



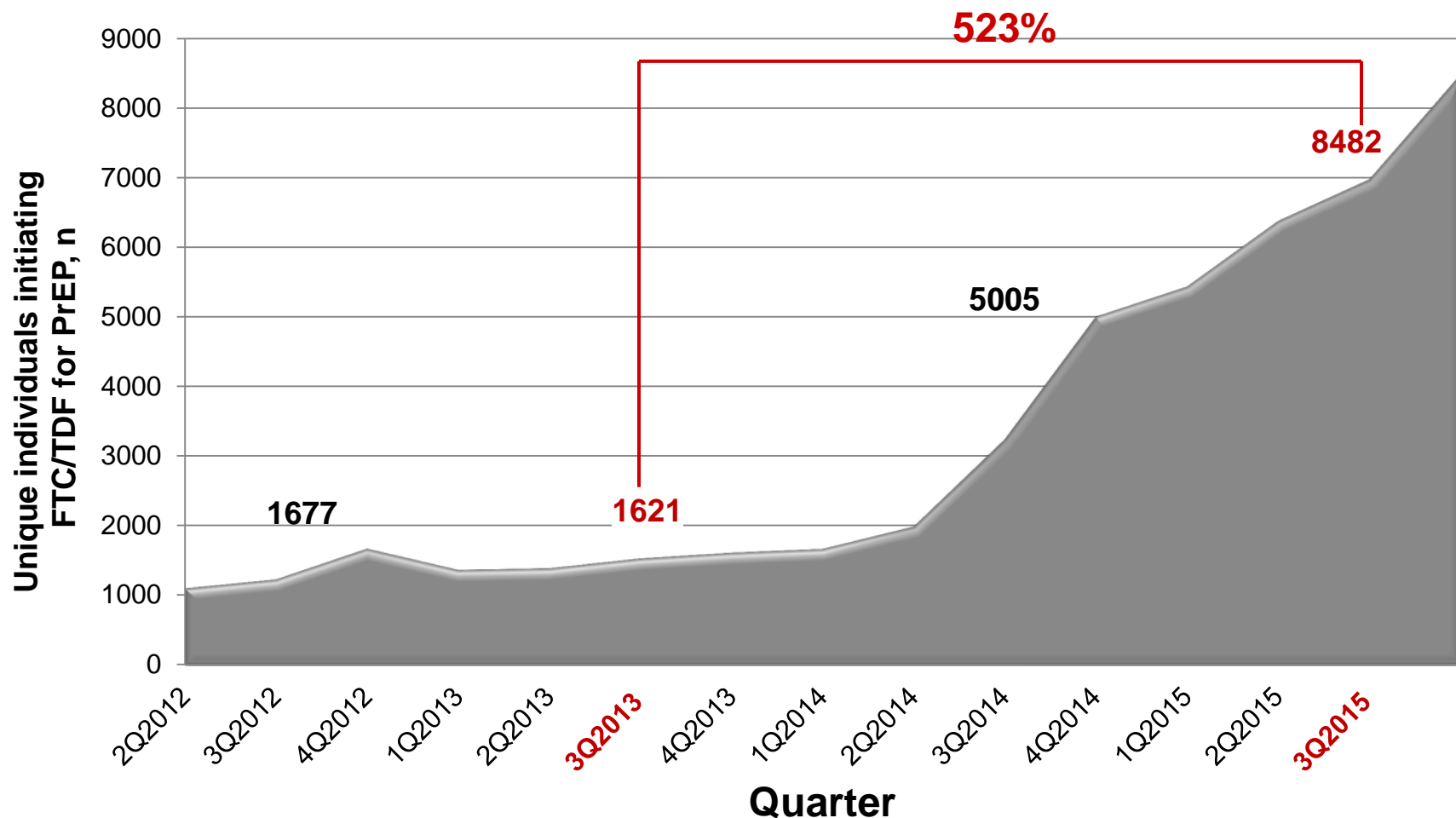
PREP RESEARCH: A WORK IN PROGRESS

Kenneth Mayer, MD

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PrEP Research and Regulatory Issues Planning Meeting
June 23rd, 2016

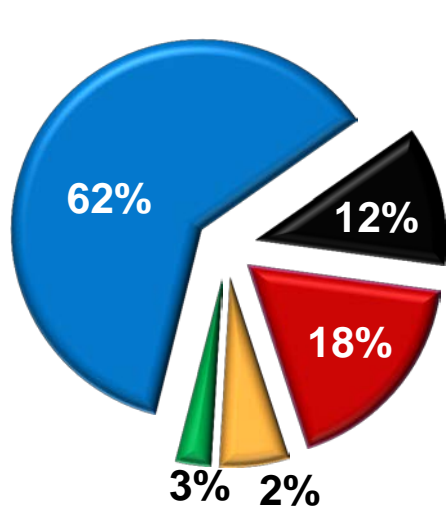
Total Incidence and Growth Trend of FTC/TDF for PrEP



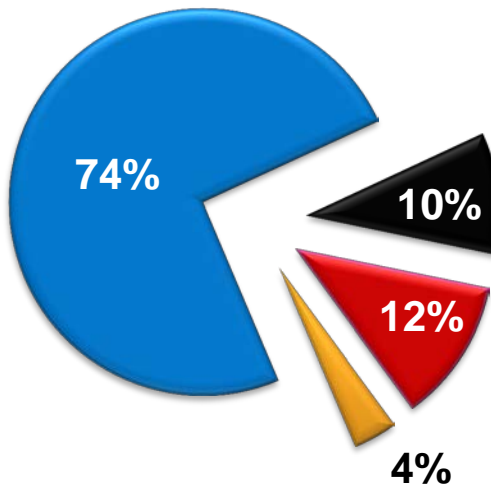
**49,148 Unique individuals initiated FTC/TDF for PrEP
in the US 2Q2012 – 3Q2015**

FTC/TDF for PrEP Utilization Compared With Population and New HIV Infections

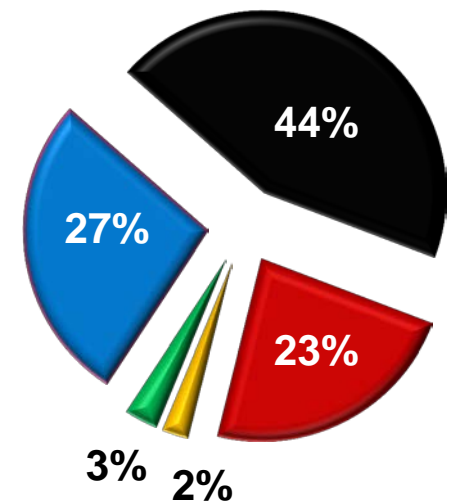
Estimated Population Distribution by Race/Ethnicity, 2014, US^a



Total FTC/TDF for PrEP Utilization by Race/Ethnicity, Sept 2015, US^b



Estimated New HIV Infections, 2014, US^c

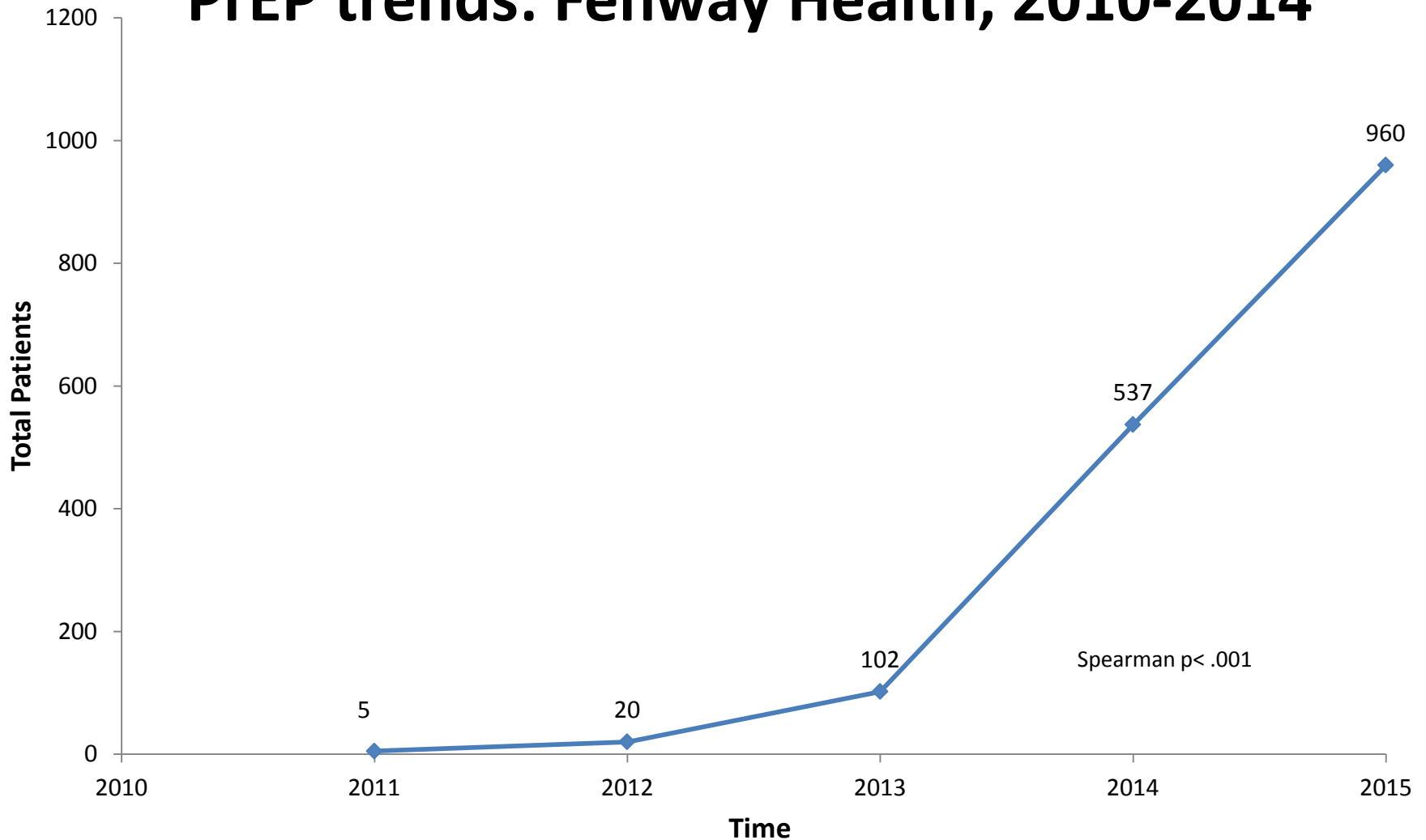


■ AA ■ White ■ Hispanics ■ Asians ■ Multiracial/Other

FTC/TDF for PrEP use among AA and Hispanics is low relative to the rate of new HIV infections

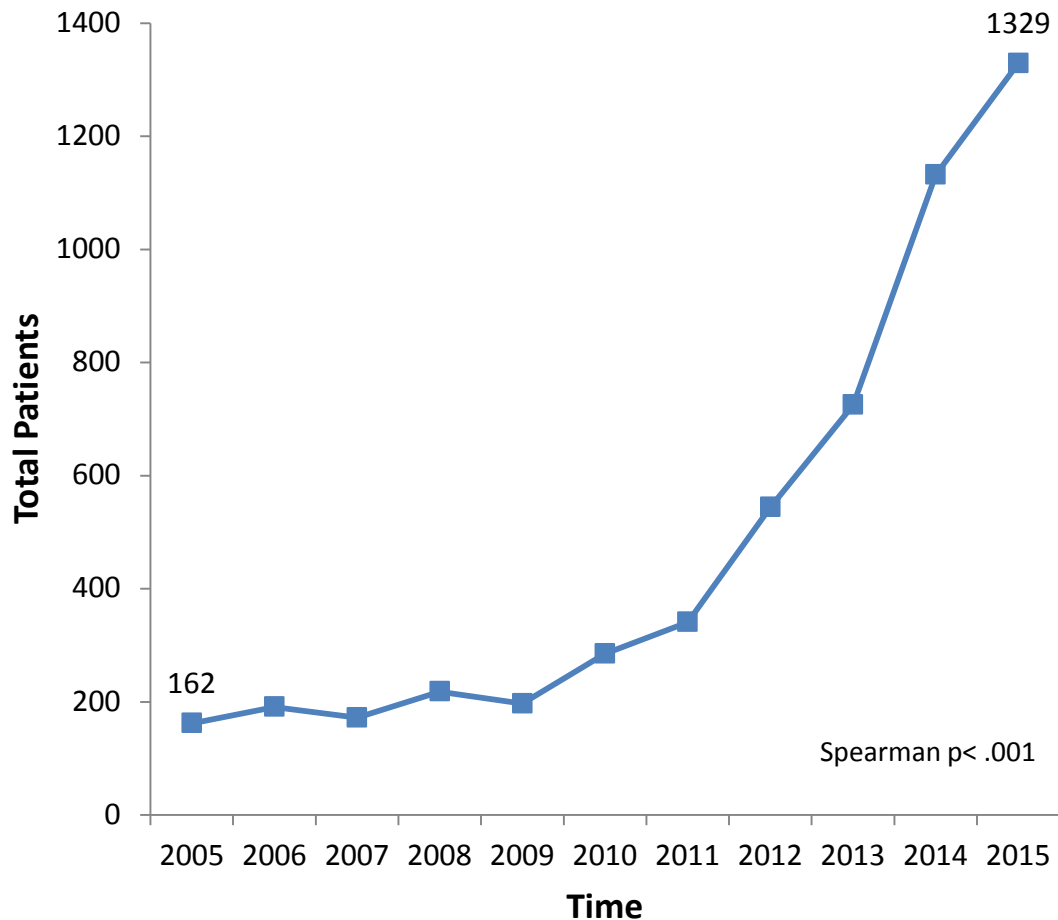
b. These data represent 43.7% (n=21,463) of unique individuals who have started TVD for PrEP from 2012-3Q2015.

PrEP trends: Fenway Health, 2010-2014



- PrEP was first used by 5 pts outside of a clinical trial in 2011
- More than 83% of PrEP initiators still using PrEP.

Incident STDs



-Since 2005, 1/2 of new syphilis diagnoses were in HIV+ patients, while 80% of incident GC/CT infections were in HIV- MSM.

-More than one third (36%) of MSM who initiated PrEP in 2014 had a recent bacterial STD.

PrEP Use and HIV Seroconversion (2011-2015)

	PrEP	No PrEP
Seroconversion	5	93
No HIV diagnosis	659	4154
Total	664	4247*
Risk**	<1%	>2.2%

*Patients who indicated they were MSM when registered for care, i.e. overestimate of those at risk

** $p < 0.001$

PrEP Demonstration Projects: Planned, ongoing and completed project locations

36

OLE, demo, feasibility,
implementation studies planned,
ongoing, completed globally

1

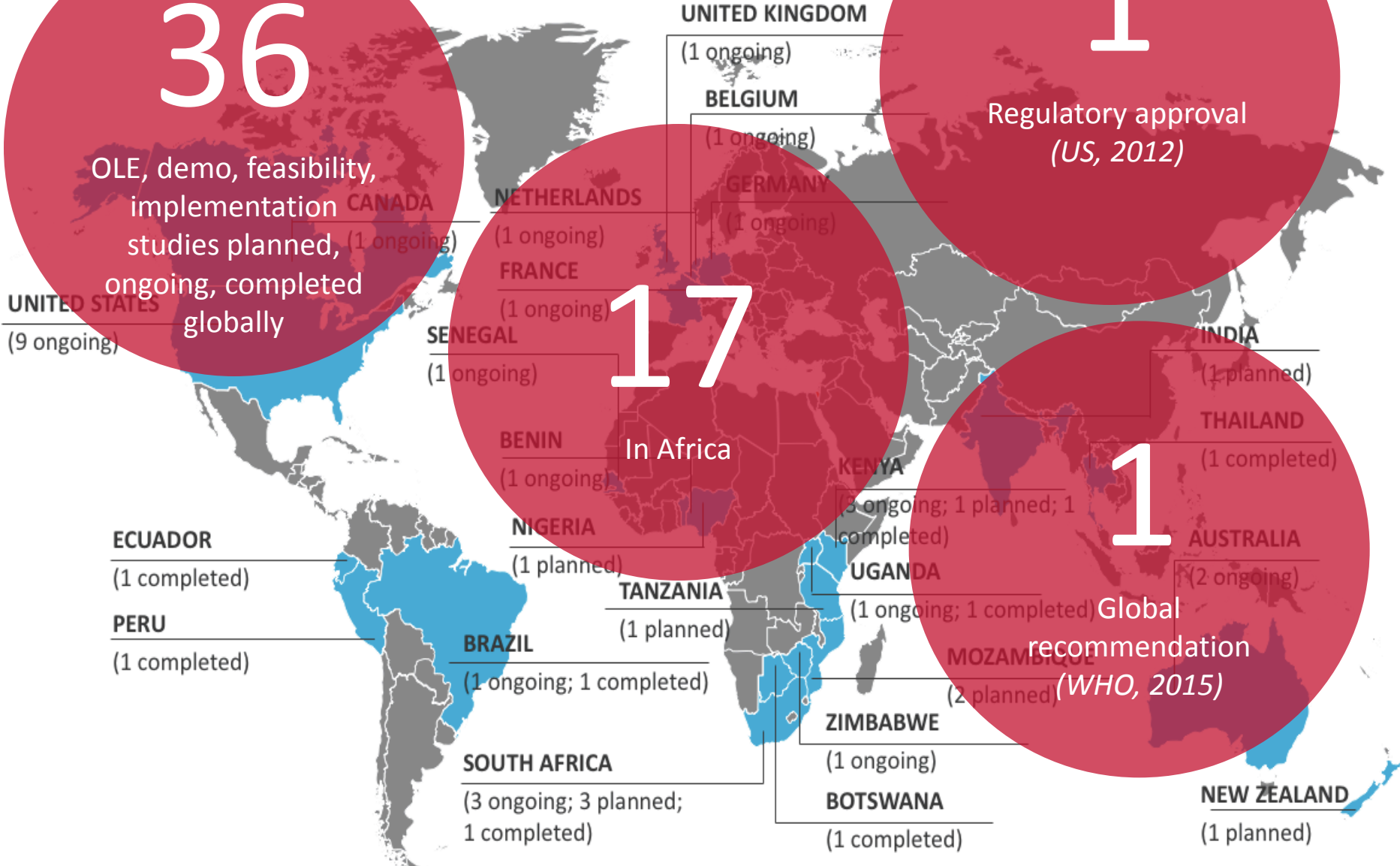
Regulatory approval
(US, 2012)

17

In Africa

1

Global recommendation
(WHO, 2015)



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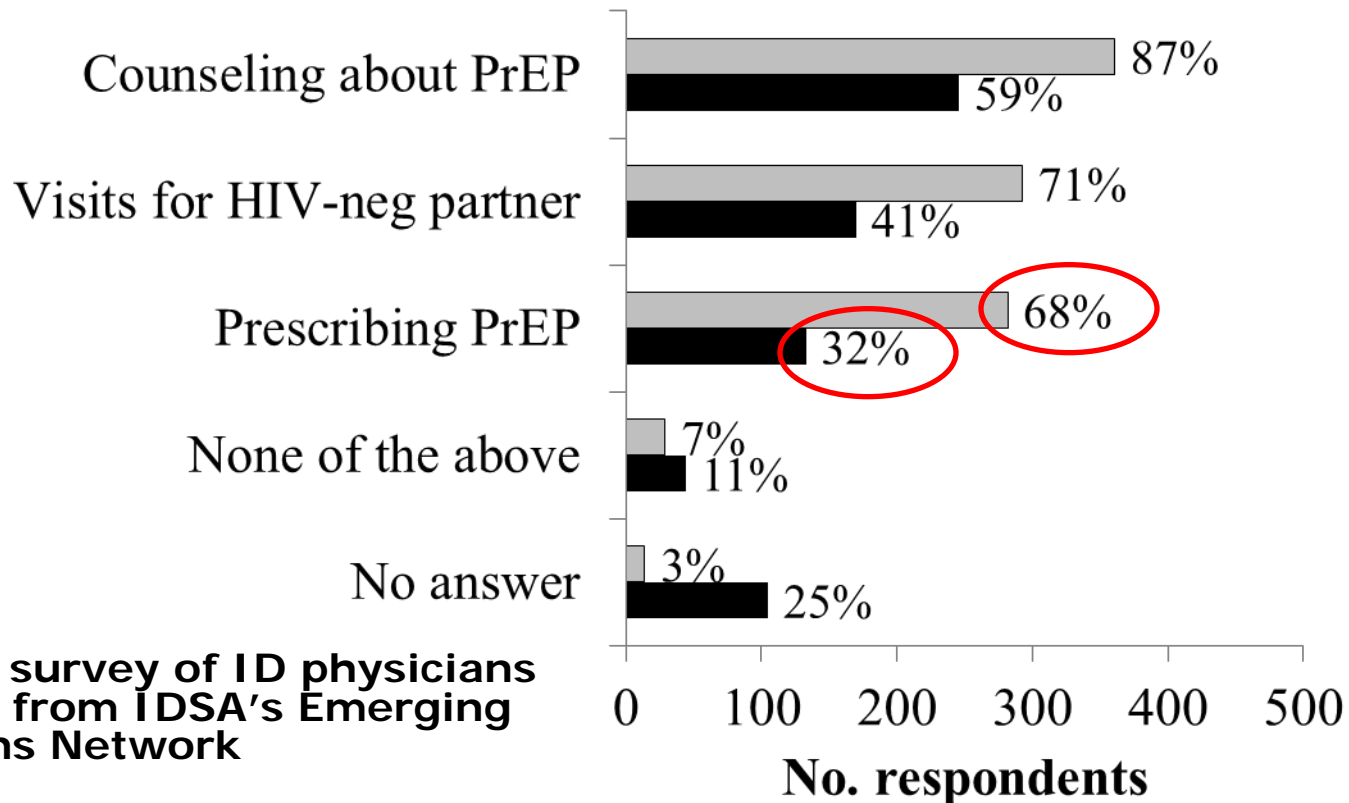


What is PrEP?

Chat Securely with NURX

A majority of US HIV specialists would prescribe PrEP; only 1 in 3 has done so

- Consider part of clinical role
- Have done in practice

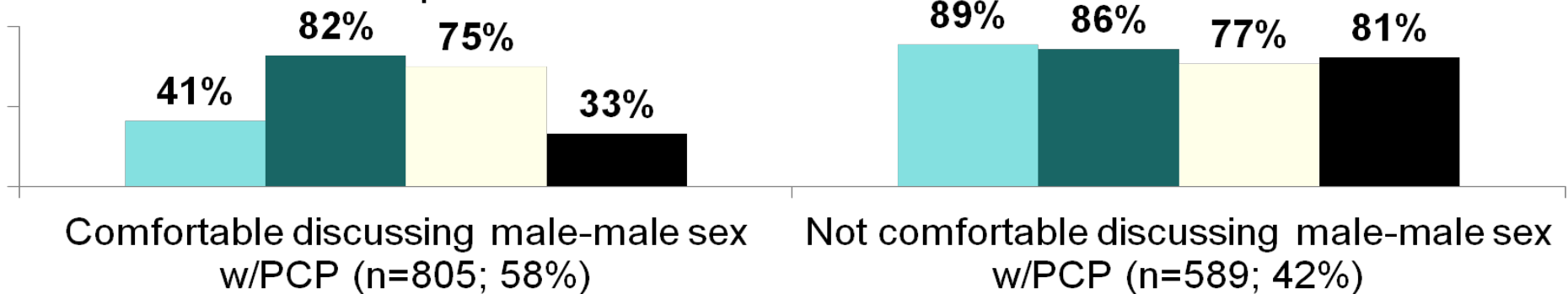


National survey of ID physicians (n=415) from IDSA's Emerging Infections Network

Need to improve communication about sexual risk behaviors and PrEP in primary care

- ❑ Survey of 1,394 MSM using partner-seeking website
- ❑ 42% were uncomfortable discussing male-male sex with their PCP
- ❑ Even when comfortable, few MSM had discussed PrEP with their PCP
- ❑ Most MSM perceived that PCPs would be unwilling to prescribe PrEP

- Have not discussed CAS w/PCP
- Have not discussed PrEP w/PCP
- Perceive that PCP would not be willing to prescribe PrEP
- Would prefer to obtain PrEP from source other than PCP**



**Versus other healthcare provider, the Internet, or other source

PrEP Research: A Work in Progress

- Health disparities: how to enroll those who are most likely to benefit into PrEP clinical trials?
- How should trials address other risks, e.g. STDs?
- Should PrEP-experienced people be enrolled in new PrEP trials?
- Should underground PrEP use be anticipated (e.g. drug monitoring in placebo-controlled studies)?
- Does provider work force need additional training to enhance the conduct of pragmatic community-based trials?