A Global Perspective of PrEP Use and Delivery: 2018

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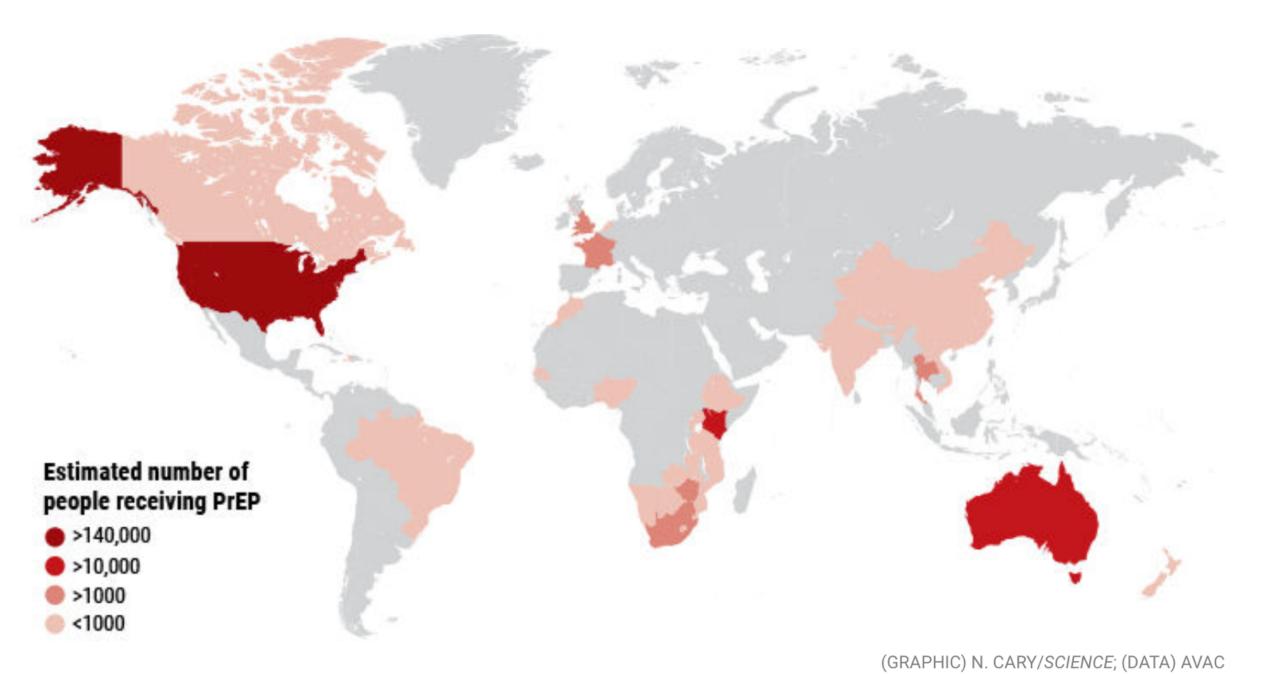
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Competing Interest Disclosure

- I act as a consultant to Merck and GlaxoSmithKline
- I speak at company sponsored events on behalf of Gilead Sciences and Merck
- I have received research grants for my institution from Gilead Sciences, GlaxoSmithKline and Merck.

There are approximately 200,000 high risk individuals taking TDF/FTC as PrEP worldwide



Estimated number of adults with PrEP indications in the United States: 2015

	MSM	HET	PWID	Total*
50 States, DC	814,000	258,000	73,000	1,145,000
Vital Signs estimate	492,000	624,000	115,000	1,232,000
Lower Limit of VS estimate	212,000	404,000	45,000	661,000
Upper Limit of VS estimate	772,000	846,000	185,000	1,803,000

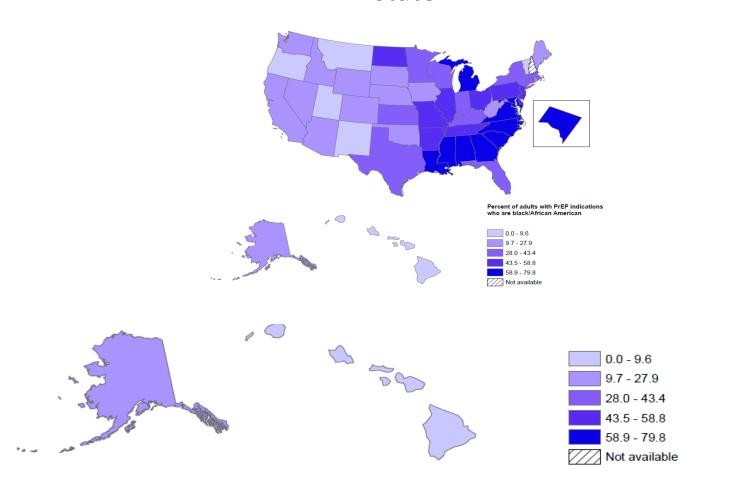
^{*}Estimates are rounded and may not sum to the total

Estimated number of adults wit PrEP indications by race/ethnicity/risk group in the U.S. in 2015

	То	Total Black/Africa		an American Hispanio		c/Latino	White, non-Hispanic	
Transmission risk group	Estimated no.	% of Total	Estimated no.	% of risk group total	Estimated no.	% of risk group total	Estimated no.	% of risk group total
MSM	813,970	71.1	309,190	38.0	220,760	27.1	238,670	29.3
HET	258,080	22.5	164,660	63.8	46,580	18.0	36,540	14.2
Men	81,410	7.1	NA	NA	NA	NA	NA	NA
Women	176,670	15.4	NA	NA	NA	NA	NA	NA
PWID	72,510	6.3	26,490	36.5	14,920	20.6	28,020	38.6
Total	1,144,550	100.0	500,340	43.7	282,260	24.7	303,230	26.5

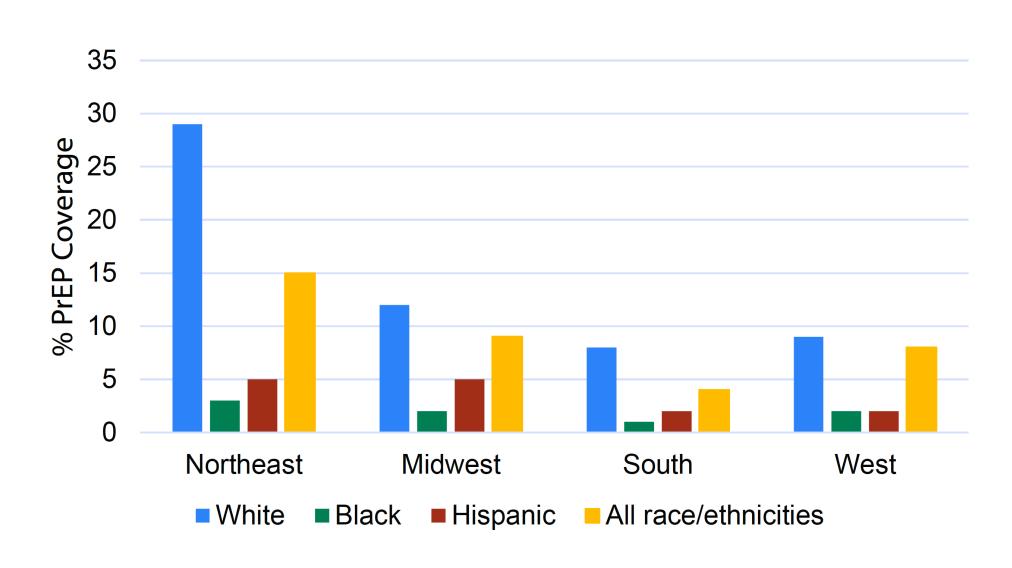
Estimated percentage of adults with PrEP indications who are Black/African American by state

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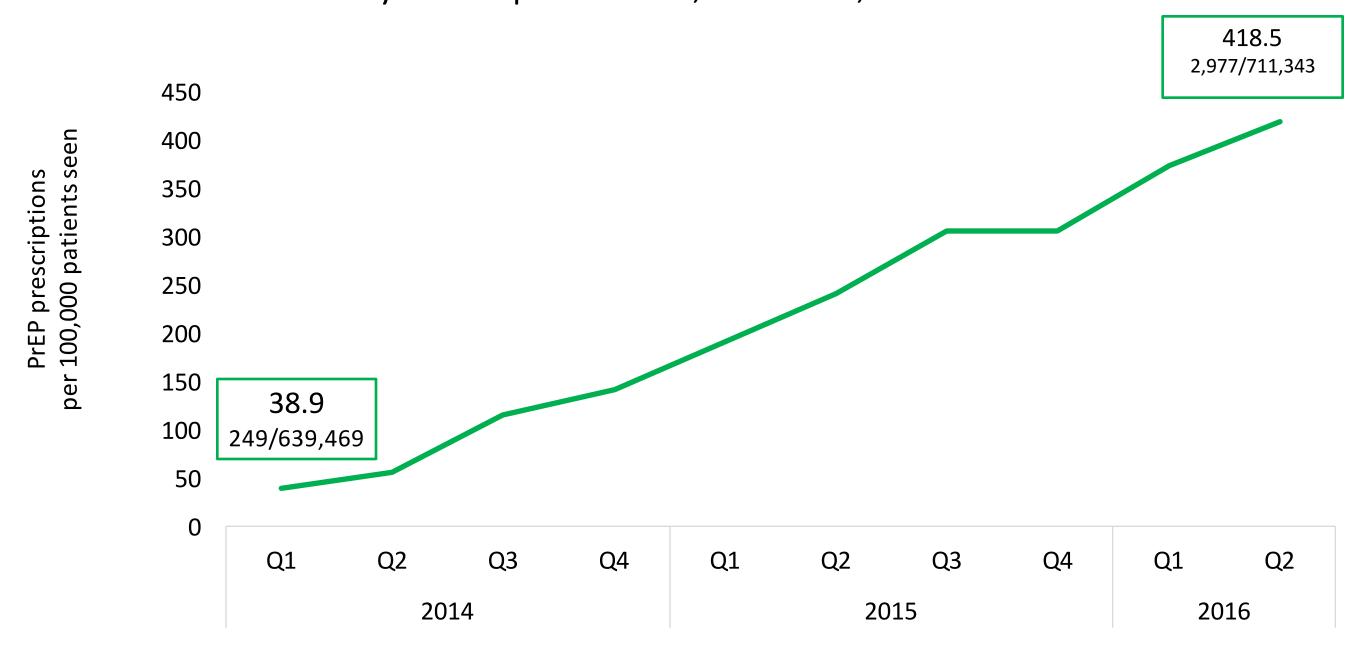


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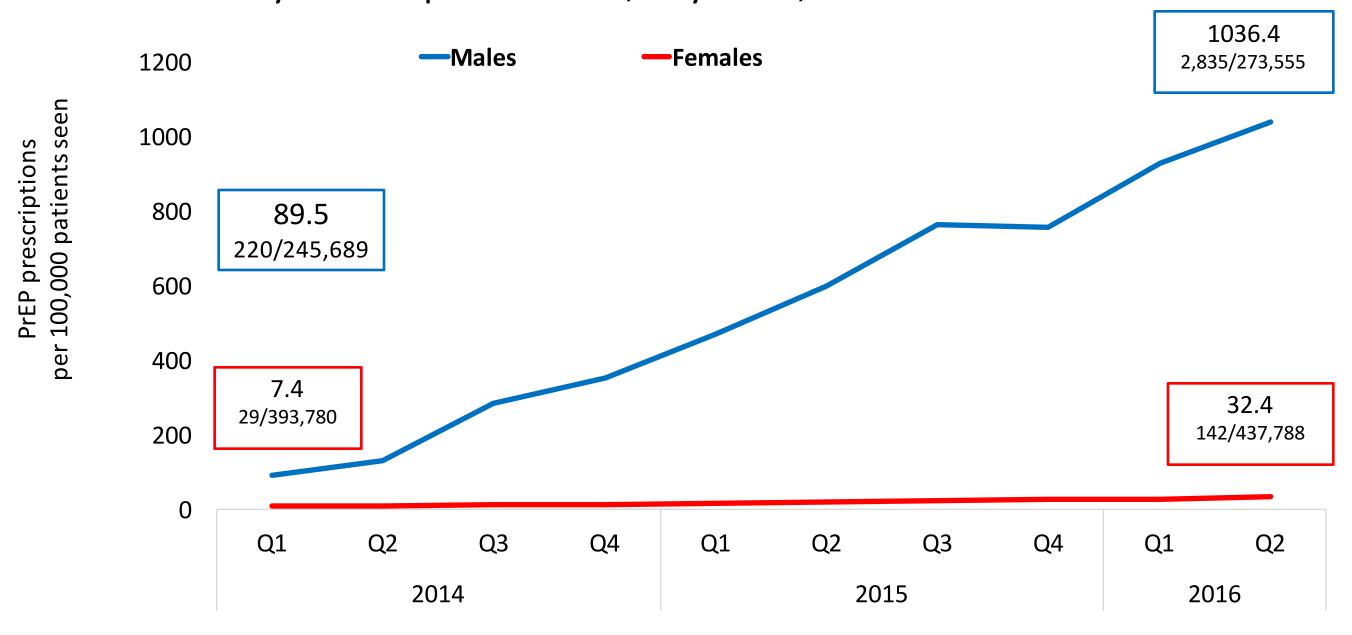
Minimal estimate of PrEP coverage in 2015-2016 by region and race/ethnicity



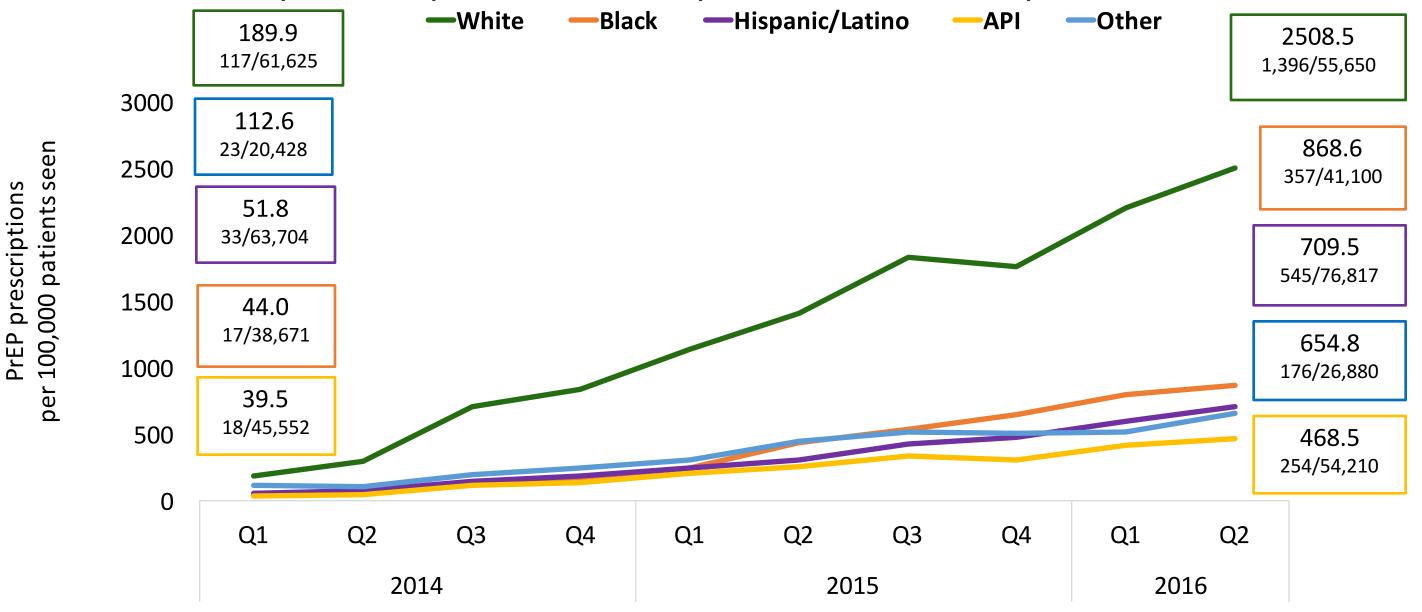
PrEP prescription rates per 100,00 patients seen in 602 ambulatory care practices, overall, NYC 2014-2016



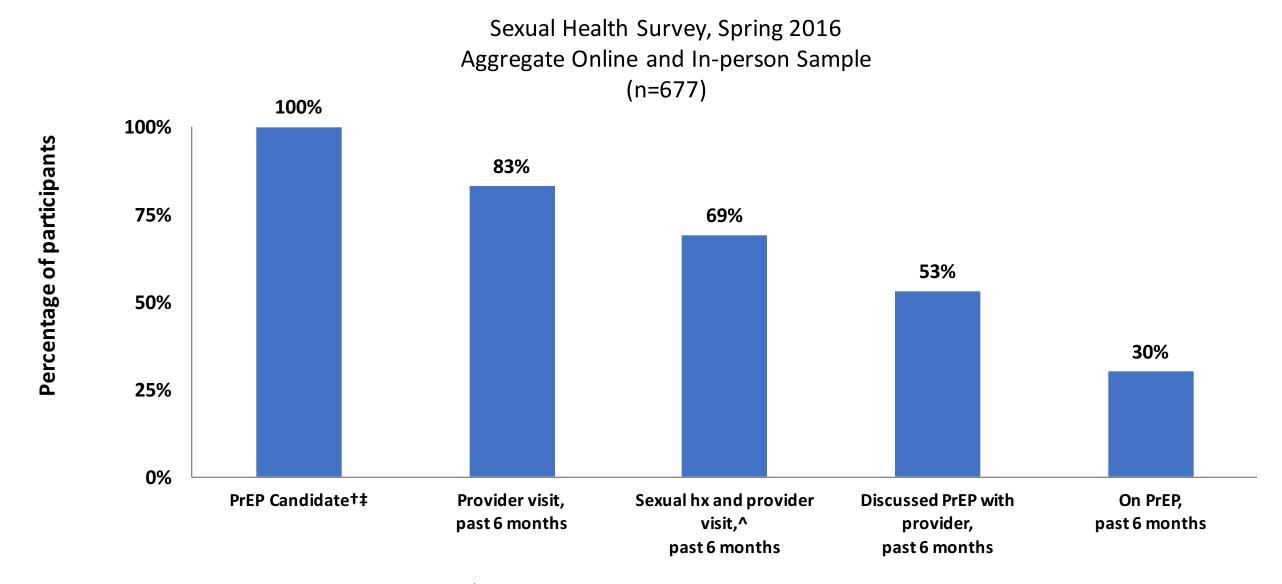
PrEP prescription rates per 100,000 patients seen in 602 ambulatory care practices, by sex, NYC 2014-2016



PrEP prescription rates per 100,000 males seen in 602 ambulatory care practices, by race/ethnicity, NYC 2014-2016



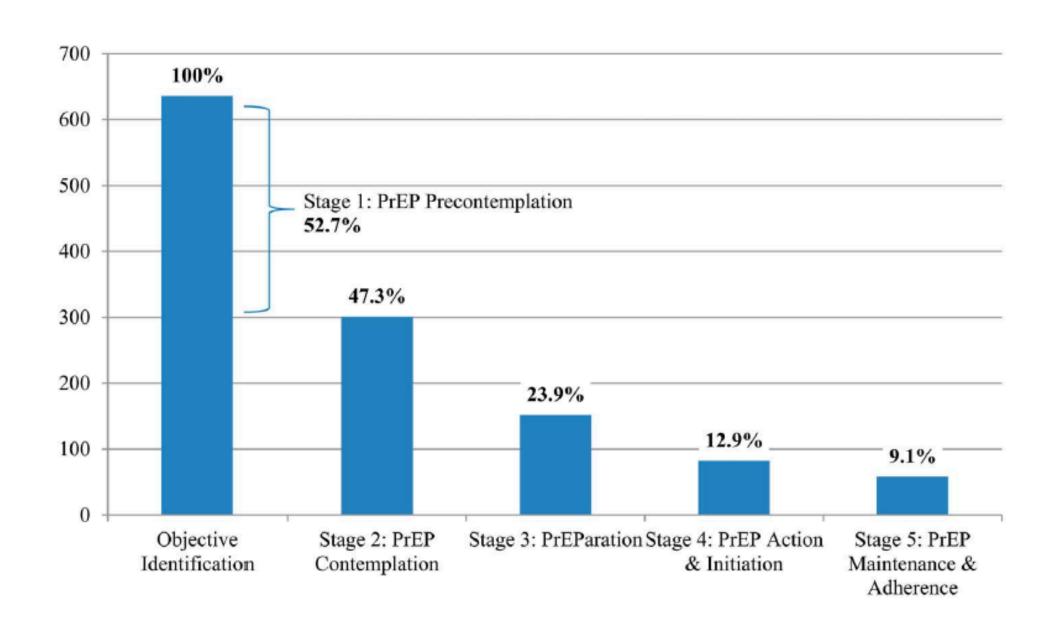
HIV Prevention Continuum in NYC



^{*}Sample includes sexually active MSM aged 18-40 years and who report HIV-negative/unknown status

†PrEP candidates defined as reporting diagnosis of an anal STI in the past year or any of the following in the previous 6 months: unprotected anal intercourse, transactional sex, use of cocaine, crack, methamphetamines, or injection drugs, using PEP or having had an HIV-positive partner. Definition mirrors NYS PrEP guidance. ‡PrEP candidates represent 83 % of all HIV-negative respondents. ^Sexual history ever taken by a provider visited in past 6 months

PrEP uptake in a national cohort of gay and bisexual men in the U.S.

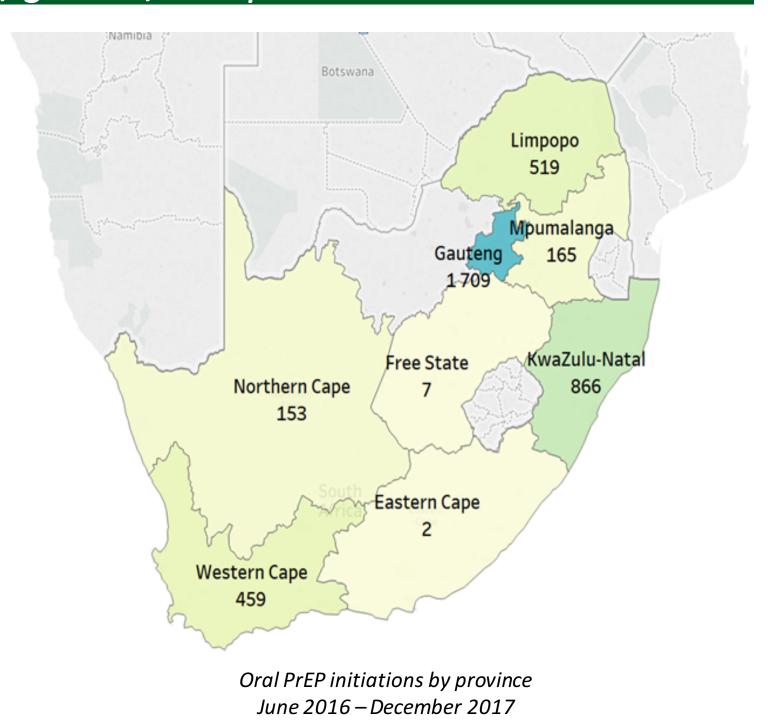


Oral PrEP initiations Disaggregated by age, gender, and province

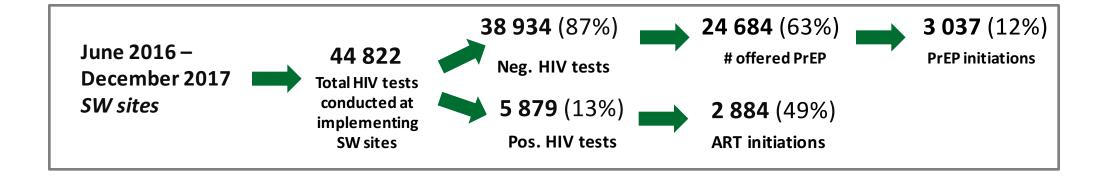
Of the **3 880 oral PrEP initiations** to date:

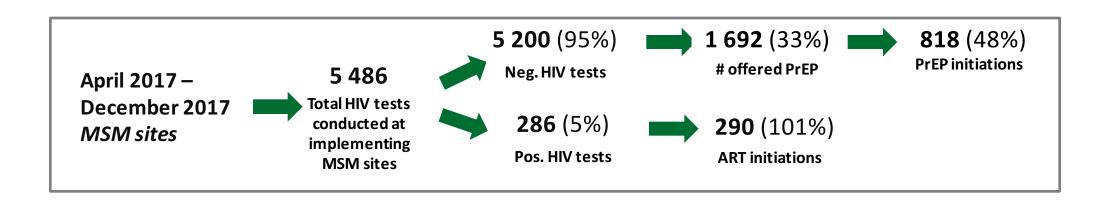
- **0.4%** were between the ages of **0-15 years**
- 3% were between the ages of
 16-18 years
- 29% were between the ages of 19-24 years
- 43% were between the ages of 25-34 years
- 24% were 35 years or over

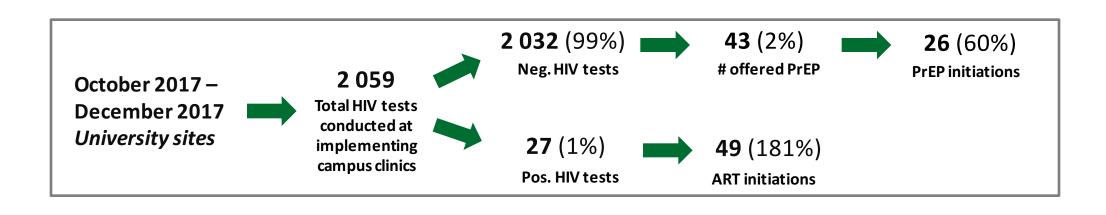
Two-thirds (2 577) of PrEP users identified as female when they initiated, and around exactly a third identified as male (1 296), and a very small number (8) reported themselves as transgender.



Oral PrEP Implementation Oral PrEP and ART commencements by site type







Oral PrEP expansion: She Conquers priority subdistricts secondary school and TVET clusters

Providing PrEP to at-risk adolescent girls and young women will be a key component of the next phase of PrEP implementation.

Beginning implementation in the She Conquers priority sub-districts ensures that combination prevention, including PrEP, will be available to young people at highest risk. The cluster system, described below, will reach a large numbers of AGYW.

In each sub-district, a focal facility will be selected based on the following criteria:

Education institutions

Clinics closest to clusters of Q1-Q3 secondary schools, TVETs, and universities were prioritised.

Catchment

The selected facility should ideally be located as close as possible to the largest number of educational institutions, ensuring that learner/student catchment is high.

Distance

The distance between educational institutions and the focal health facility is critical to both uptake of services and retention in care.

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Health
facility
capacitation
and
sensitisation

Demand
generation in
selected schools
through She
Conquers,
HEAIDS, and
partner
activities

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Provision of

PHC, family

planning, and

combination

prevention

services –

including PrEP

Appointing or electing peer "youth champions" to continuously promote and normalise clinic services

Facility audit and selection

School cluster selection



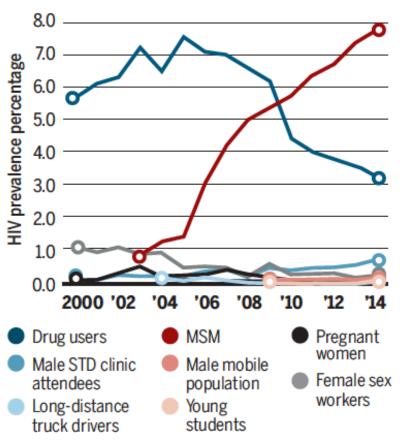
PUBLIC HEALTH

HIV infections are spiking among young gay Chinese

Officials strive to understand infection routes and promote prevention and testing

Risky rise

Surveys of different populations at risk of HIV/AIDS in China have charted a steep rise in the percentage of men who have sex with men (MSM) living with HIV.



HIV incidence among MSM in China

(at least 400 patient years)

First author	Study Period	Location	Person- Years	Incidence (per 100 py)	Reference
Jia ZW	2007-12	Beijing	6,209	7.1	Sci Rep 2015
Liu GW	2009-2012	Beijing	1046	5.9	PLOS One, 2015
Gao, YJ	2009-11	Beijing	857	7.6	Thesis, Hebei Med U. 2012
Li, DL	2009-2010	Beijing	593	8.1	BMJ Open, 2012
Zhao, T	2010-12	Nanyang	587	3.4	China J AIDS and STI 2013
Fu, ZH	2010-12	Suzhou	487	4.9	CJPH, 2014
Yan, HJ	2008-10	Nanjing	463	3.5	CJAIDS 2012
Li, SM	2008-2009	Beijing	445	3.4	CJPM, 2011
Wang, Y	2009-2013	Mianyang	437	4.1	Sex Health, 2015
Li, DL	2006-2008	Beijing	425	2.6	AIDS Pt Care STDs 2010

Response to epidemic among MSM in China

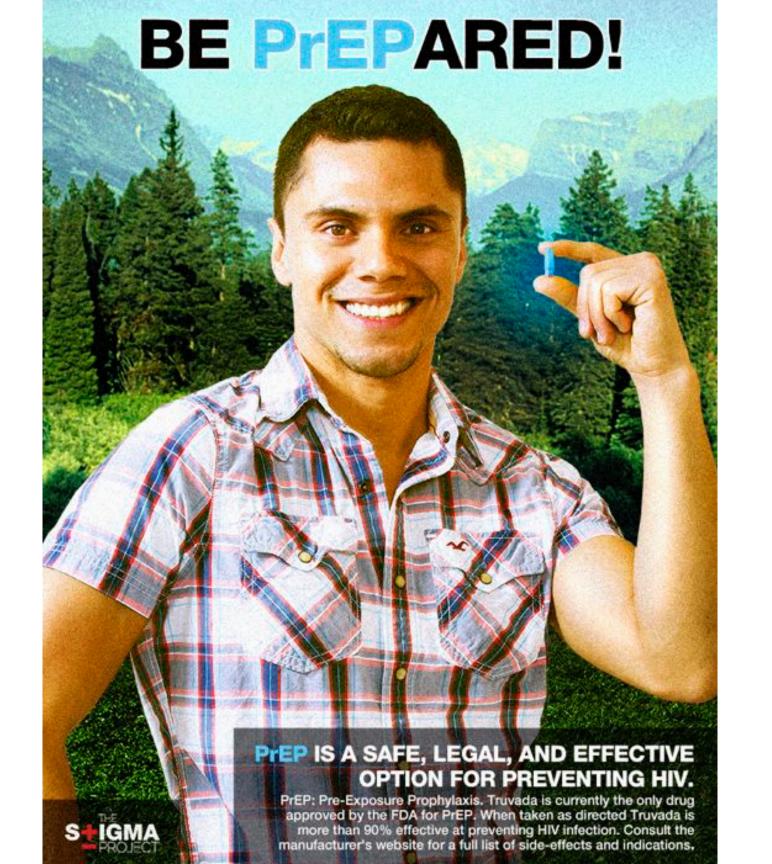
- Increased HIV testing and condom use
- ART for HIV-infected individuals
 - Earlier treatment: median CD4 at treatment initiation increased from 100 in 2006 to 300 in 2015
 - No STR provided by the government sponsored programs
 - Must have a positive Western Blot to enroll in the government program
 - TDF-3TC-EFV is the only regimen provided for first line therapy
 - Limited numbers of centers that provide ART
- Access to PEP or PrEP
 - Access is a challenge via select hospitals
 - Limited knowledge of PEP and PrEP due to recent crackdowns on foreign NGOs aiming to provide education, testing, prevention, and treatment-
 - Recent online survey of 6,500 Chinese MSM-60% never heard of PrEP
 - PEP is very costly- \$750 U.S. for the drugs and clinical care
 - PrEP cost is approximately \$350/month and not approved as PrEP
 - No primary care physicians to provide continual care for HIV-uninfected individuals
 - ARVs need to be prescribed by HIV physicians only
- Currently no support for use of TDF/FTC as PrEP by China Ministry of Health
- Plans to test TDF/FTC daily vs. on demand TDF/FTC as per IPERGAY vs choice of no PrEP
- MSM and TGW are a highly stigmatized and marginalized population

Early Lessons

- Once past the first wave of early users, novel strategies need to be developed to address "harder to reach" populations
- Increased self-awareness of risk and acceptance of a biomedical approach to prevention is needed
 - "Health maintenance" and "Sex positive" messaging as opposed to "medicalization" and "fear based"
- Health care systems must adapt to meet the challenges of providing PrEP to large numbers of high risk individuals
- Health care providers must be educated and integrate sexual health and well being into their assessments of patients
- Cost issues must be addressed
 - Drug
 - STI monitoring
 - Effective HIV testing algorithms
- Need to decriminalize and destigmatize high risk groups
- Need to destigmatize PrEP use

The Future of PrEP Globally

- Testing of novel PrEP agents
 - Streamlined and novel study designs to reduce size, cost, and duration
- PrEP agents
 - Oral FDC TDF/FTC versus TAF/FTC
 - Daily versus intermittent
 - Injectable
 - Cabotegravir 600 mg every 8 weeks
 - Establish efficacy
 - Understand the significance of the tail as it affects drug resistance
 - Implantable
 - TAF
 - EFdA
 - Infusible/injectable
 - Monoclonal antibodies



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