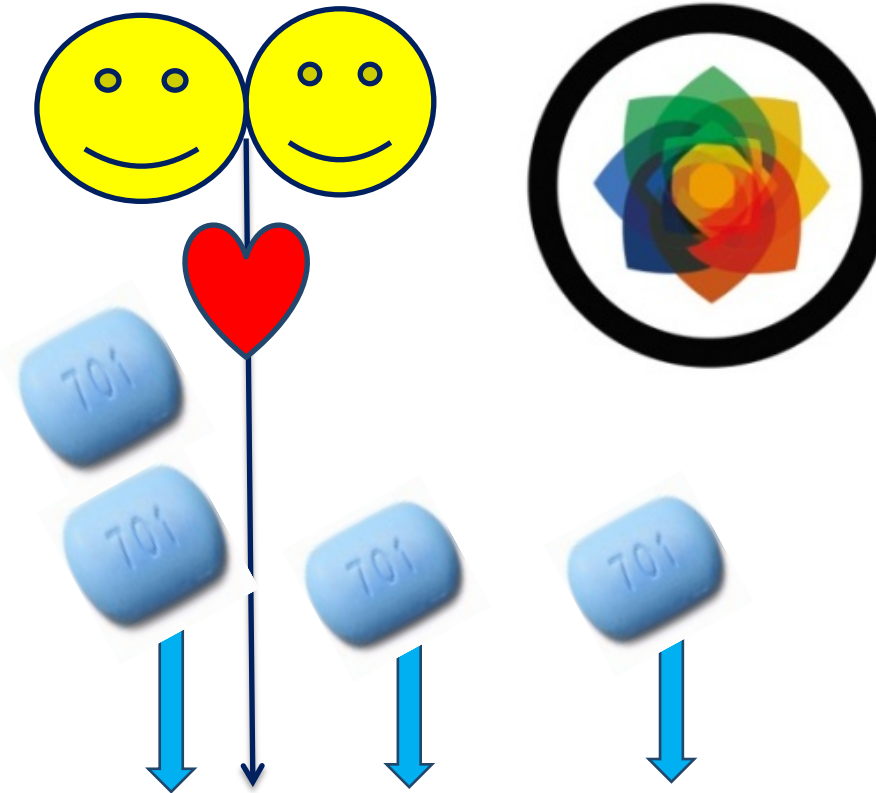
## WHO (2019)

Event-driven PrEP dosing is an option for MSM who would find intermittent PrEP more effective and convenient, those who have sex less frequently, and those who can plan for sex at least 2 hours in advance.

# ipergay

## Intermittent dosing strategy

- ✓ 2 tablets 2-24 hours before sex
- ✓ 1 tablet 24 hours later
- ✓ 1 tablet 48 hours after first intake



**ipergay**

ANRS

Intervention Préventive  
de l'Exposition aux Risques  
avec et pour les Gays

Friday

Saturday

Sunday

Monday

Tuesday

Wednesday

Thursday

Friday

Saturday

Sunday

# ipergay

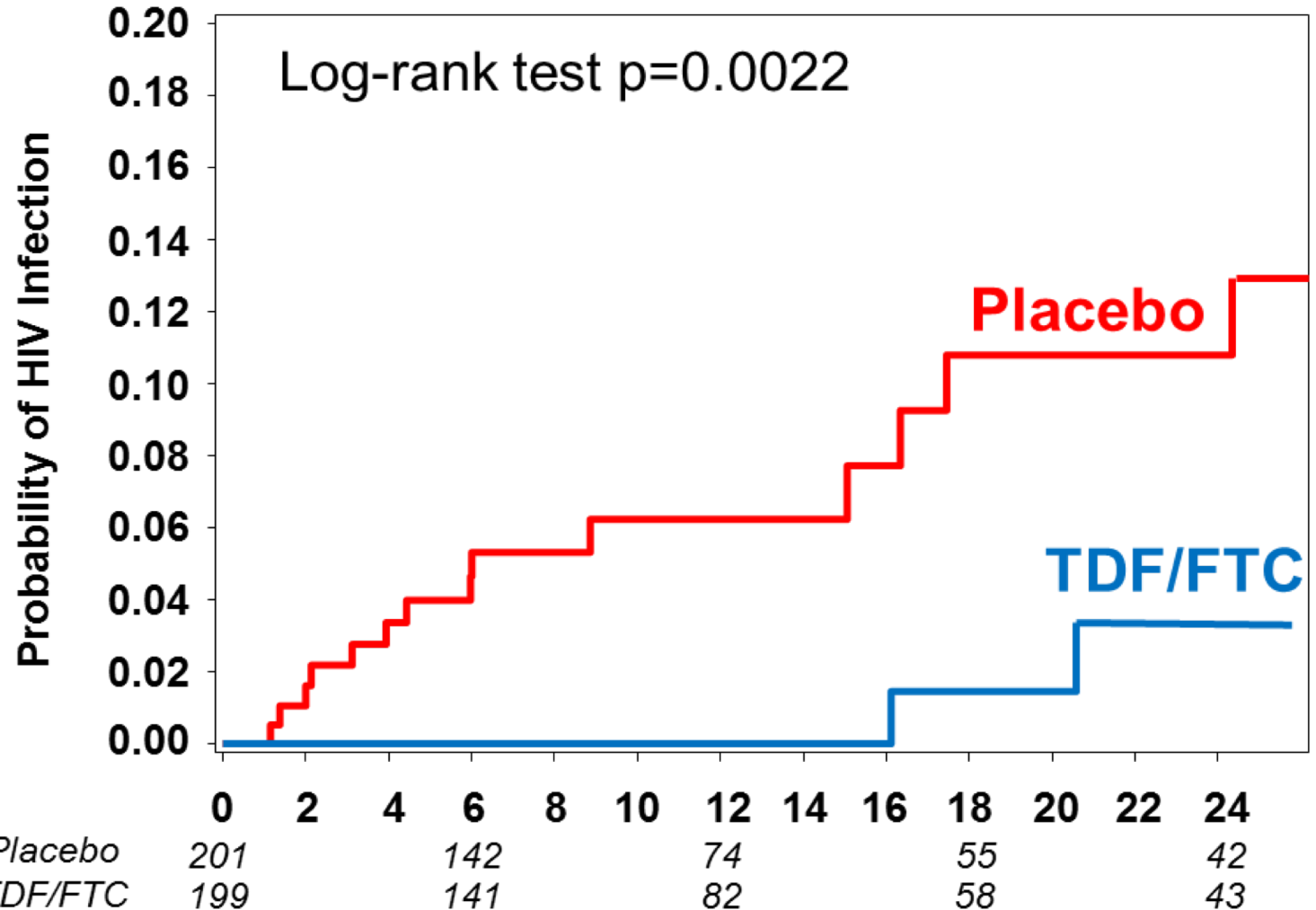
## Time to HIV Infection (mITT)

Median follow-up 9.3 months.

**14 in placebo arm**  
(incidence: 6.6/100 PY)

**2 in TDF/FTC arm**  
(incidence 0.91/100PY)

86% relative reduction  
(95% CI: 40-98, p=0.002)





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# ipergay OLE HIV Incidence – RCT v OLE

Treatment	Follow-Up Pts-years	HIV Incidence per 100 Pts-years (95% CI)
Placebo (double-blind)	212	6.60 (3.60-11.1)
TDF/FTC (double-blind)	219	0.91 (0.11-3.30)
TDF/FTC (open-label)	515	0.19 (0.01-1.08)

Median Follow-up in Open-Label Phase 18.4 months (IQR:17.5-19.1)

**97% relative reduction vs. placebo**

# On-demand PrEP among MSM with infrequent sexual intercourse: A substudy of ipergay

	<b>Person-Years</b>	<b># HIV infx</b>	<b>Incidence rate/100p-y</b>	<b>RRR (95% CI)</b>	<b>p</b>
Placebo	64.8	6	9.3 (3.4-20.1)		
TDF/FTC	68.9	0	0 (0-5.4)	100% (39-100)	0.013

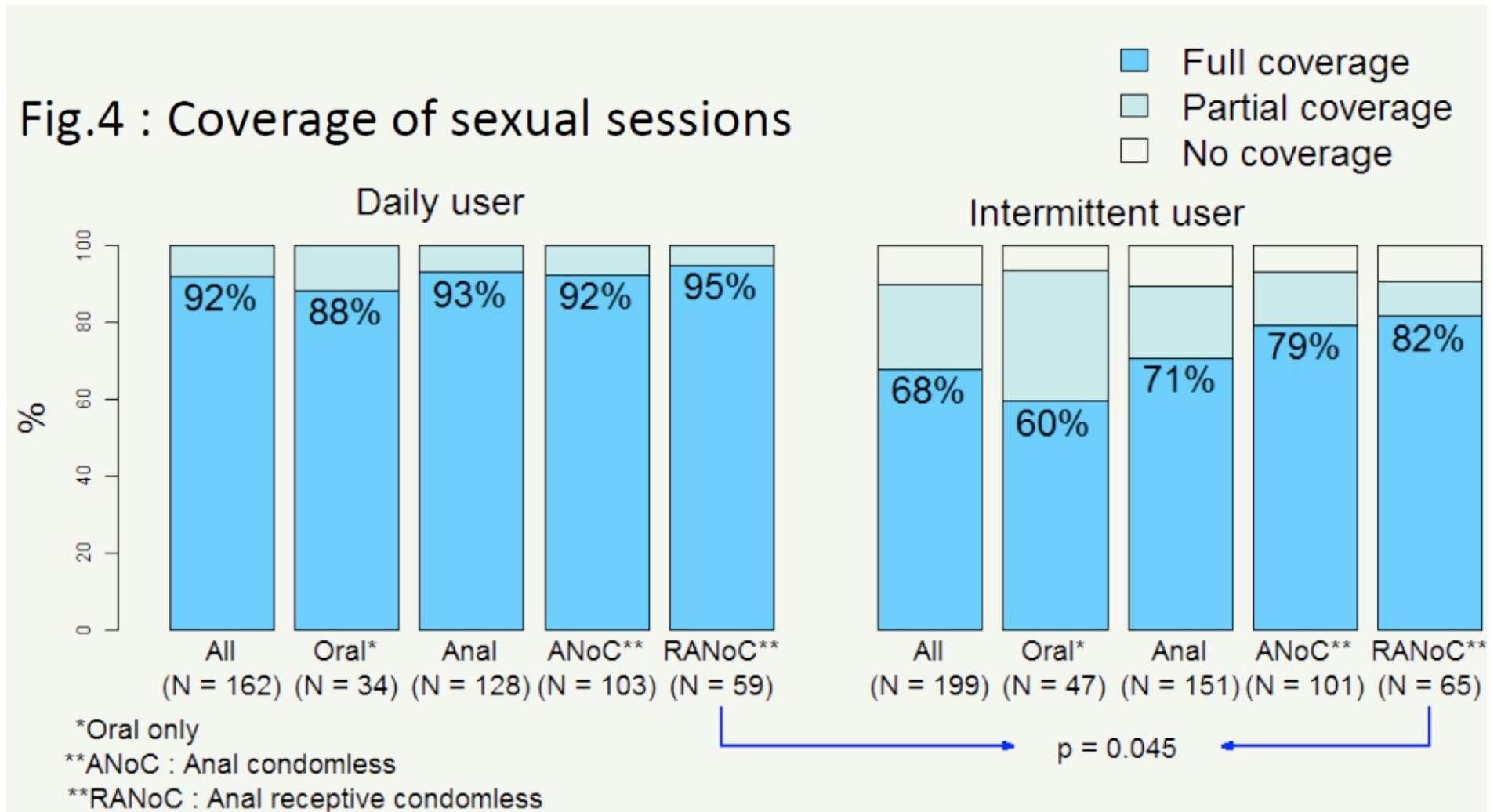
## Conclusion

“On-demand PrEP is an adequate alternative to daily PrEP for MSM with high risk but infrequent sexual intercourse.”



# Coverage of sex events with on demand PrEP

## A MEMS substudy of the ANRS ipergay trial



# Real world data

## Effectiveness of 2-1-1

- Kaiser CA
  - 279 MSM, 0 infections in 136 person-years
- Be-PrEP-ared, Belgium and AMPrEP, the Netherlands
  - 571 MSM
  - 148 (25.9%) chose edPrEP at baseline
  - 31.7% of participants switched regimen at least once
  - 2 infections among users of daily PrEP, 0 for edPrEP
- One failure was reported but has never been verified
  - <https://www.poz.com/article/case-ondemand-prep-failure-reported-australia>

# Real world data

## Coverage of sex acts

- AMPrEP:
  - Self-report “consistently correct” 81% of time
  - Steady partners 67%, known casual partners 93%, unknown casual partners 90%
  - Jongen JIAS 2021; 24(5)
- Hong Kong: 92% CAI self-reported coverage for both 2-1-1 and daily
  - Kwan JIAS 2021
- West Africa: Optimal adherence: 41% 2-1-1 v 71% daily
  - Laurent et al Lancet HIV 2021

# Adherence challenges in real world 2-1-1

- ipergay OLE (Ciaccio et al. AIDS 2020)
  - 19% of AI was CAI
  - Factors associated with CAI – depression, high number of sex acts, alcohol
- Camp and Saberi (Camp & Saberi PLoS One 2021)
  - Survey of 140 U.S. MSM who had taken 2-1-1 PrEP at least once
  - Barriers reported
    - Unplanned encounters 44%
    - Trouble remembering follow-up dosing 29%
    - Lack of provider knowledge 24%

# Why do people choose 2-1-1 dosing?

Reasons for switching from daily to 2-1-1 dosing

fewer sexual encounters (64%)

desire for fewer pills (46%)

reduced cost (22%)

desire to reduce side effects (19%)

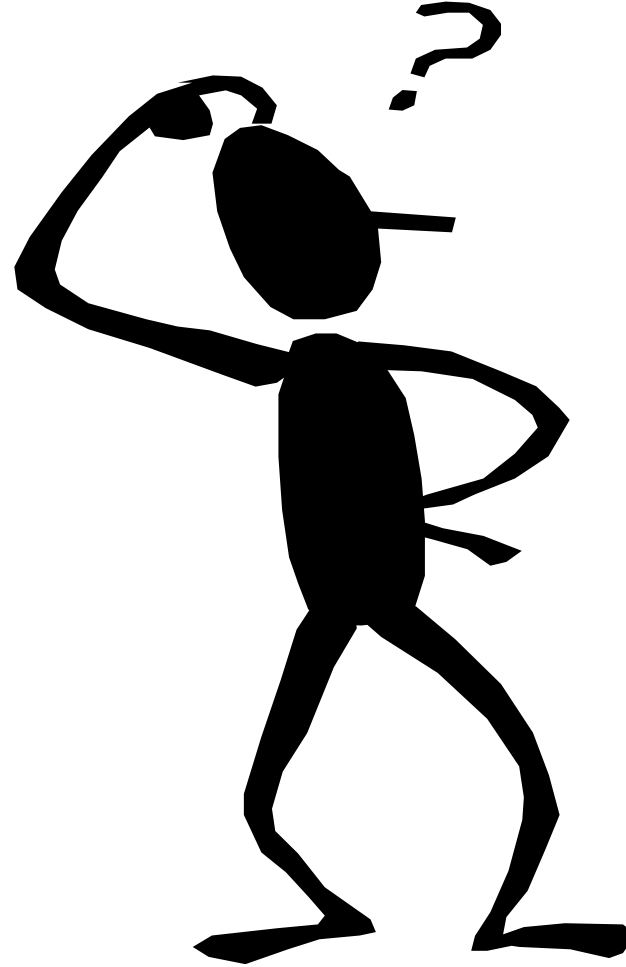
# How to prescribe

- Cisgender MSM only
- F/TDF only
- No active HBV infection
- 30 days (written as daily dosing) with 0 refills
- Quarterly visits
- Communicate about changing back and forth

# Counseling points

- The importance of both pre- and post-sex doses
- Use PrEP for all sexual encounters.
- The possibility of recurrent “start up” symptoms
- Inadvertent disclosure of same sex behavior
- How to change back and forth between daily and 2-1-1 (and 1-1-1)
- The continued need for HIV/STI testing
- The possibility that 2-1-1 might not be covered by insurance

# Questions?





# Acknowledgment

The Mountain West AIDS Education and Training (MWAETC) program is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling \$2,886,754 with 0% financed with non-governmental sources.

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