

# "SOPHOCLES – P4G" The experience of the first interventional implementation PrEP pilot program in Athens

Sophocles Chanos Checkpoint Head









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# Prepe Neurope







- Diagnose all individuals with HIV as early as possible after infection
- Treat HIV infection rapidly and effectively to achieve sustained viral suppression (U=U) ullet
- Prevent at-risk individuals from acquiring HIV infection, including the use of pre-exposure prophylaxis (PrEP)
- Rapidly detect and respond to emerging clusters of HIV infection to further reduce new transmissions

Anthony Fauci et al., JAMA, 2019 National Institute of Allergy and Infectious Diseases (NIAID)



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#### Ending the HIV Epidemic A Plan for the United States

Anthony S. Fauci, MD; Robert R. Redfield, MD; George Sigounas, MS, PhD; Michael D. Weahkee, MHA, MBA Brett P. Giroir, MD

In the State of the Union Address on February 5, 2019, Presi- Office of the Assistant Secretary of Health, will focus on geo +

Supplemental content

jama.com

While landmark biomedical and scientific research advances infection; have led to the development of many successful HIV treat- 2. treat HIV infection rapidly and effectively to achieve sus ment regimens, prevention strategies, and improved care for tained viral suppression; persons with HIV, the HIV pandemic remains a public health 3. prevent at-risk individuals from acquiring HIV infection, crisis in the United States and globally.

In the United States, more than 700 000 people have died 4. rapidly detect and respond to emerging clusters of HIV inas a result of HIV/AIDS since the disease was first recognized in 1981, and the Centers for Disease Control and Prevention (CDC) A key component for the success of this initiative is active estimates that 1.1 million people are currently living with HIV, partnerships with city, county, and state public health depart about 15% of whom are unaware of their HIV infection.<sup>1</sup> Ap-ments, local and regional clinics and health care facilities, cli proximately 23% of new infections are transmitted by individu- nicians, providers of medication-assisted treatment for opioid als who are unaware of their infection and approximately 69% use disorder, and community- and faith-based organizations. of new infections are transmitted by those who are diagnosed The implementation of advances in HIV research achieved with HIV infection but who are not in care.<sup>2</sup> In 2017, more than over 4 decades will be essential to achieving the goals of the ini-38 000 people were diagnosed with HIV in the United States. tiative. Clinical studies serve as the scientific basis for strate The majority of these cases were among young black/African gies to prevent HIV transmission/acquisition. In this regard, as American and Hispanic/Latino men who have sex with men reviewed in a recent Viewpoint in JAMA,<sup>5</sup> large clinical studies (MSM). In addition, there was high incidence of HIV among have recently proven the concept of undetectable = untranstransgender individuals, high-risk heterosexuals, and persons mittable (U = U), which has broad public health implications for who inject drugs.<sup>1</sup> This public health issue is also connected to HIV prevention and treatment at both the individual and socithe broader opioid crisis: 2015 marked the first time in 2 de- etal level. U = U means that individuals with HIV who receive cades that the number of HIV cases attributed to drug injec- antiretroviral therapy (ART) and achieve and maintain an untion increased.<sup>3</sup> Of particular note, more than half of the new detectable viral load do not sexually transmit HIV to others.<sup>5</sup> HIV diagnoses were reported in southern states and Washing- U = U will be invaluable in helping to counteract the stigma aston, DC. During 2016 and 2017, of the 3007 counties in the United sociated with HIV, and this initiative will create environments States, half of new HIV diagnoses were concentrated in 48 in which all people, no matter their cultural background or risk "hotspot" counties, Washington, DC, and Puerto Rico.<sup>4</sup>

dent Donald J. Trump announced his administration's goal to graphic and demographic hotspots in 19 states, Washington, end the HIV epidemic in the United States within 10 years. DC, and Puerto Rico, where the majority of the new HIV cases The president's budget will ask Republicans and Democrats are reported, as well as in 7 states with a disproportionate octo make the needed commit- currence of HIV in rural areas (eFigure in the Supplement). ment to support a concrete The strategic initiative includes 4 pillars:

plan to achieve this goal. 1. diagnose all individuals with HIV as early as possible after

including the use of pre-exposure prophylaxis (PrEP); and

fection to further reduce new transmissions.

profile, feel welcome for prevention and treatment services. The US Department of Health and Human Services (HHS) Results from numerous clinical trials have led to signifi-

has proposed a new initiative to address this ongoing public cant advances in the treatment of HIV infection, such that a health crisis with the goals of first reducing numbers of inci- person living with HIV who is properly treated and adherent dent infections in the United States by 75% within 5 years, and with therapy can expect to achieve a nearly normal lifespan then by 90% within 10 years. This initiative will leverage criti- This progress is due to antiviral drug combinations drawn from cal scientific advances in HIV prevention, diagnosis, treat- more than 30 agents approved by the US Food and Drug Adment, and care by coordinating the highly successful pro- ministration (FDA), as well as medications for the prevention grams, resources, and infrastructure of the CDC, the National and treatment regimens of HIV-associated coinfections and co-Institutes of Health (NIH), the Health Resources and Services morbidities. Furthermore, PrEP with a daily regimen of 2 oral Administration (HRSA), the Substance Abuse and Mental antiretroviral drugs in a single pill has proven to be highly ef-Health Services Administration (SAMHSA), and the Indian fective in preventing HIV infection for individuals at high risk. Health Service (IHS). The initial phase, coordinated by the HHS In addition, postexposure prophylaxis provides a highly ef-

JAMA Published online February 7, 2019 E1

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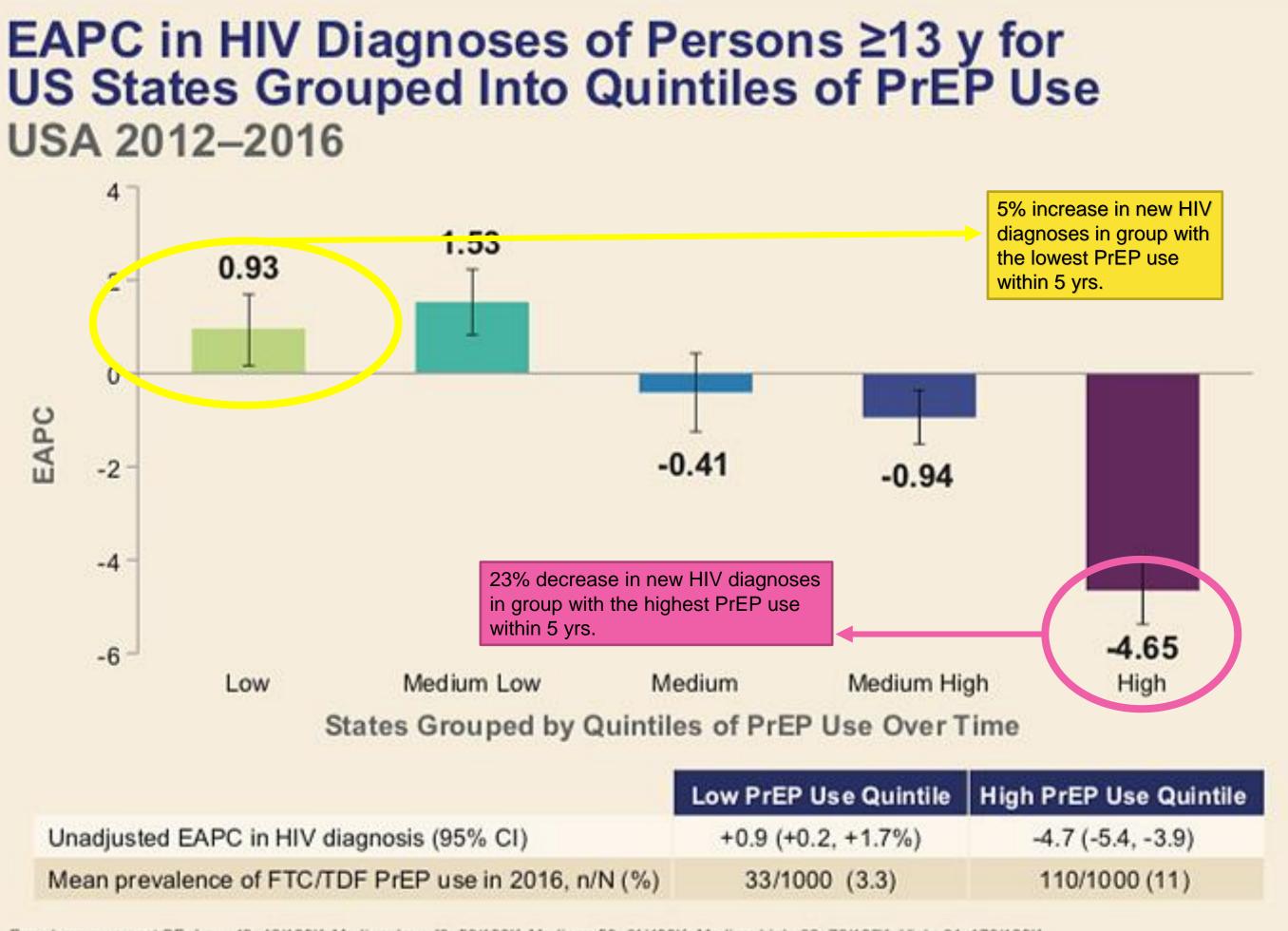






# PrEP scales up, HIV incidence decline.

# USA 2012-2016



Error bars represent SE. Low: 13-42/100K; Medium low: 42-53/100K; Medium: 53-61/100K; Medium high: 62-78/100K; High: 81-178/100K.



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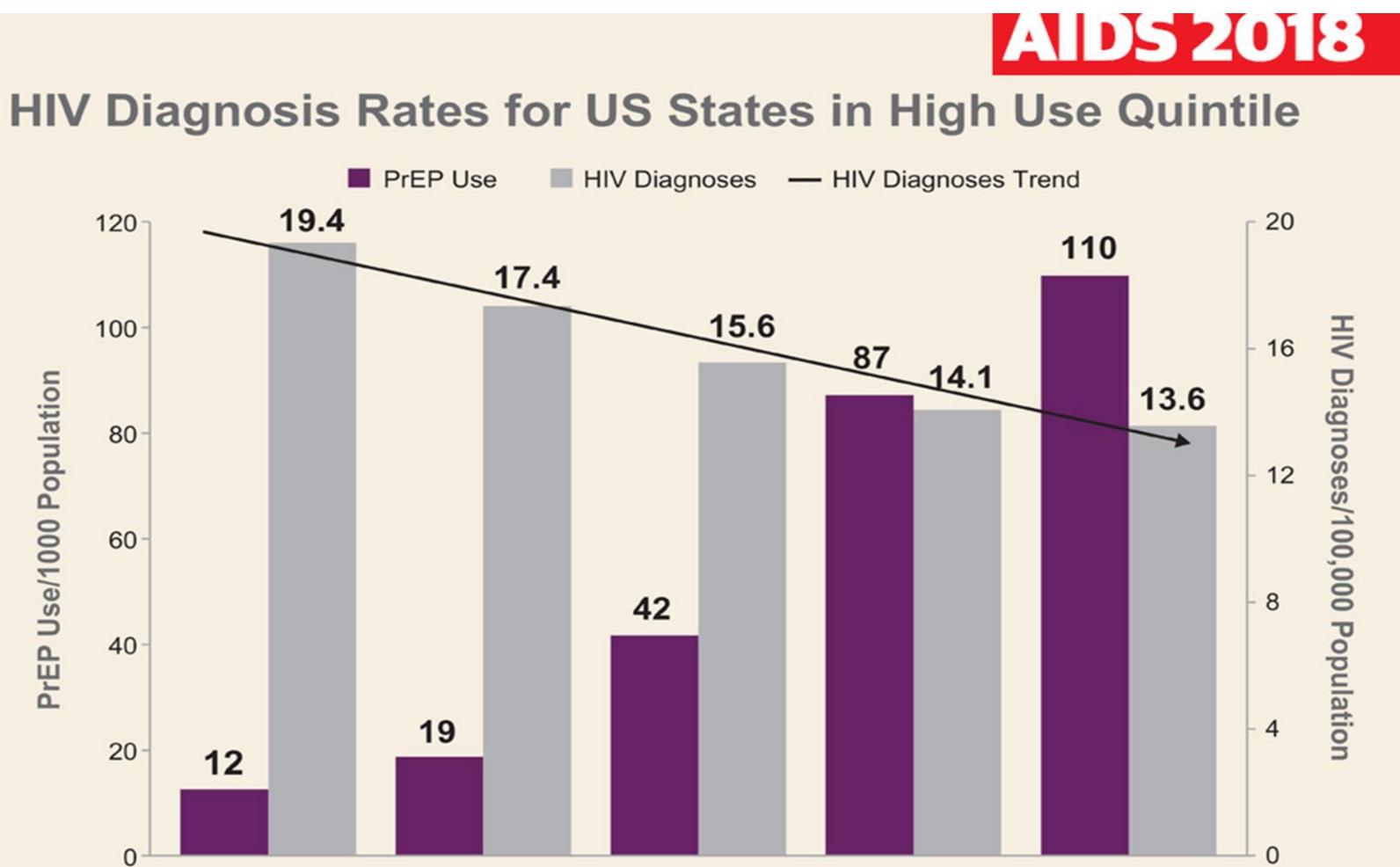


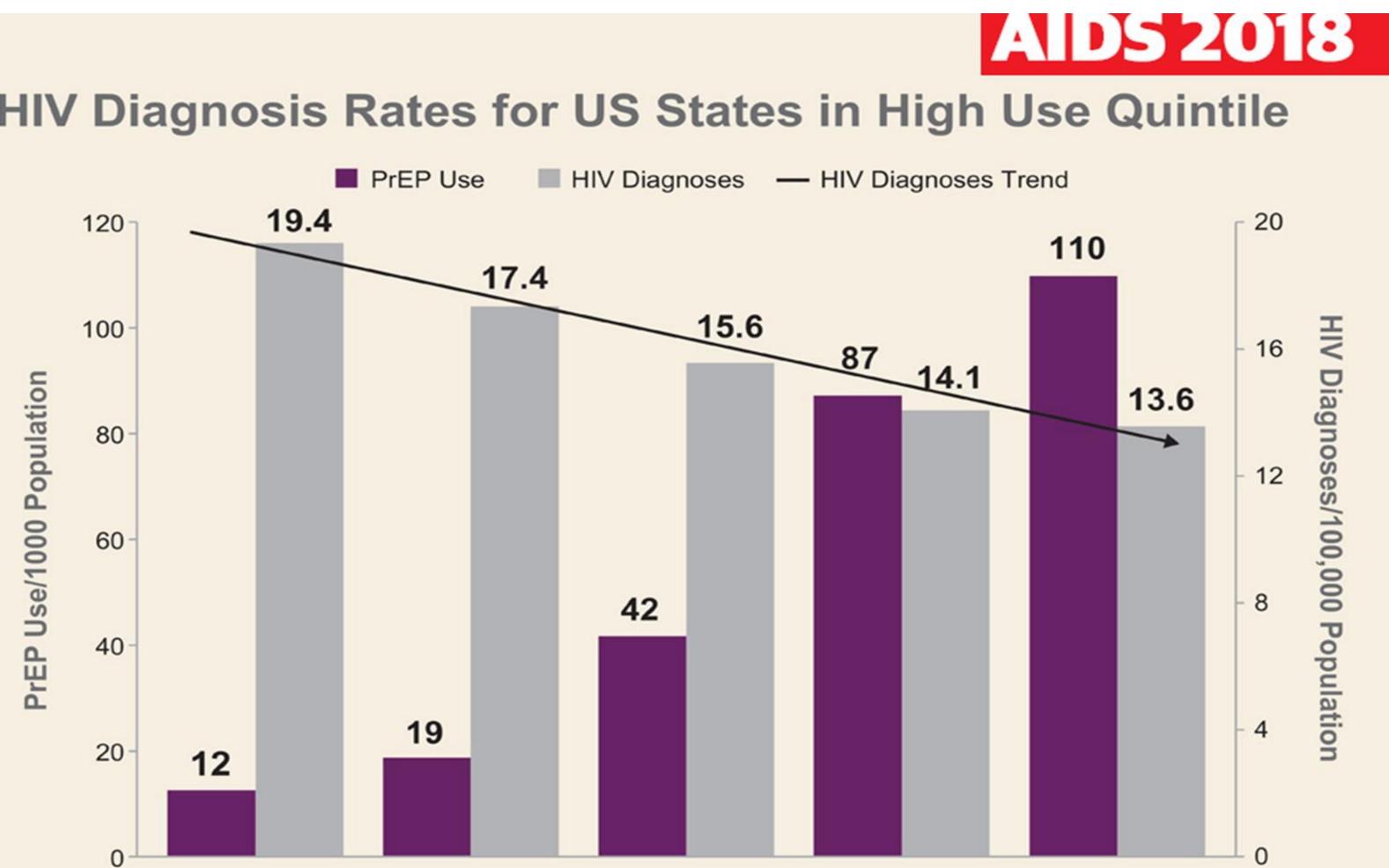






PrEP scales up, HIV incidence decline..







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# "SOPHOCLES - P4G": Targeted administration of PrEP to HIV+ networks



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Funding:  $\bullet$ 



US National Institutes of Health – NIH & Gilead Sciences International Ltd.

- Aims:  $\bullet$
- Determining the demographic and behavioral characteristics of MSM receiving PrEP \*\*
- Emphasizing the importance of linkage to care aimed at administering PrEP to 'high risk' HIV-negative MSM •••
- \* The collection of data regarding the early parameters of the PrEP cascade so that they can be used in PrEP effectiveness s and models as a public health intervention



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effectiveness of PrEP is ove



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## Method 1: "SOPHOCLES" program Aim: Recruitment of 100 HIV-negative "high risk" MSM

MSM recruitment procedure:

- Ath Checkpoint
- Respondent Driven Sampling
- Test for HIV
- Interview through structured questionnaire (max 1,5 hrs)
- Financial incentive
- ✤ MSM search period: 11/2016 04/2018



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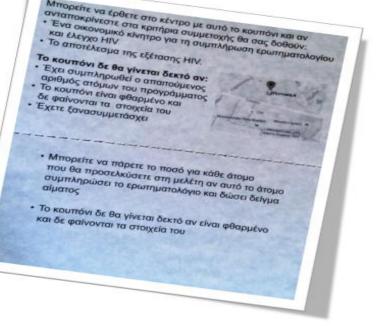


PrEP



#### ΚΟΥΠΟΝΙΑ ΣΥΜΜΕΤΟΧΗΣ

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### ✤ 308 participants:

- 282 HIV-
- 21 HIV+
- 5 with new HIV diagnosis
- ✤ Greek origin: 91,2%
- ✤ Median age: 28,9 (8,2) yrs.
- ✤ Median no of yrs. of education (SD): 15,7 (2,5)
- ✤ 54 (19.4%) unemployed
- ✤ 40 (14.2%) bisexual sexual orientation



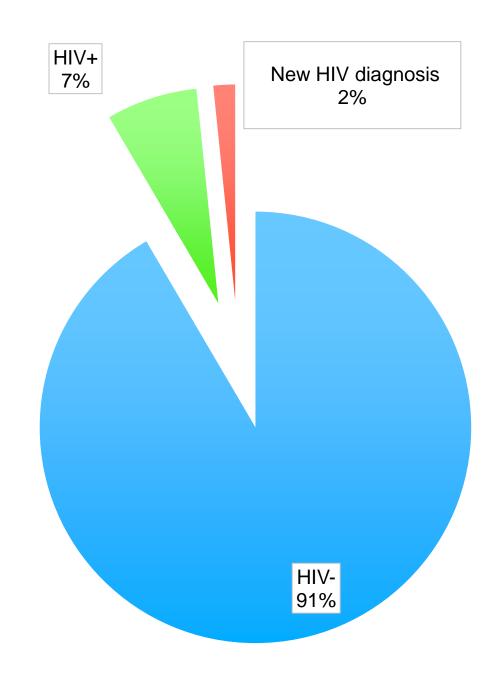
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#### **Participants' Demographics**

#### SOPHOCLES Participants' HIV Status





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- ✤ 211 (74,8%) have been tested for HIV in the past year
- ✤ 71 (25,4%) reported an STI in the past year
- Median no (250, 750) of the size of their sexual network: 10 (3,30) persons in the last 6 months.
- ✤ 84 (31,2%) reported symptoms of depression

• PrEP eligibility criteria were met by **129** / 282 (41.9%) • **107** continued in the clinical trial

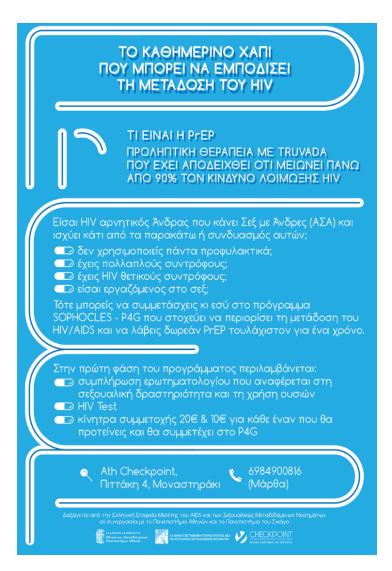


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## Participants' Behavioral & Psychosocial Characteristics





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## Method 2: "P4G" (PrEP4Greece) clinical trial

### PrEP eligibility criteria

- HIV-
- HBV-
- No of sexual partners
- STIs
- UI
- PEP
- ChemSex

### Monitoring 1 yr.: 6 visi

Visit 0 - Screening

Visit 1 – Start of PrEP use

Visit 2 - 1 month after the start of PrEP

Visit 3 – 3 months after the start of PrEP

Visit 4 - 6 months after the start of PrEP

Visit 5 – 9 months after the start of PrEP

Visit 6 – 12 months after the start of PrEP

Daily TDF/FTC (Truvada)







its in t	total
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- Regular screening (HIV1, HAV, HBV, HCV, STIs)
- STIs treatment
- Vaccination planning
- Identification of potential side effects
- Renal function monitoring
- PrEP adherence monitoring
- Keeping of daily diary (e.g. sexual intercourse, drug use)



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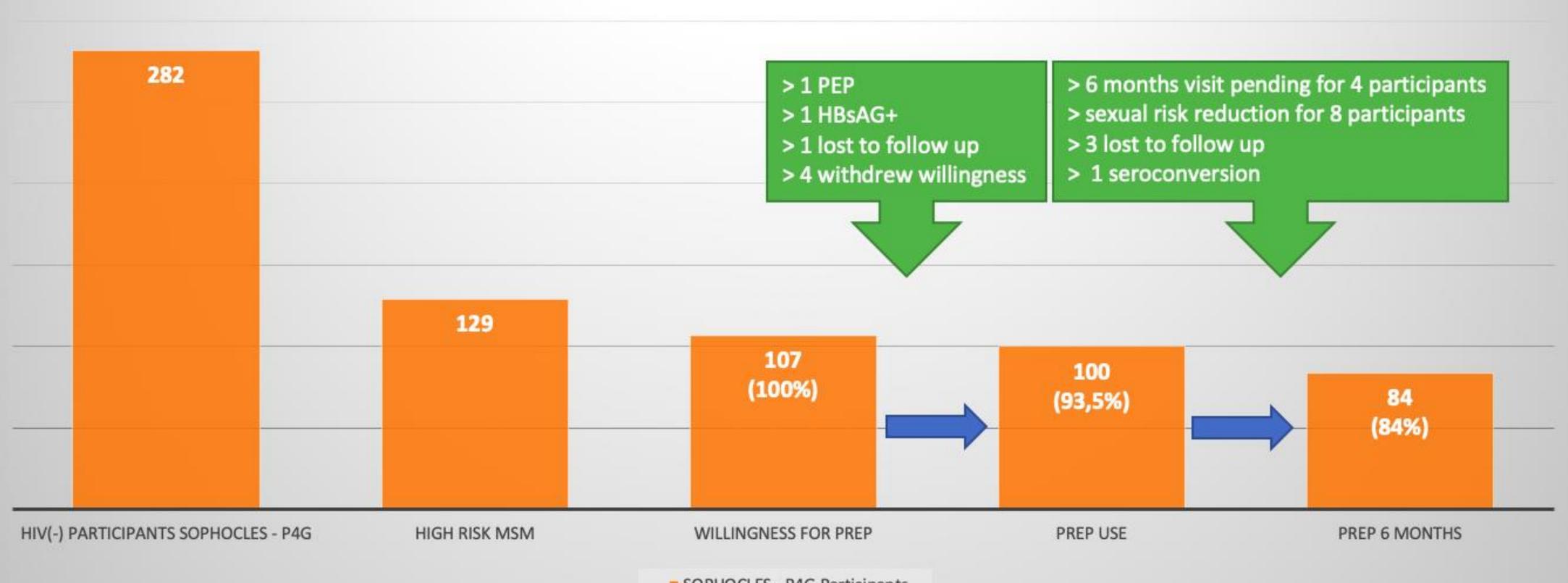
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# The PrEP Care Cascade 6 months



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SOPHOCLES - P4G Participants



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- Median age (SD:9,3): 33,5 yrs.
- Median no of yrs. of education (SD:2,4): 15,9 (majority: higher education)
- Full time employment: 56.1% (46/84)
- No of sexual partners: Median no (250, 750) of the size of their sexual network: 30 (15,60) people
- Participation in group sex: 96,4%
- Search of sexual partners through mobile apps: 64% (Grindr, Planet Romeo, Scruff)
- Drug use: 79,7%
- Chemsex (Crystal Meth, Meph, GHB/GBL, cocaine): 66,7%



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Results I, N = 84**Characteristics, Screening for PrEP** 



effectiveness of PrEP is over



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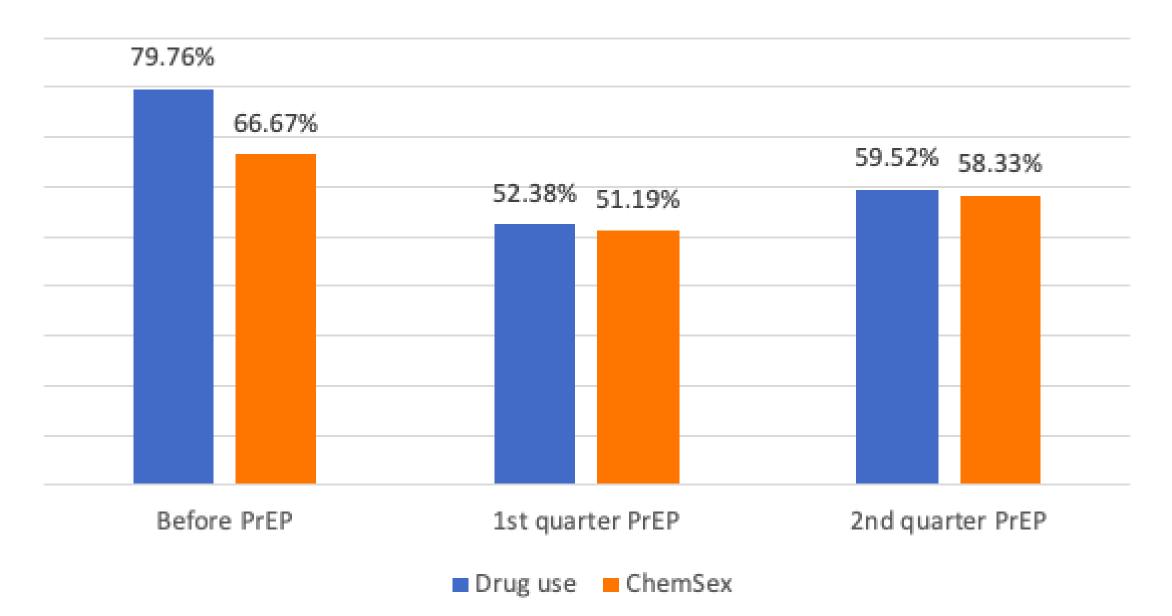
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### Participants' Behavioral Characteristics





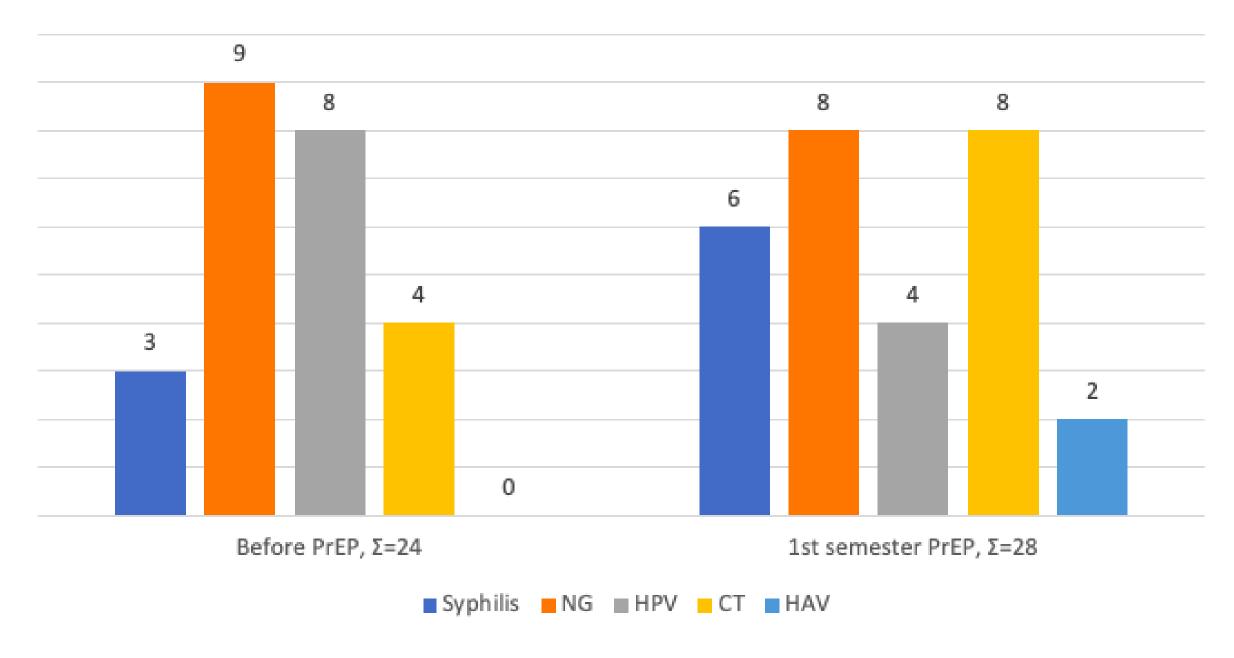
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#### Results II, N = 846 months PrEP use

Participants' Behavioral Characteristics





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## Results II, N = 84 6 months PrEP use

## PrEP adherence: 96%, <u>Stable in both quarters</u>

	ျst quarter Median no (250, 750)	2 <sup>nd quarter</sup> Median no (250, 750)	p value
% UAI	91,7% (62.4% - 100.00%)	97,4% (78.1% - 100.00%)	p=0.009
UAI [Passive] (times)	5,5 (2 - 11.5)	8 (2 - 22)	p<0.001
UAI [Top] (times)	8,5 (2 - 20)	14 (5 - 28)	p<0.001
N sexual partners (individuals)	26 (17.5 - 35.5)	19,5 (14 - 39)	p=0.007









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## Results IV, N = 1006 months PrEP use

✓ 6 syphilis cases ✓ 9 NG cases ✓ 5 HPV cases ✓ 2 acute HAV cases ✓ 2 ureaplasma cases

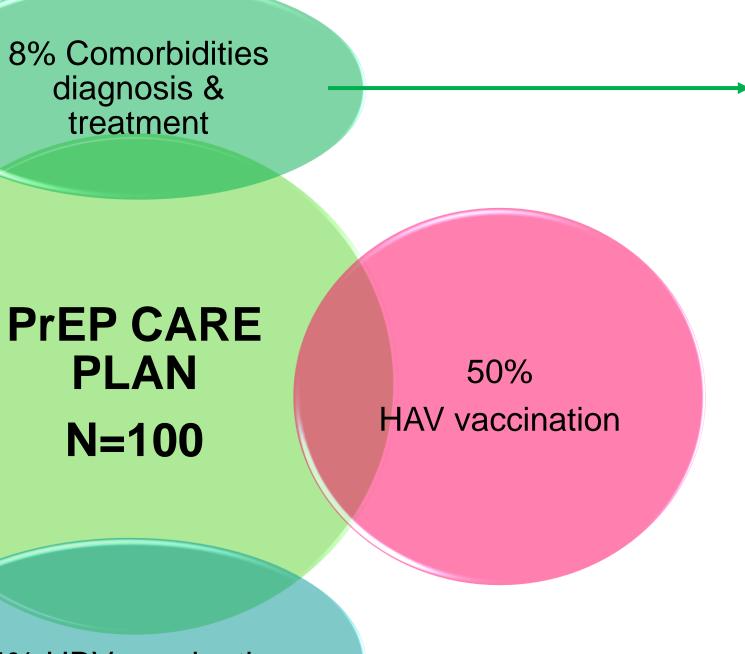
24% STIs diagnosis & treatment

24% HBV vaccination

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- Arterial hypertension
- Dyslipidemia
- Autoimmune thyroiditis
- Mental health

#### **#PrEP**WORKS

The time for debate on the effectiveness of PrEP is over





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## Conclusions

Adoption of a PrEP administration program for both primary and secondary STI and HIV transmission prevention

The creation of special sexual health structures through which PrEP will be available

Collaboration with the community in the design and implementation of HIV prevention programs.

✤ 74 PrEPers completed the program...

Implementation of PrEP in Greece seems that it is not associated with an increase in high-risk behaviors and the frequency of STIs

Excellent PrEP adherence









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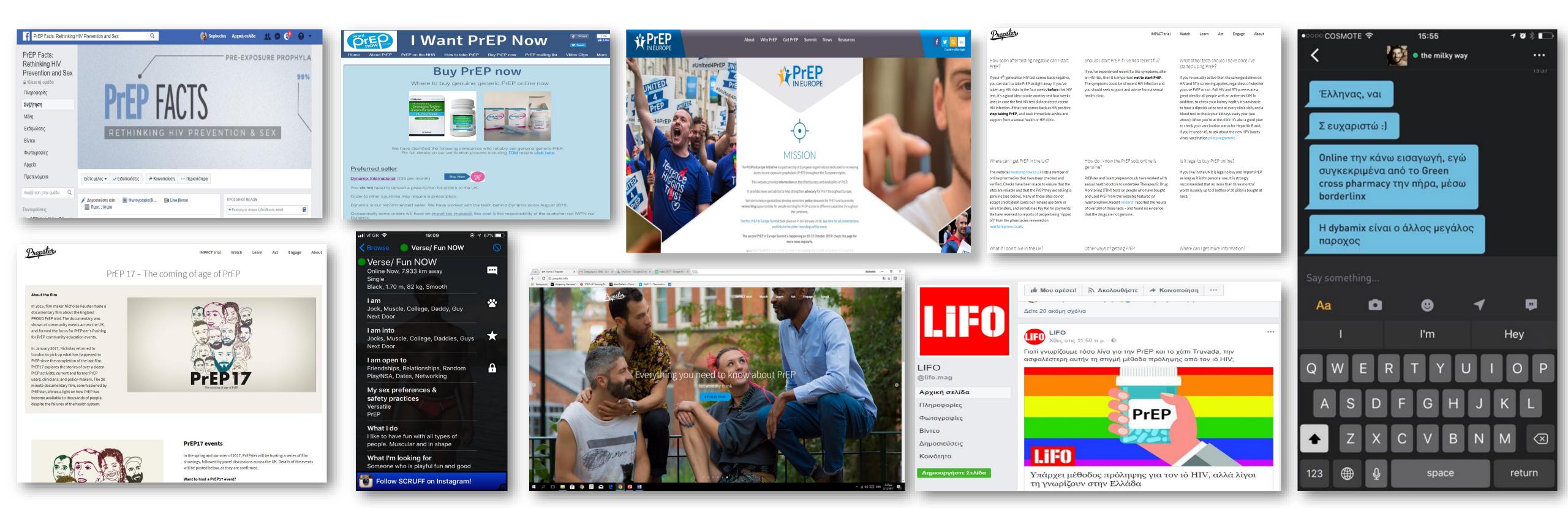


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#### News travel fast and demand is increasing



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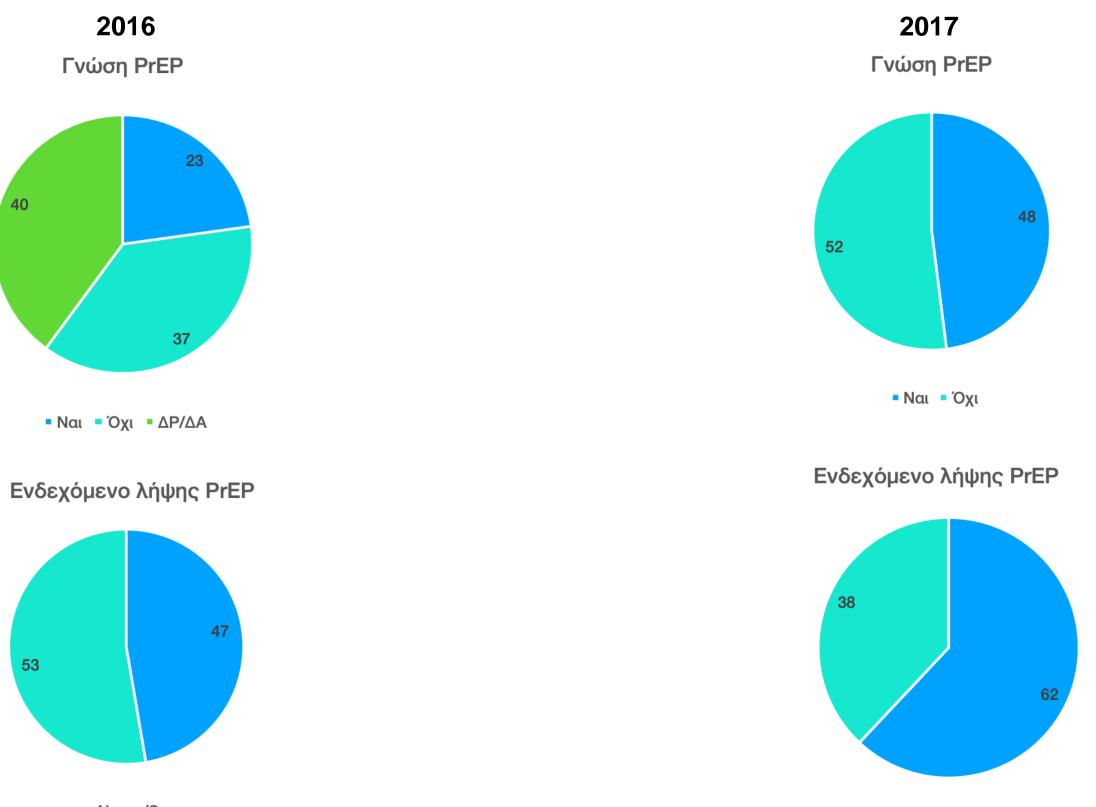
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## Knowledge is increasing...







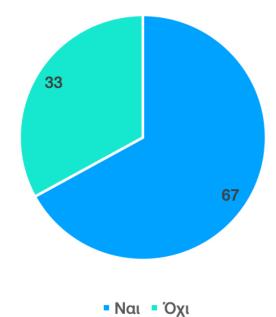
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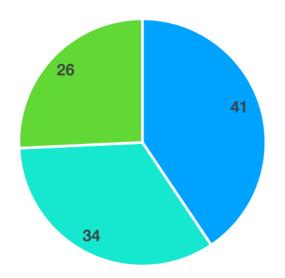


2018

Γνώση PrEP



#### Ενδεχόμενο λήψης PrEP





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'Give the power to the people, put the pill in their palms'

Prof. Sheena McCormack



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(IAS, Paris 2017)





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