



NORTHWEST AIDS EDUCATION AND TRAINING CENTER

PrEP 201: Beyond the Basics

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February 19, 2015

Disclosures and Disclaimers



I have no financial conflicts of interest.

Only Truvada is approved by the FDA for use as daily PrEP. Other antiretroviral medications (e.g. tenofovir, maraviroc) have been studied in off-label use.

Objectives

Move beyond the basics of PrEP to learn about

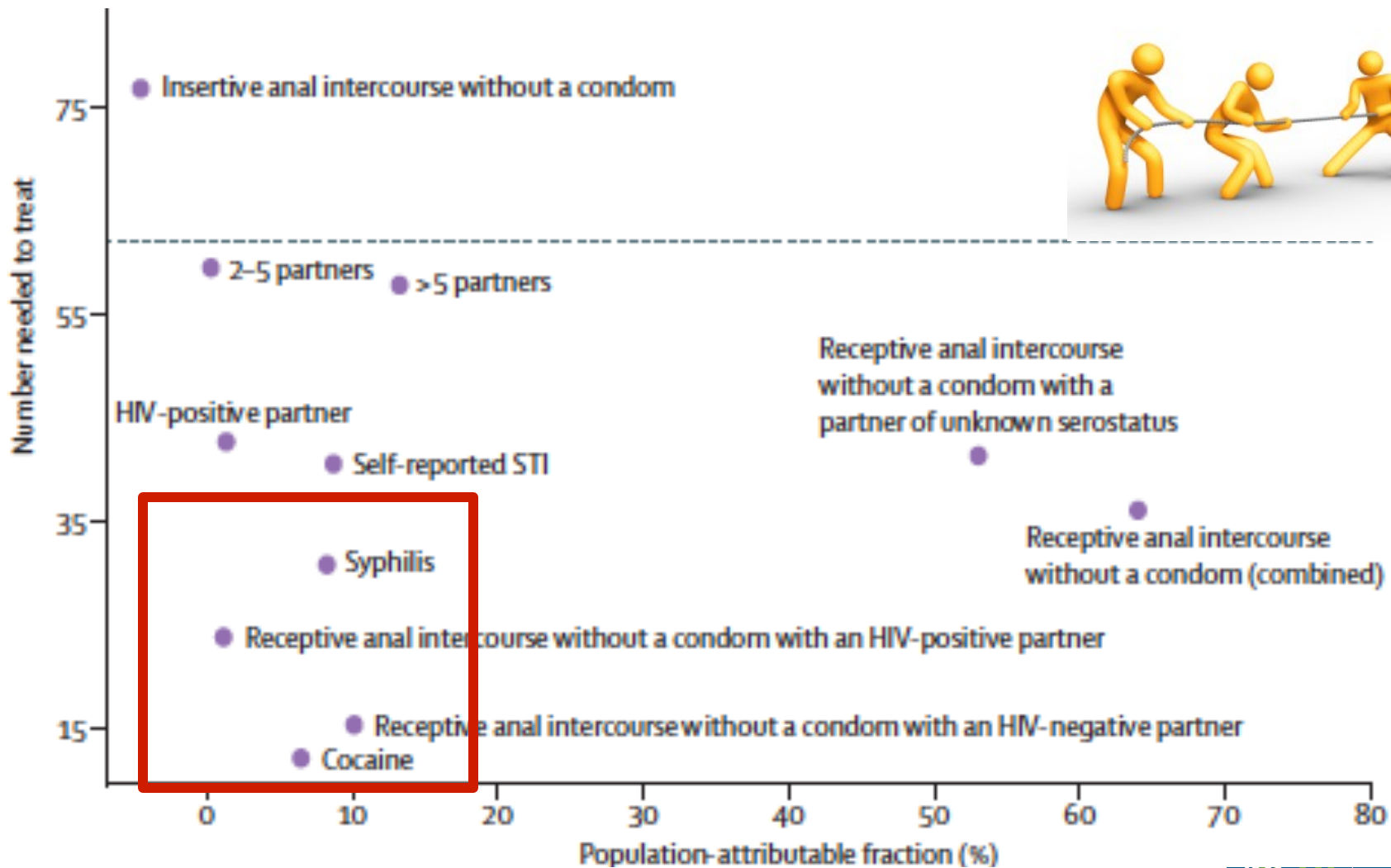
- a Seattle PrEP demonstration project experience with
 - Interest in, eligibility for, and refusal of PrEP
 - Adherence
 - Side effects and monitoring
 - The concern for behavioral disinhibition
 - Prescribing and insurance companies (and PrEP DAP)
- Resources for prescribing providers

PrEP implementation in Seattle

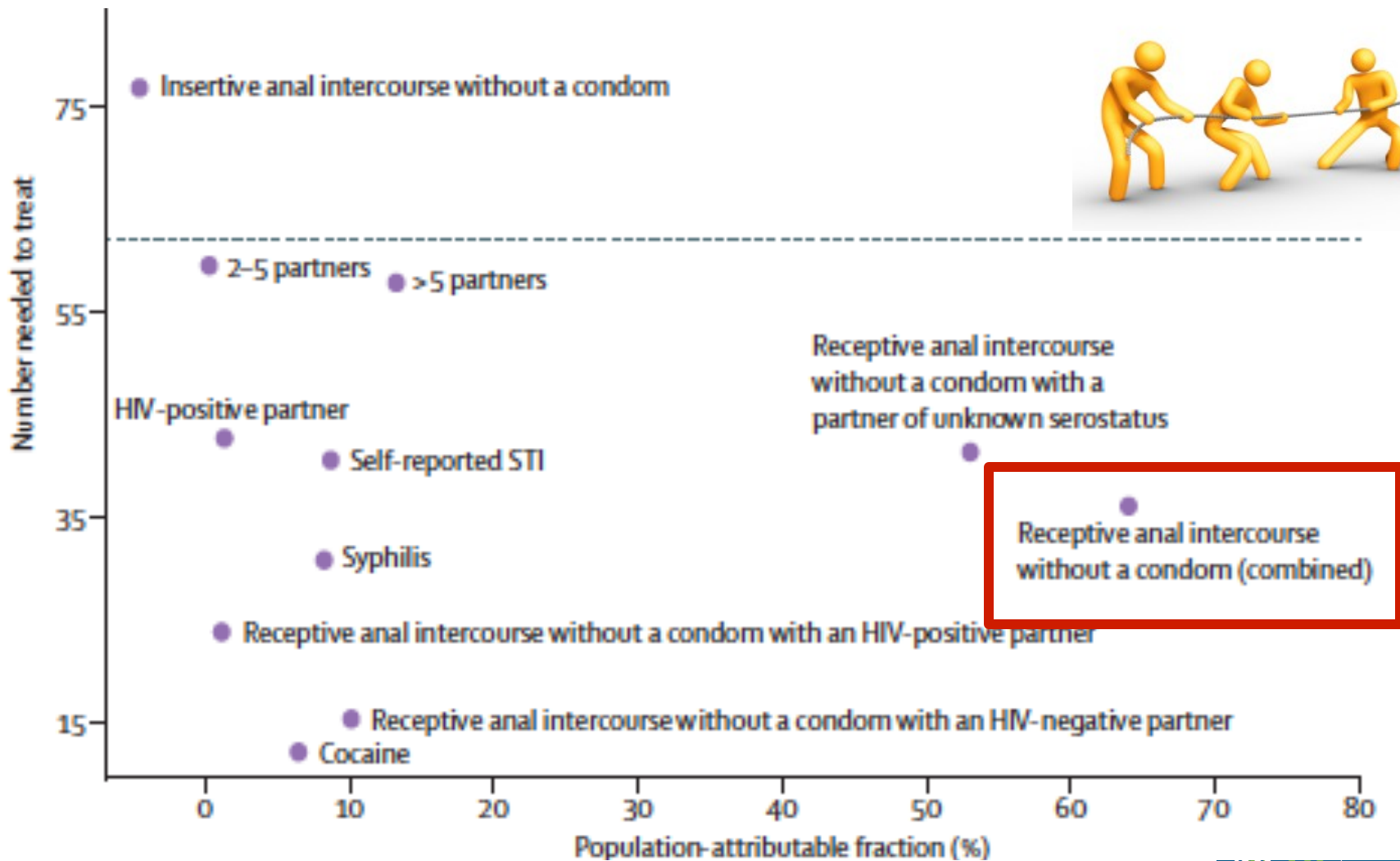
Important questions

- Can we get PrEP to the folks at greatest risk?
- Will they be willing to take PrEP?
- Will they be adherent?
- How do we monitor PrEP?
 - HIV testing
 - Recognition of acute HIV infection
 - Drug resistance
- Will PrEP change sexual behavior?
- How do we pay for it? Will insurance cover it?

Who Should Get PrEP? (Results from iPrEx)



Who Should Get PrEP? (Results from iPrEx)



Preparing for PrEP in Seattle Study Schema

- **Purpose:**
 - Assess uptake/demand for PrEP among high risk persons in Seattle
 - Describe uptake & patterns of use by insurance status
 - Explore use of Wisepill as a novel technology for adherence support
- **Design:** open-label cohort study, started in October 2013
- **Population:**
 - High risk MSM
 - Men and women reporting unprotected sex in discordant couples
- **Study size:** >50 subjects, followed for at least 6 months
- **Partners:** Funded by UW Royalty Research Fund



Preparing for PrEP in Seattle

Inclusion criteria

- high risk HIV-negative
- 18 years old

Exclusion criteria

- symptoms of acute HIV infection
- abnormal kidney function
- active hepatitis B infection
- pregnant
- use of PEP or PrEP in the last 30 days

Preparing for PrEP in Seattle

Visits (consistent with national guidelines)

- Five visits: Screening, Entry, week 4, week 12, week 24, 1-2 hours each
 - talk about the study, adherence and about behavior
 - take a survey on a computer
 - blood draw
 - STD testing at entry, week 12, and week 24
- \$20 per visit for all visits except Screening
- Truvada, prescribed for daily use
- Adherence monitoring and support by
 - Weekly SMS reminders
 - Wisepill

Preparing for PrEP in Seattle

71 persons screened, 50 enrolled

Baseline Characteristics of Total Cohort N=47

Males	96%
Median Age (years)	37 (range 20-65)
Race/ethnicity - Non-Hispanic white	85%
Median annual income	\$24,000 - \$34,999
Annual income <\$15,000	26%
Median # sex partners in past 3mos	6.5 (range 1-125)
Has HIV+ regular sex partner	40%
Any bacterial STD	38%
Syphilis	6%
Gonorrhea	23%
Chlamydia	17%
Methamphetamine use	2%
Popper use	49%

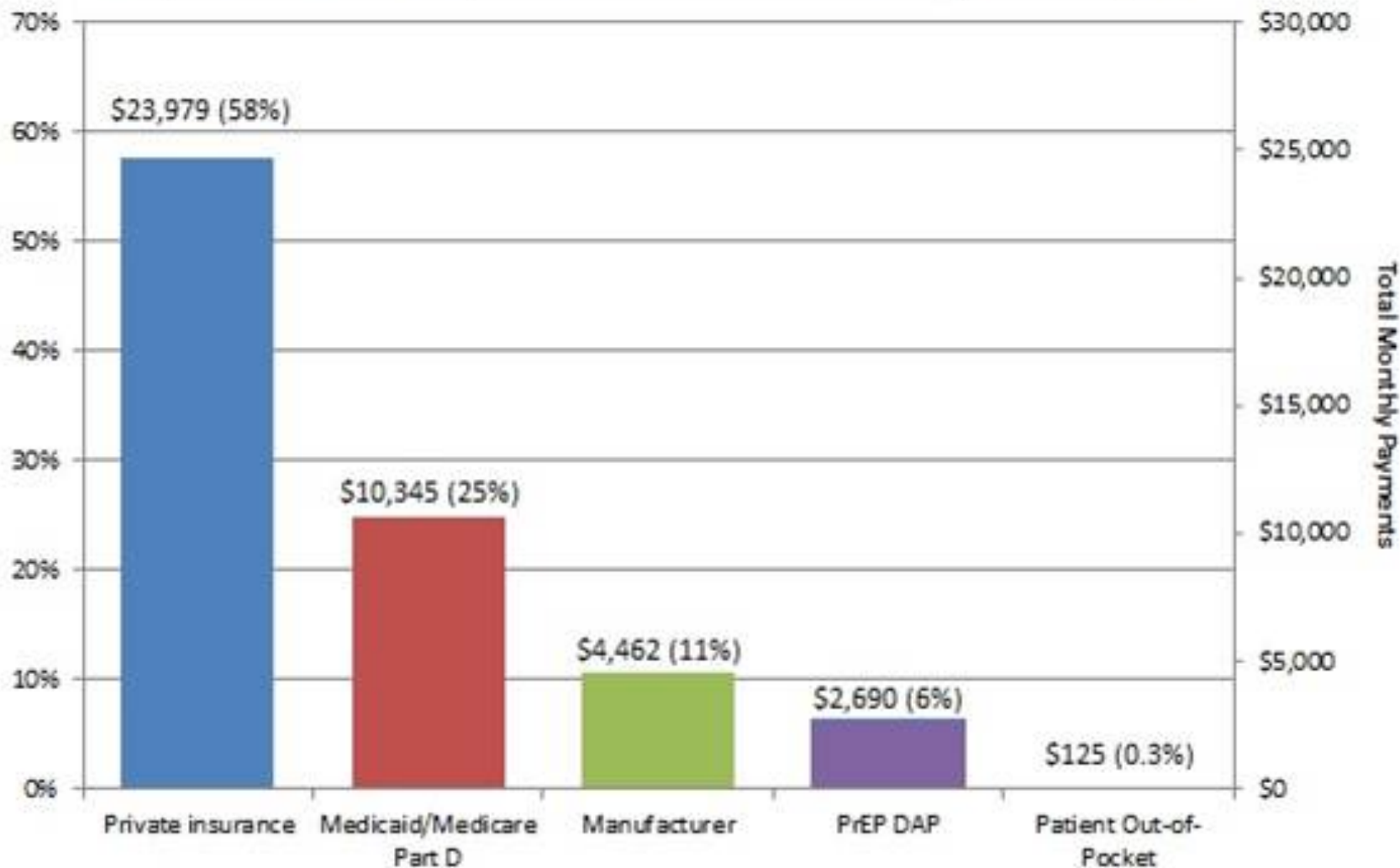
Preparing for PrEP in Seattle

Adherence

	Self-report	Wisepill
100%	68%	17%
90-99%	29%	67%
80-89%	3%	11%
70-79%	0%	3%
60-69%	0%	0%
50-59%	0%	3%

Payers for PrEP in Seattle

Payers for PrEP in an Open-Label Demonstration Study in Seattle, WA



- Family Planning ▼
- Food Safety ▼
- Healthy Aging ▼
- Healthy Home ▼
- Illness and Disease ▲
- Animal Transmitted Diseases
- Antibiotic Resistance ▼
- Asthma ▼
- Autism ▼
- Avian Influenza
- Birth Defects ▼
- Brucellosis
- Campylobacter
- Cancer ▼
- Chickenpox (Varicella)
- Cryptococcosis
- Cryptosporidium
- Death with Dignity Act ▼
- Diabetes ▼
- Diphtheria
- Ebola ▼
- E. coli
- Enterovirus D68
- Epilepsy
- Flu ▼

Pre-Exposure Prophylaxis Drug Assistance Program (PrEP DAP)

What is PrEP?

Pre-Exposure Prophylaxis (PrEP) is an HIV prevention method in which HIV-negative people take a daily pill to reduce their risk of becoming infected.

When used consistently, PrEP has been shown to reduce the risk of HIV-1 infection among adult men and women at very high risk for HIV infection through sex or injection drug use. TRUVADA® has been approved by the Federal Drug Administration for use in PrEP.

If you are interested, your prescribing medical provider can answer your questions.

Where can I find additional information on PrEP?

- [What is PrEP?](#)
- [PrEP Facts](#)

What is PrEP DAP?

PrEP DAP is a drug assistance program for HIV-negative people who have risk factors that expose them to HIV. PrEP DAP will pay for TRUVADA® for people who want to be on PrEP.

[Learn about PrEP DAP in our brochure - English \(PDF\)](#)

[PrEP DAP brochure - Spanish version \(PDF\)](#)

PrEP DAP update (as of 2/3/15)

227 applications

- 184 active
- 25 denied (on Apple Health or Gilead pt assistance, out of state)
- 18 incomplete

184 active persons

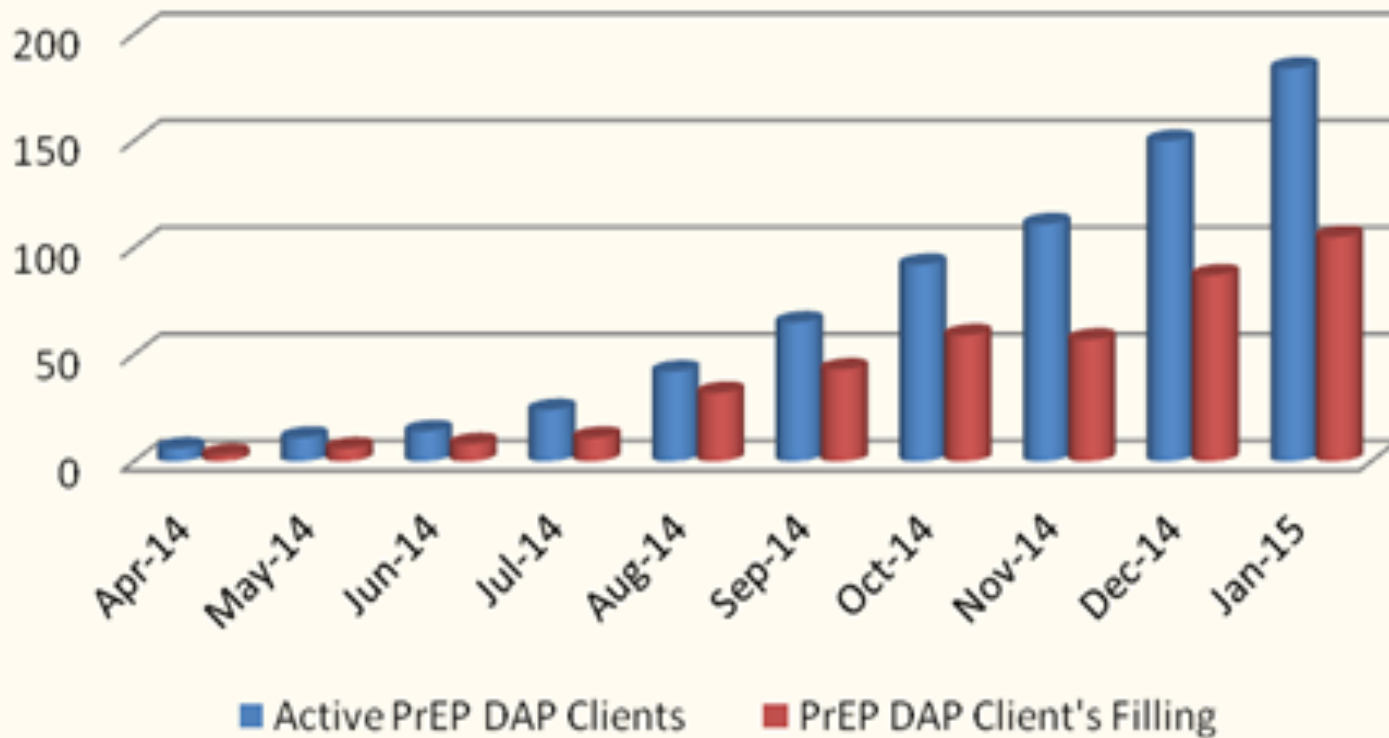
- 34 (18%) uninsured
- 150 (82%) insured

Mostly King but also Pierce (8), Clark (2), Snohomish (1), Spokane (1)

Total cost \$250k, mostly (\$230k) prescription cost

PrEP DAP

PrEP DAP Utilization As Of 1/25/2015



PrEP Tools for Providers

Billing codes (Behavioral counseling to prevent STIs)

- CPT 99401-99404
- ICD-9 and 10 “high risk behavior” or “contact to viral communicable diseases.”

EPIC templates and lab smartsets

PrEP hotline (CDC/UCSF): 855-448-7737

11a– 6p EST

US Public Health Service

**PREEXPOSURE PROPHYLAXIS
FOR THE PREVENTION OF HIV
INFECTION IN THE UNITED
STATES - 2014**

A CLINICAL PRACTICE GUIDELINE

Resources

National

- CDC

<http://www.cdc.gov/hiv/prevention/research/prep>

www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

- Gilead's Medication Assistance Program

<http://www.gilead.com/responsibility/us-patient-iaccess/truvada%20for%20prep%20medication%20assistance%20program>

Washington State

- PrEP DAP (also has list of PrEP providers by county)

<http://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS/HIVCareClientServices/PrEPDAP>

Conclusion: “Highly active HIV prevention”

