



Improving Access to Quality Medical Care Webinar Series

Presented by
Southwest Telehealth Resource Center,
Arizona Telemedicine Program
& AIDS Education & Training Center

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Desert Expertise

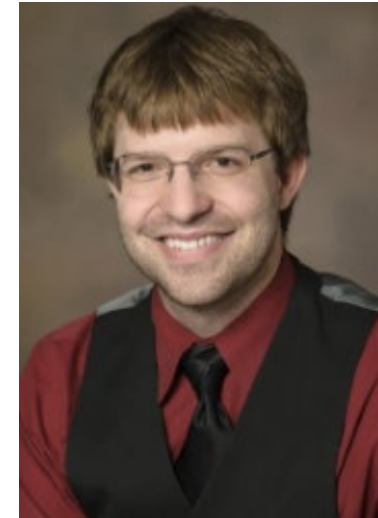
HIV PrEP The Theory, Practice and Results



Stephen Klotz, MD
Professor of Medicine and
Community and Family
Medicine



Cesar Egurrola
Program Coordinator



Larry York
Clinical Infectious Diseases
Pharmacist

What are we trying to accomplish?

A Case Study



Herman, a 54-year old man (HIV-negative) comes into the hospital unable to talk normally. He is the longtime partner of Bill, a 35-year old man who is HIV-positive, compliant with anti-retroviral therapy and whose HIV-1 RNA (viral loads) are nearly always non-detectable.



Bill was hospitalized for 10 days for diabetes mellitus, neuropathy and renal failure. He came to clinic weeks later; his HIV-1 viral load was >3,000 copies of RNA.



Herman was hospitalized 1 month later slurring his speech and could move his tongue only to the right. The HIV-1 RNA was >1,000,000 copies and the platelets <30,000/dL.



Herman was treated with plasmapheresis and ART. He is doing well and compliant with ART.

Another Case Study

Roger is a 56-year old man (MSM) who has "come out" two months ago. He was an insurance executive with a good income and no sexual activity with women or men for years. In the past he occasionally had HIV tests and they were all negative. (The testing was done at his place of work.)

He had one male partner 3 weeks ago and was primarily the partner on the bottom. He now complains of fever, skin rash and a sore throat.

On physical examination he has oral-pharyngeal thrush, tender lymphadenopathy and a macular rash on the extremities and abdomen.

The HIV-1 RNA was >2,000,000 copies and the RPR was negative.

He was started on ART and has done well.

What is PrEP?



One pill once a day to reduce risk of contracting HIV



≥ 90% protective against sexually acquiring HIV



Reduces HIV acquisition risk in intravenous drug users (IVDU)



Currently only two agents approved for PrEP

Truvada (FTC/TDF)

Single pill containing two medications

- Emtricitabine (FTC) 200 mg
- Tenofovir disoproxil (TDF) 300 mg

One tablet once a day

- No more than 90 day prescription provided

Can be taken with or without food

Take missed doses as soon as remembered

- If close to next dose, wait until then and take 1 tablet

Descovy (FTC/TAF)

Single pill containing two medications

- Emtricitabine (FTC) 200 mg
- Tenofovir alafenamide (TAF) 25 mg

Same instructions for use as Truvada

ONLY studied in MSM and transgender women

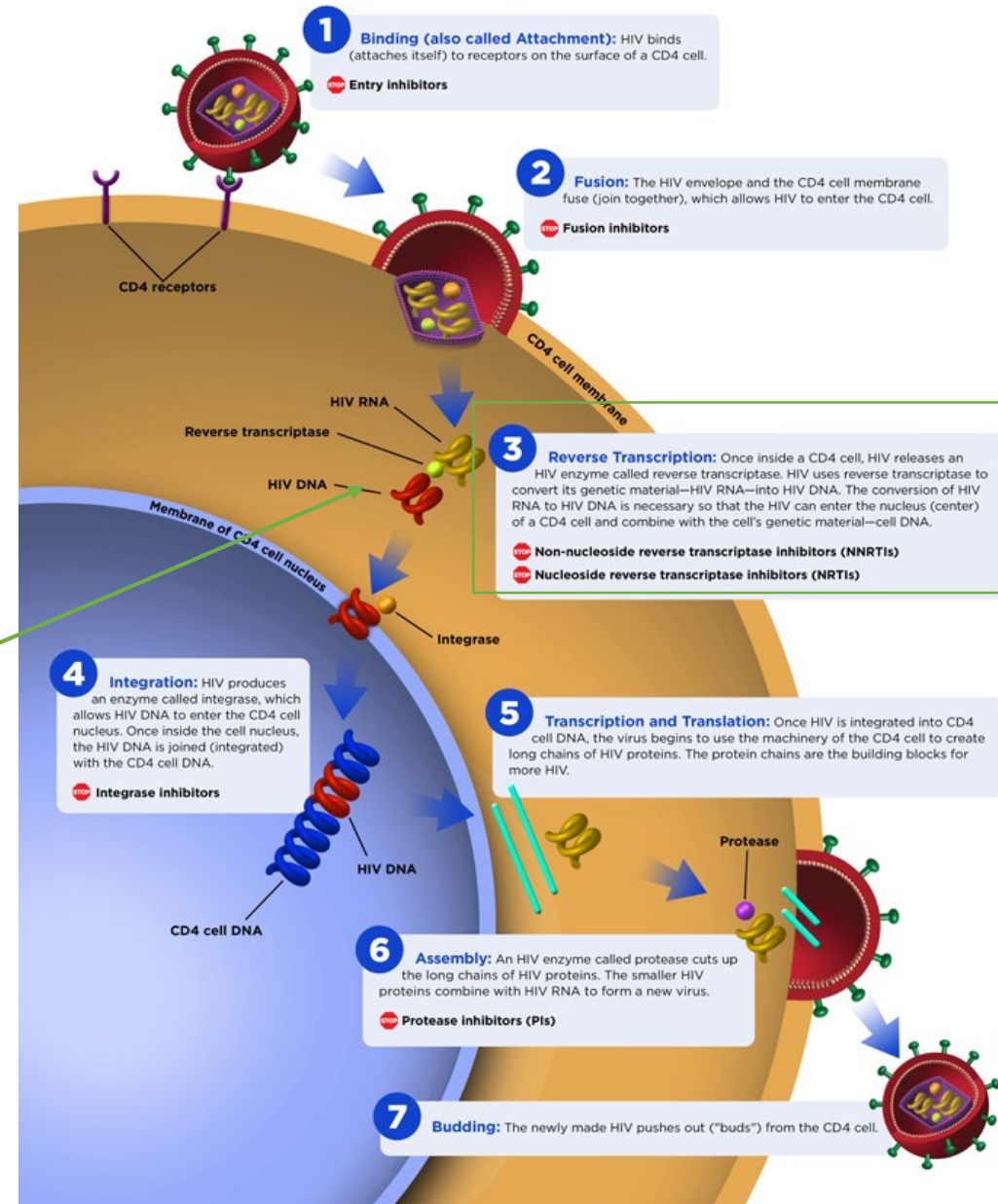
- Not recommended for use in cisgender women or for IVDU

NRTIs Nucleoside/ Nucleotide Reverse Transcriptase Inhibitors

Indirectly
inhibits
enzyme
required to
copy viral
RNA to DNA.

The HIV Life Cycle

HIV medicines in six drug classes stop HIV at different stages in the HIV life cycle.



Side Effects of PrEP

May experience nausea, bloating upon initiation

- Usually resolves within 2-3 weeks

Headache

Increased risk of decreased renal function

- Uncommon but known adverse effect from TDF
- Renal function usually returns to normal if PrEP stopped

Increased risk of decreased bone mineral density

Tenofovir Disoproxil (in Truvada) Drug Issues



Primarily known for its potential renal issues



Risk of renal dysfunction may be multifactorial

- Age
- Addition of other nephrotoxic agents



May also lead to decreased bone mineral density

- Possibly 1-3% greater loss with TDF
- Calcium/vitamin D supplementation may help

Tenofovir Alafenamide (in Descovy) Drug Issues



Same concerns as
TDF but appears to
be lower risk

Improved
renal/bone
adverse effect
profile



Not as well studied
for PrEP

- Only recently approved
- Effects of missing doses less clear than with TDF regimen

Descovy for PrEP

DISCOVER study
looked at MSM
and transgender
women

Found to be
equivalent to
Truvada

Major concerns
again relate to
female use

A previous PK study
with TAF found poor
tissue levels

- 11-fold lower in
cervicovaginal fluid

Uncertain how
important
adherence is for
use

When PrEP is NOT Recommended

Do not begin Truvada if $\text{CrCl} < 60 \text{ mL/min}$

If CrCl declines to $< 50 \text{ mL/min}$, stop Truvada

FTC and TDF have recommended dose adjustments

Renally-adjusted doses were not studied for PrEP

Descovy should be stopped if $\text{CrCl} < 30 \text{ mL/min}$

An option for PrEP in patients with mild-moderate CKD

PrEP (Truvada) Drug Interactions

Table 11: PrEP Medication Drug Interactions ^{6,80}

	TDF	FTC
Buprenorphine	No significant effect. No dosage adjustment necessary.	No data
Methadone	No significant effect. No dosage adjustment necessary.	No data
Oral contraceptives	No significant effect. No dosage adjustment necessary.	No data
Acyclovir, valacyclovir, cidofovir, ganciclovir, valganciclovir, aminoglycosides, high-dose or multiple NSAIDs or other drugs that reduce renal function or compete for active renal tubular secretion	Serum concentrations of these drugs and/or TDF may be increased. Monitor for dose-related renal toxicities.	No data
Ledipasvir/sofosbuvir	Serum concentrations of TDF may be increased. Monitor for toxicities.	No significant effect

PrEP (Descovy) Drug Interactions

Descovy more likely to have interactions than Truvada

TAF more susceptible to p-glycoprotein effects

- Efficacy may be compromised with select agents

Avoid use with:

- Barbiturates
- Carbamazepine/oxcarbazepine
- Phenytoin
- Rifamycins
- St John's Wort

PrEP in Tissues

Truvada deposits at varying rates into different tissues

Estimate ~7 days for maximal rectal tissue levels

Estimate ~20 days for maximal vaginal tissue/blood levels

This data is not yet known for Descovy

On-Demand PrEP (Truvada)

Recent evidence supports this potential approach

- 2 tablets 2-24 hours before sexual encounter
- 1 tablet 24 hours after sexual encounter
- 1 tablet 48 hours after sexual encounter

Missing doses here may not be as forgiving

Reliant on anticipation of a sexual encounter

Not officially recommended as of yet

Vaginal Exposures and Adherence

Far less clear how levels are
affected in this tissue

DOES appear to be much more
susceptible to missed doses

Would avoid on-demand PrEP
in this group

Indications – MSM

BOX B1: RECOMMENDED INDICATIONS FOR PREP USE BY MSM²

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see Box B2)
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following

- Any anal sex without condoms (receptive or insertive) in past 6 months
- A bacterial STI (syphilis, gonorrhea, or chlamydia) diagnosed or reported in past 6 months

Indications - Heterosexuals

BOX B2: RECOMMENDED INDICATIONS FOR PREP USE BY HETEROSEXUALLY ACTIVE MEN AND WOMEN

- Adult person
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Is a man who has sex with both women and men (behaviorally bisexual) [also evaluate indications for PrEP use by Box B1 criteria]
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (PWID or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner
- A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months

Indications – IVDU

Box B3: RECOMMENDED INDICATIONS FOR PREP USE BY PERSONS WHO INJECT DRUGS

- Adult person
- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following

- Any sharing of injection or drug preparation equipment in past 6 months
- Risk of sexual acquisition (also evaluate by criteria in Box B1 or B2)

Patient Visits



Typically PrEP patients are seen every 3 months



Visits should be focused around:

- Risk reduction counseling
- Assessment of HIV status/signs and symptoms of acute infection
- STI screening as recommended or needed
- Medication adherence counseling

Baseline Testing

HIV screening test

Estimated creatinine clearance

Hepatitis B serologies (HBsAb, HBcAb, HBsAg)

- Follow up with HBV DNA if HBsAg is positive

Hepatitis C screening

Bacterial STI testing

Pregnancy test (cis-gender females)

HIV 4th Generation Screening Test

Preferred test, quickest
identification of HIV

Can detect a new infection
10-14 days after exposure

May affect decision to
initiate PrEP

- If unprotected encounter within 2 week period, may repeat test

Every 3 Month Monitoring

HIV testing
(preferably 4th
generation)

Pregnancy testing for
women who may
become pregnant

Bacterial STI testing
if signs/symptoms
present

Bacterial STI testing
for asymptomatic
MSM patients

- If history of STI or
multiple partners

Every 6 Month
Monitoring

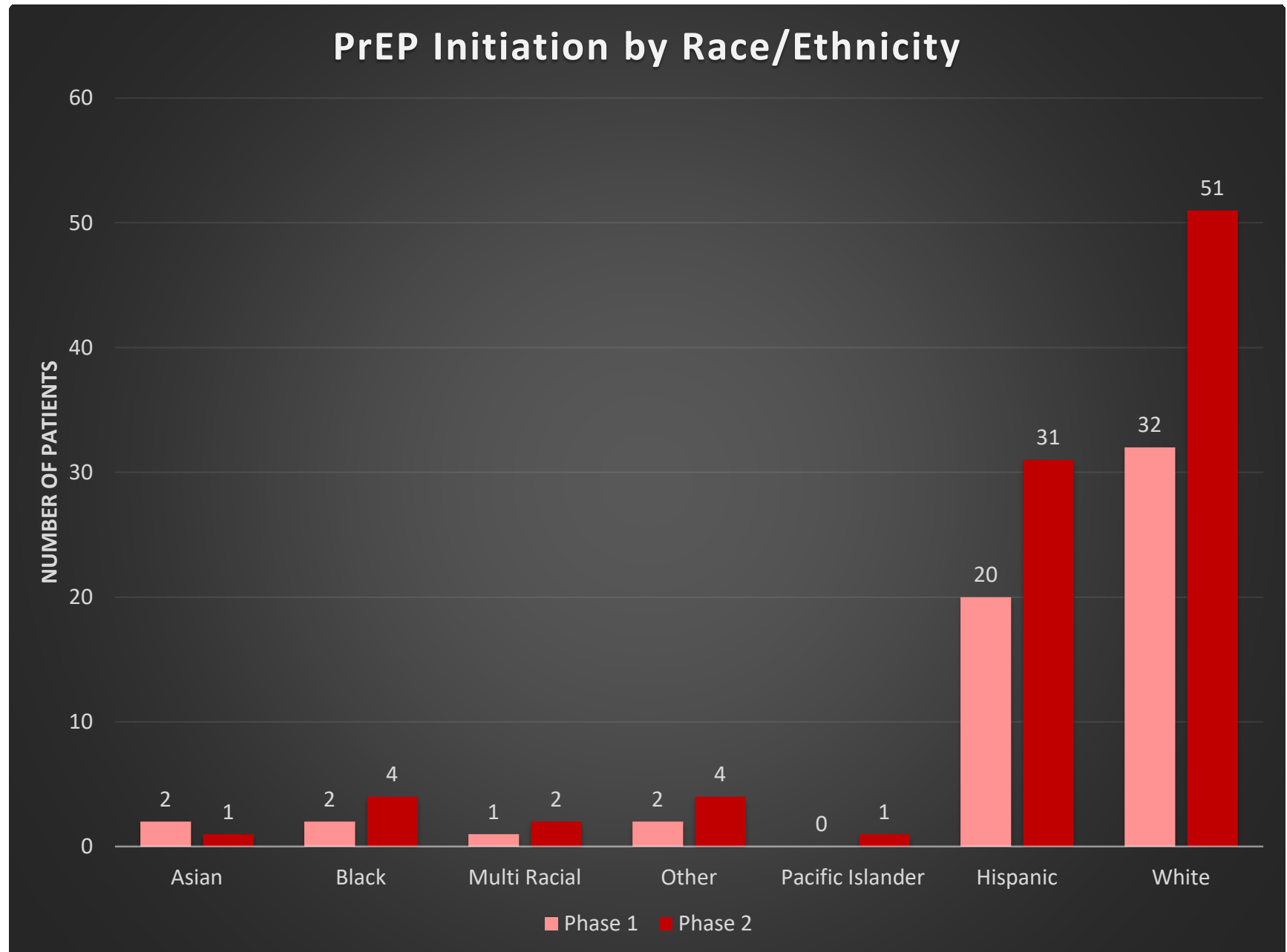


Monitor estimated creatinine
clearance

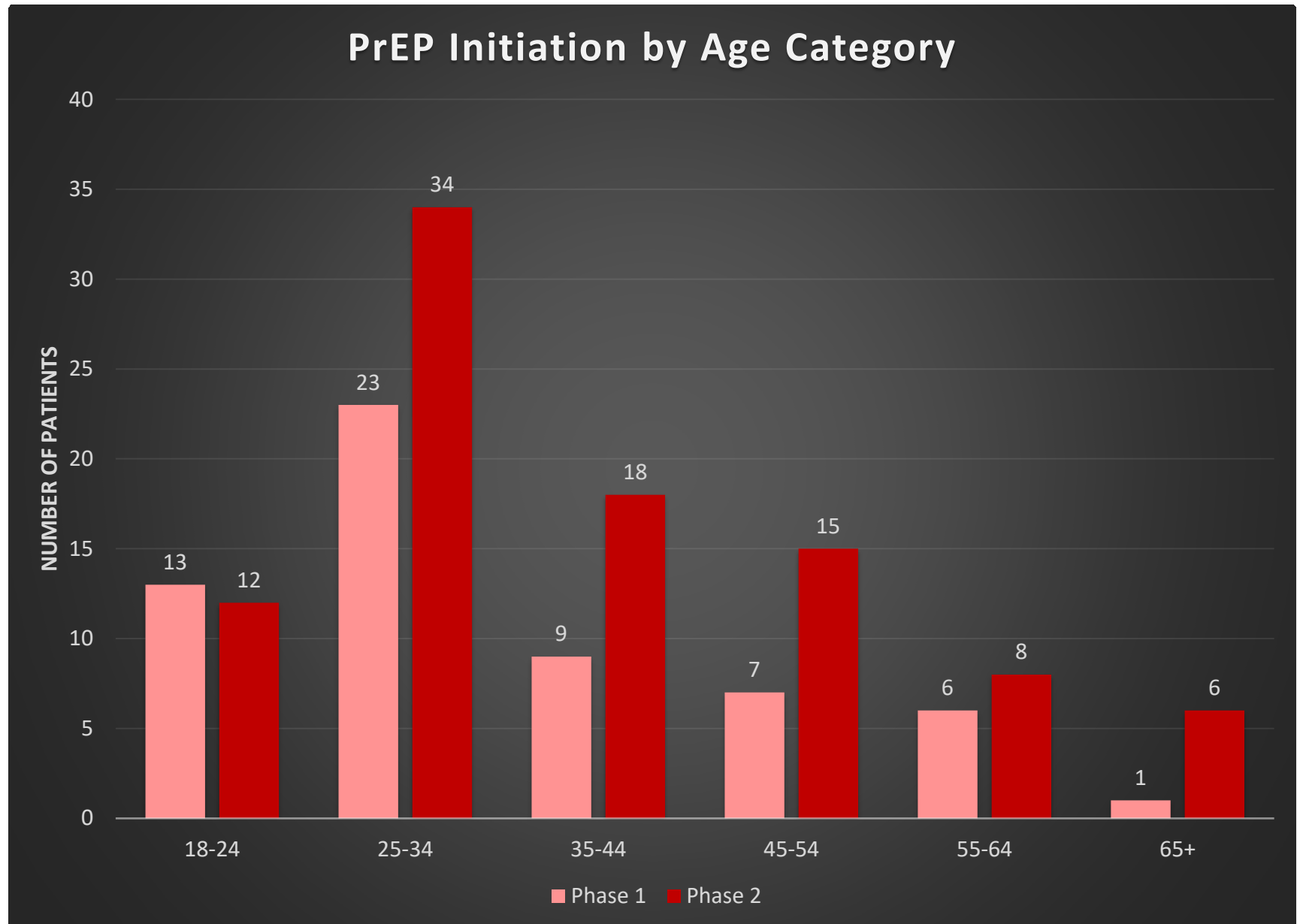


Bacterial STI testing for all sexually
active patients

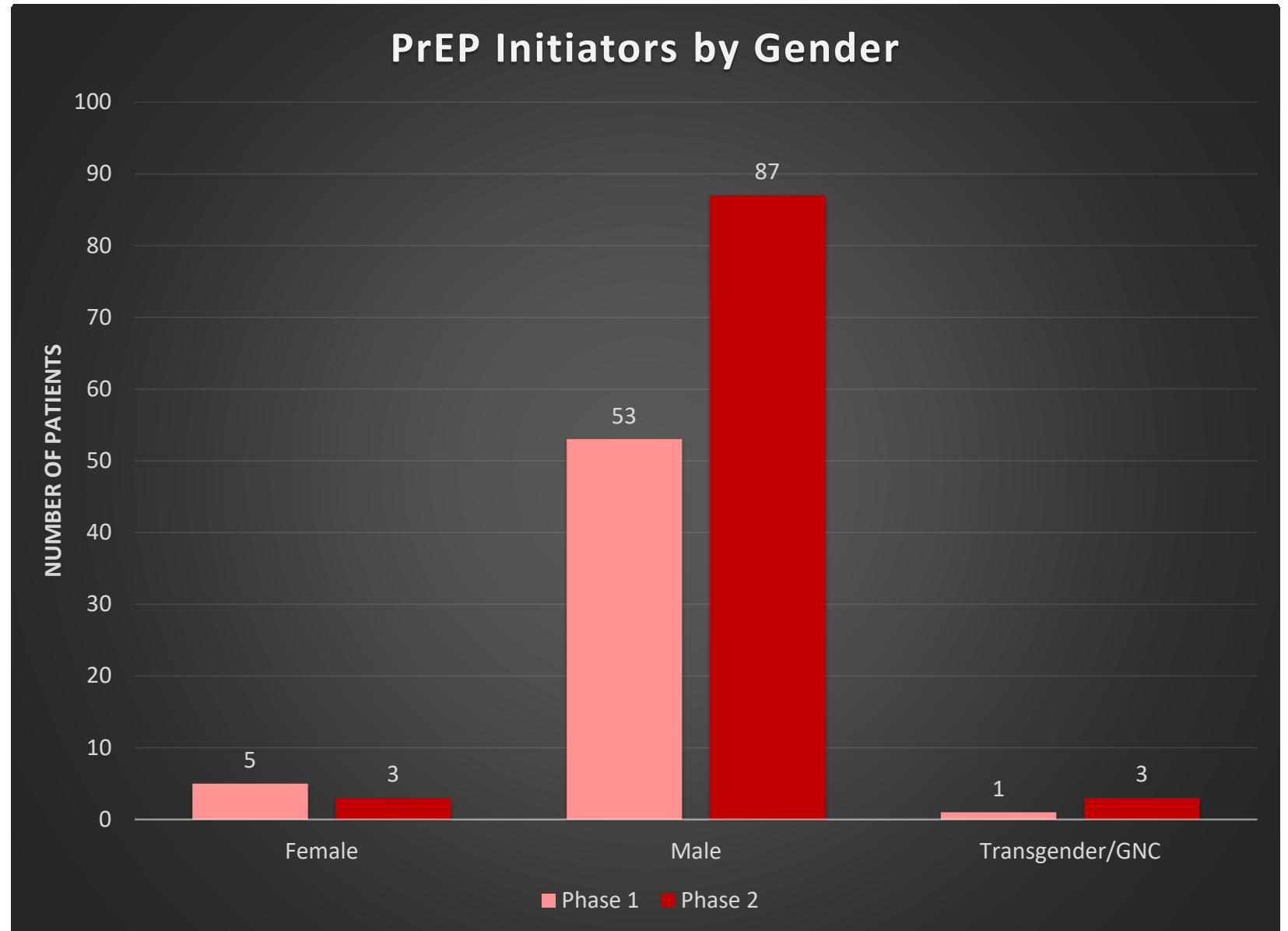
Patient Snapshot



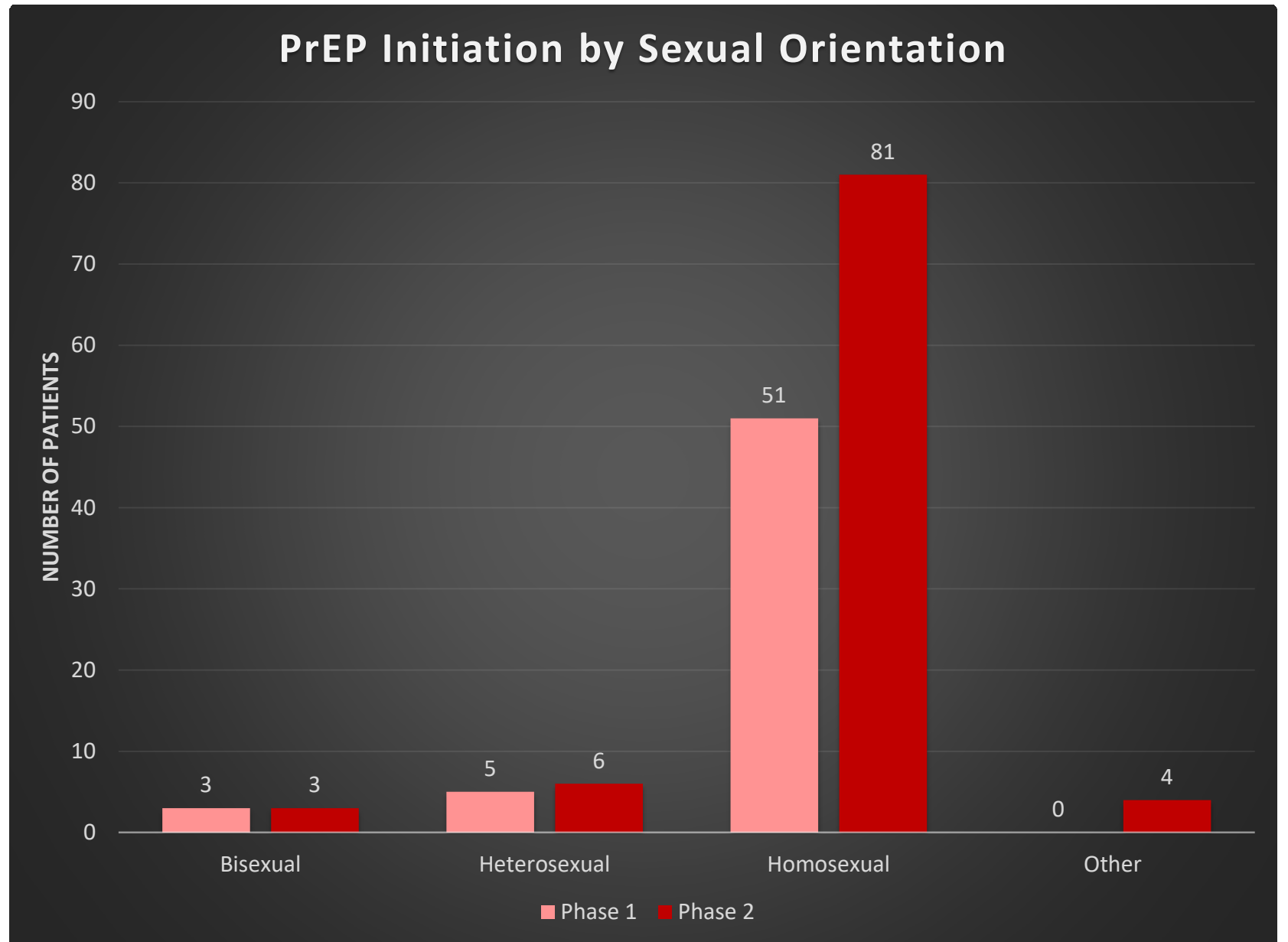
Patient Snapshot



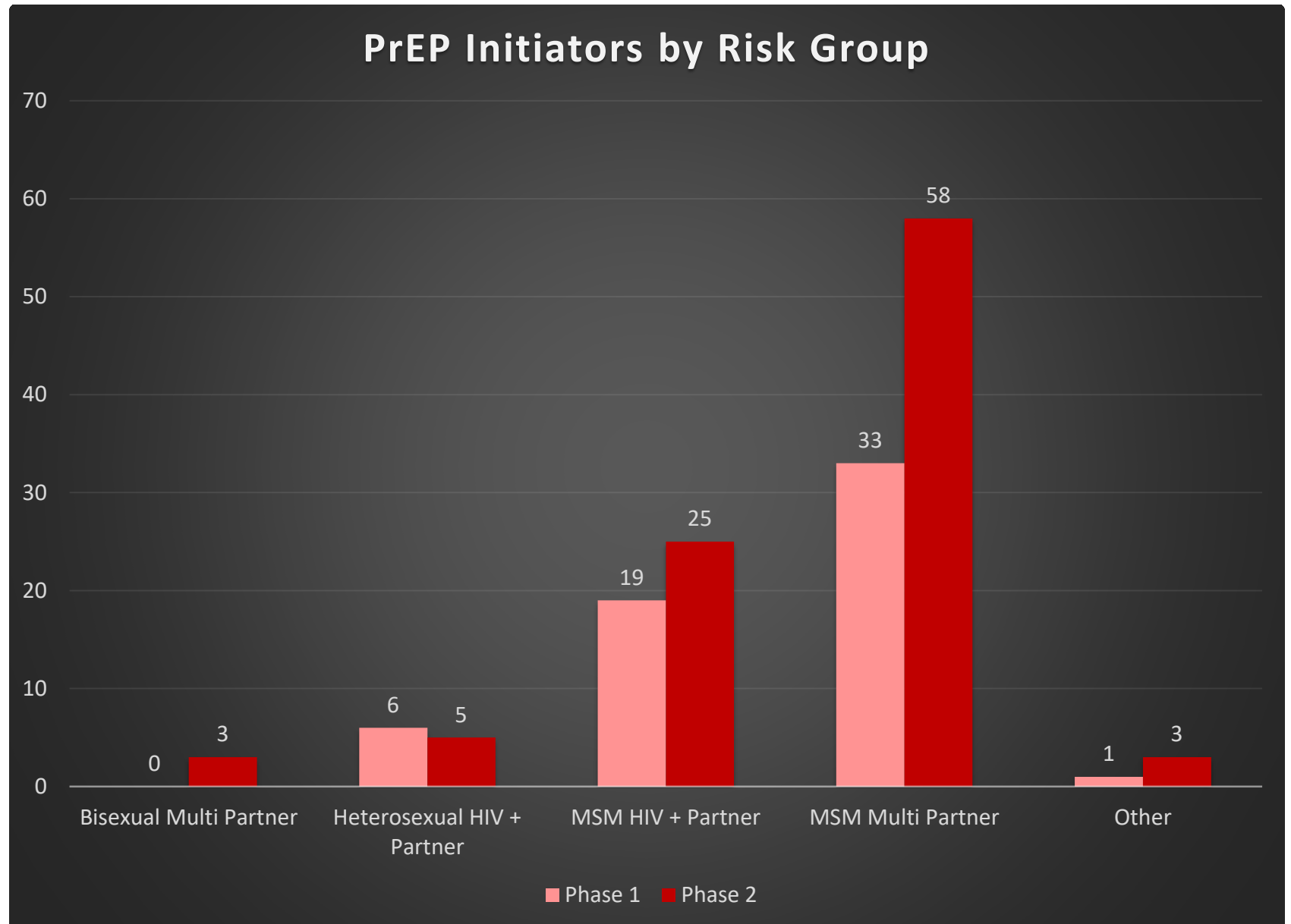
Patient Snapshot



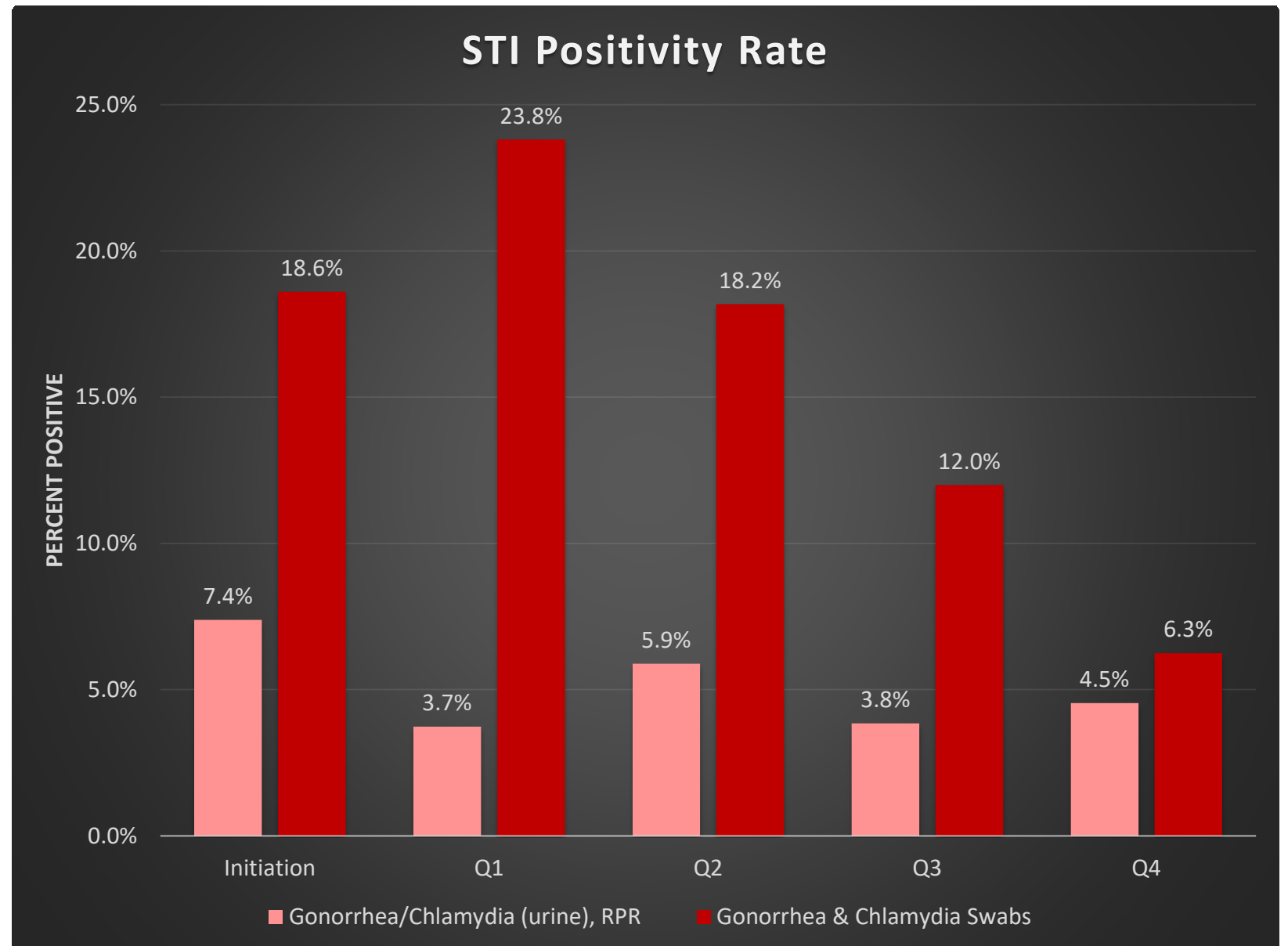
Patient Snapshot



Patient Snapshot

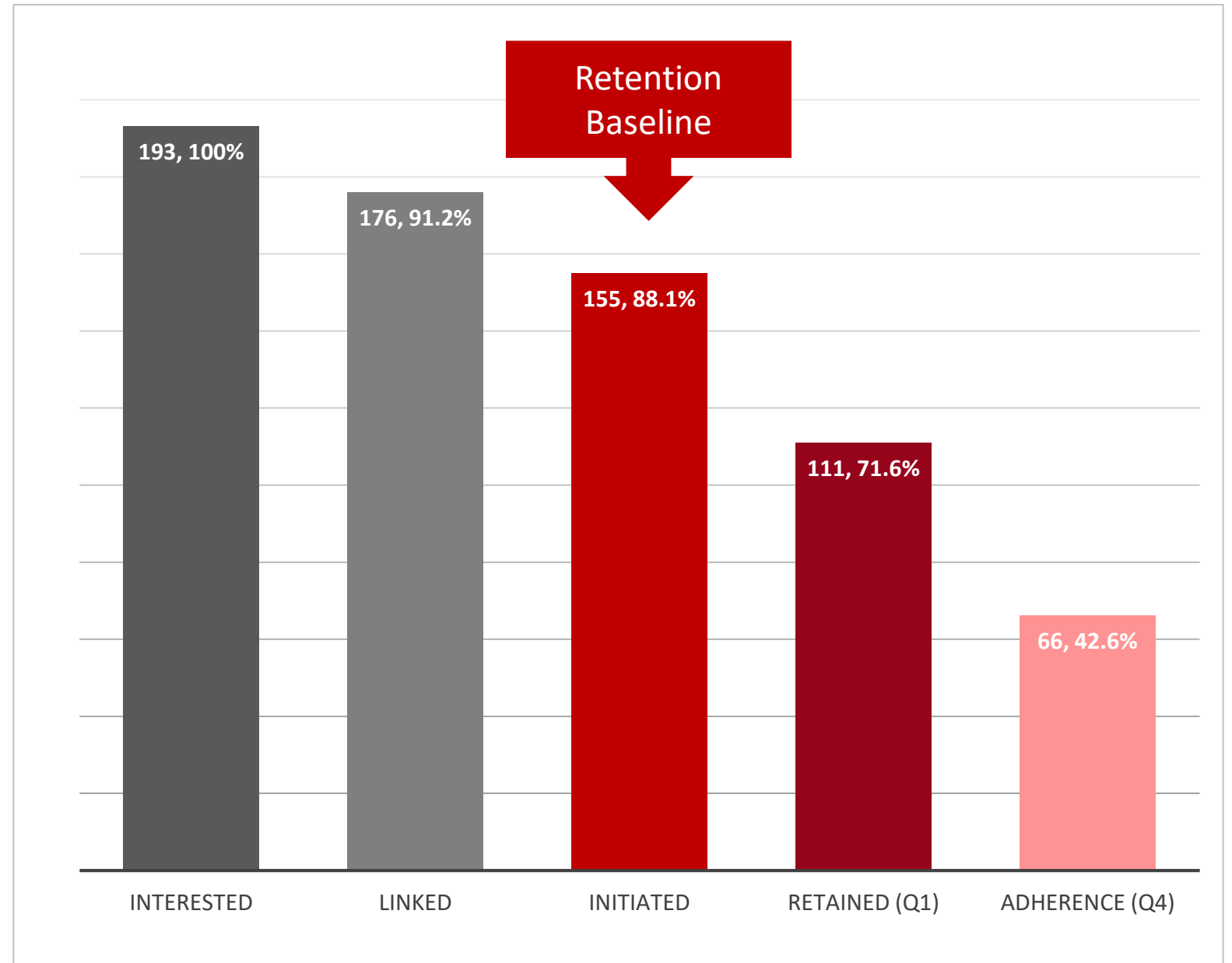


Patient Snapshot



HIV Positivity Rate for those maintained in care: 0%

Clinical PrEP Cascade



Paying for PrEP

AWP per tablet = \$73.69

If high copays:

- Gilead offers a copay card good for several thousand (~\$7,000) dollars/year

If insurance will not cover or a PA appeal is denied:

- Gilead may pay for medication

Q & A



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