Update on Current Research and Rollout of PrEP for Women in the US

Featuring

- Dr. Sharon Hillier, University of Pittsburgh Medicine, MTN
- Dr. Sally Hodder, Rutgers NJ Medical School, HPTN
- Dr. Dawn Smith, US Centers for Disease Control

This is the first in a series of webinars coordinated by partners in the US Women and PrEP Working Group – learn more at www.prepwatch.org/#women.

SisterLove, Inc.

AVAC
Global Advocacy for HIV Prevention

US Women and PrEP Working Group

- Coalition of more than 50 women from leading AIDS and women's health organizations—formed in March 2012—to build a common understanding of what PrEP as a new HIV prevention tool could mean for women in the United States.
- Focus on:
  - How will PrEP be used for HIV prevention by women in the US?
  - What data are needed regarding PrEP's acceptability and effectiveness among those women?
  - How will PrEP be promoted, made accessible and financed for use by US women?
- Recent work includes a statement calling for a coordinated, timely and adequately funded US government response to PrEP for women that involves the full participation and leadership of individuals and communities most in need of effective, comprehensive HIV prevention.
- For more visit www.prepwatch.org/#women and if interested in joining the group please send your request to avac@avac.org.

PrEP Study Results				
Study	Population	N	Treatment(s)	Results
iPrEx Brazil, Ecuador, Peru, South Africa, Thailand, US	Gay men, other MSM, transgender women	2499	Daily oral Truvada	44% efficacy
TDF2 Study Botswana	Men and women	1200	Daily oral Truvada	62% efficacy
Partners PrEP Study Kenya, Uganda	Serodiscordant couples	4758	Daily oral Tenofovir Daily oral Truvada	67% efficacy 75% efficacy
Bangkok Tenofovir Study Thailand	IDUs	2400	Daily oral Tenofovir	49% efficacy
FEM-PrEP Kenya, South Africa, Tanzania	Women	1950	Daily oral Truvada	No effect
VOICE South Africa, Uganda, Zimbabwe	Women	5029	Daily oral Tenofovir Daily oral Truvada Daily vaginal TFV gel	No effect

Ongoing and Planned PrEP Demonstration Projects and Trials in Women, August 2013

Trial/project	Location	Population	Sponsor/funder	Status
Partners Demo Project	Kenya, Uganda	Serodiscordant couples	Scientists from Kenya, Uganda and the US; funded by NIMH/NIH, USAID and BMGF	Ongoing; results expected in 2016.
LVCT and SWOP	Kenya	Young women, female sex workers, MSM	National partners, O'Neill Institute, LSHTM, Imperial College, UNAIDS and WHO; funded by BMGF	In development
Nigerian National Agency for the Control of AIDS	Nigeria	Serodiscordant couples		In development
Wits Reproductive Health and HIV Institute	South Africa	Female sex workers		In development
Durbar (DMSC) and Ashodaya Samithi	India	Female and transgender sex workers		In development
Choices For Adolescent Methods Of Prevention In South Africa (CHAMPS)	South Africa	Heterosexual men and women	NIAID	Ongoing; results expected June 2015.
Victorian PrEP Demo Project	Australia	At risk-population	Victorian AIDS Council/Gay Men's Health; funded by Victorian Government	In development
CDC Foundation Demo Project	US	MSM and heterosexual women	Funding pending	In development
CDC 494 (TDF2 Follow-Up)	Botswana	Heterosexual men and women	Botswana MOH, CDC, Gilead	Ongoing; results expected in Nov. 2013.
HPTN 069/ACTG 5305 (NEXT-PrEP)	US	MSM and at-risk women	ACTG, HPTN, NIAID	Ongoing; results expected Dec. 2014.

For a complete list of ongoing and planned PrEP demonstration projects and trials in all populations see www.avac.org/prepdemo

Discussion

- Unmute your line by pressing *7 and ask it on the line (remute your line by pressing *6)
- Enter it into the chat box in ReadyTalk
- Email your question to avac@avac.org
- Tweet @hivpxresearch

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Webinar recording will be available at www.avac.org/meetingreports and www.prepwatch.org

Visit www.prepwatch.org/#women for more on the working group and info on upcoming webinars

Join us for next month's webinar

PrEP-ception: sero-discordant couples using PrEP to reduce HIV transmission risk while achieving pregnancy

Monday, October 28, 2013

11:00 AM – 12:30 PM EDT

- **Introduction: Overview of PrEP and the Role of the Working Group**
  - Dazon Dixon Diallo, MPH, *Founder and President, SisterLove, Inc.*
- **Defining the Need for Safer Conception Options: The Role of "PrEP-ception"**
  - Shannon Weber, MSW, *Director, Perinatal HIV Hotline, Bay Area Perinatal AIDS Center*
- **A Framework for the Integration of PrEP**
  - Erika Arron, CRN, *Drexel University College of Medicine, Division of Infectious Diseases and HIV Medicine*
- **One Mom's Story**
  - Poppy
- **Questions and Discussion**
  - Dazon Dixon Diallo, *Moderator*

Register at www.prepwatch.org/uswomenwebinars

VOICE Results: Questions and Implications

Sharon Hillier
Microbicide Trials Network

Ready, Set, PrEP: Update on Current Research and Rollout of PrEP for Women in the US (webinar)

September 16, 2013

Overview

- VOICE results recap
- Questions still to be answered
- What does VOICE say about women and PrEP?
- Summary and conclusions

VOICE
VAGINAL + ORAL INTERVENTIONS TO CONTROL THE EPIDEMIC

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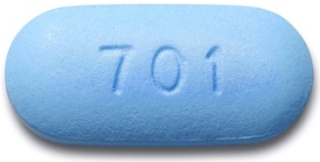
TO CONTROL THE EPIDEMIC

Tenofovir
Tablets

Tenofovir Gel



Truvada
Tablets

Which is effective?
Is each safe?
Which will women use?

Women enrolled between Sept 2009 – June 2011

Screened 12,320 women to enroll 5,029

- **UGANDA: 322 participants**
  - Makerere Univ./JHU, Kampala: 1 site
- **ZIMBABWE: 630 participants**
  - UZ-UCSF, Harare: 1 site
  - UZ-UCSF, Chitungwiza: 2 sites
- **SOUTH AFRICA: 4,077 participants**

  Durban
  - Medical Research Council: 7 sites
  - CAPRISA eThekwini: 1 site

  Johannesburg
  - WRHI: 1 site
  - PHRU Soweto: 1 site

  Klerksdorp
  - Aurum Institute: 1 site

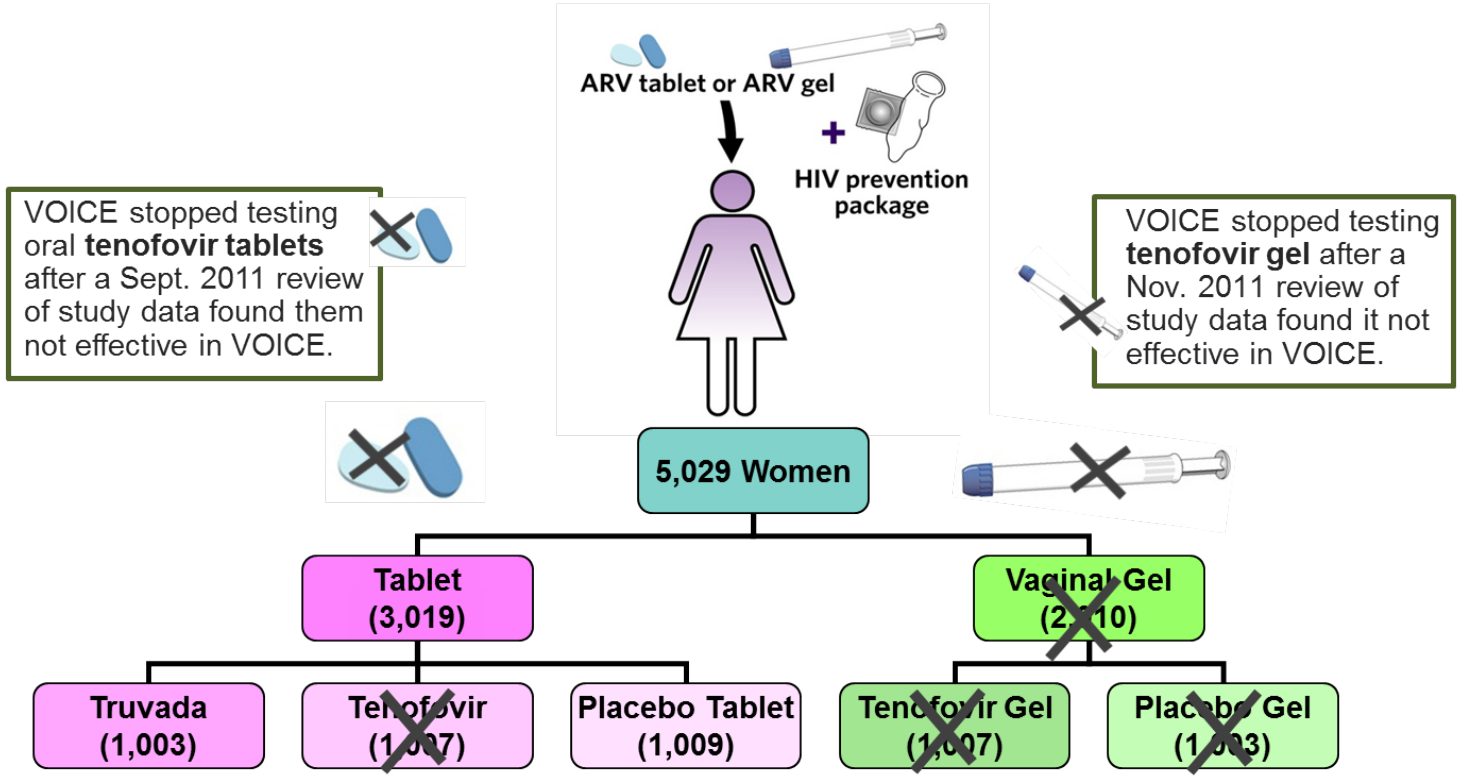
Half of the women were under 25, 80% were unmarried

How was the study done?

Women were randomized to 1 of 5 study product groups and asked to use assigned product daily

Standard HIV prevention package provided throughout study

VOICE stopped testing oral tenofovir and tenofovir gel early but continued testing daily use of Truvada until scheduled end of study



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What VOICE found

- Daily approach – gel or tablet – was not right for the population of women in VOICE
  - No product was effective
  - Most participants did not use the products
- Younger (under 25), unmarried women were least likely to use the products and the most likely to acquire HIV
- HIV incidence was 5.7% – twice what we estimated – and nearly 10% at some South African sites
- Study retention was very high (91%)
- No safety concerns with the products

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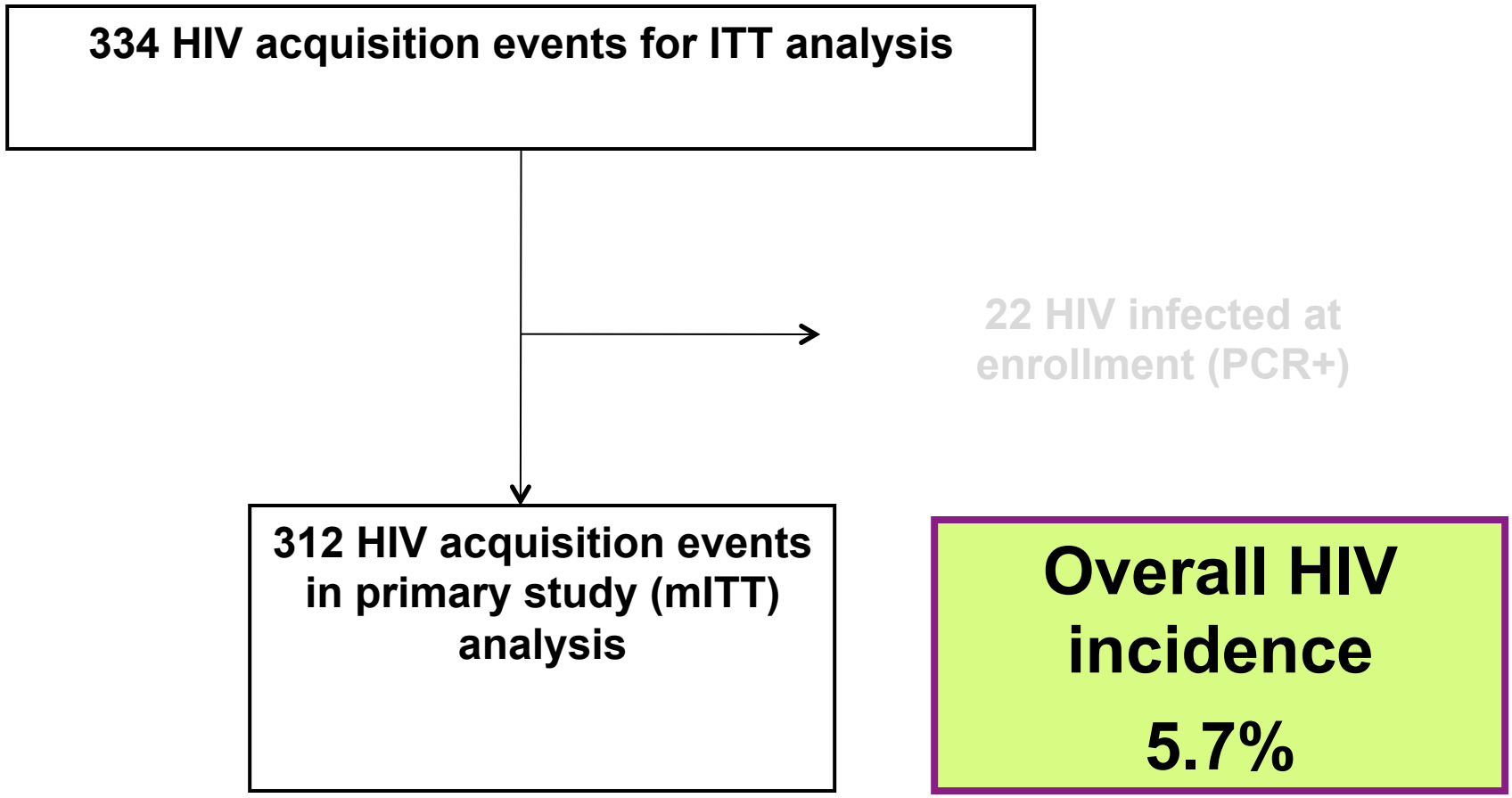
HIV seroconversion endpoints*



* Includes data through 12/6/2012

No significant difference in efficacy

	Tenofovir Tablet*	Oral Placebo*	Truvada Tablet	Oral Placebo	Tenofovir Gel	Gel Placebo
Person-yrs	823	837	1285	1306	1026	1030
No. of HIV infections	52	35	61	60	61	70
HIV incidence per 100 p-y	**6.3** [4.7, 8.3]	**4.2** [2.9, 5.8]	**4.7** [3.6, 6.1]	**4.6** [3.5, 5.9]	**5.9** [4.5, 7.6]	**6.8** [5.3, 8.6]

*Censored on date when sites were informed to take women off of tenofovir and placebo tenofovir tablets

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Results for product adherence

Analyzed blood samples from 773 participants (including 185 women who acquired HIV) for presence of drug

- Adherence to product use was low across all groups
  - Drug detected in less than 1/3 of samples from women in Truvada and oral tenofovir groups
  - Drug detected in less than 1/4 of samples from women in tenofovir gel group
  - More than 50% of women never had <u>any</u> drug detected
- Adherence estimated to be 90% based on what participants reported and counts of unused applicators and leftover pills

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Adherence from 3 Different Measures

	Truvada Tablet	Tenofovir Tablet	Tenofovir Gel
Returned Pill or Applicator Counts	92%	87%	86%
Self Report	91%	90%	90%
Drug Detected in Blood	**29%**	**28%**	**23%**
Percentage of women with no drug detected in *any* sample	50%	58%	55%

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Young, unmarried women

Compared to older, married women in VOICE, those under age 25 and not married were:

- **Least likely to use study product**
  - Drug was detected in 21% of young, unmarried women vs. 54% of the older, married women in the Truvada group
- **Most likely to acquire HIV**
  - HIV incidence was 8.8% vs.0.8%
  - Overall HIV incidence in study was 5.7%

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Social Science/ Behavioral Research

- Social/behavioral scientists engaged at every step
- Oversaw modification of counseling approach during VOICE – included client-centered motivational counseling
- Introduced community-centered, ethnographic study: VOICE C
  - Conducted at the WRHI trial site in Johannesburg
  - Looked at factors and beliefs within women's communities, social groups and households that may have influenced ability and willingness to use products
  - Involved VOICE participants, male partners, CAB members and community stakeholders

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Lots of Questions!?!

- Why did women join VOICE and attend all study visits but not use the products?
  - Did they participate for other reasons, e.g., health care services and HIV testing the study provides?
- Why did they go to great lengths to hide non-use?
- They live where incidence is very high – don't they see themselves at risk?
- Why didn't they or couldn't they use the products?
  - Was there stigma with ARV-based products?
- Even after being told that other trials found regular use effective, they still didn't use the products – why not?
  - Will they use other prevention products? Especially ones that may be easier to use?

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Seeking Answers: VOICE D

- Behavioral sub-study launched after VOICE – still ongoing
- Involves former VOICE participants at 5 sites in Uganda, Zimbabwe and South Africa
- Aims to better understand women's actual and reported use of study products and sexual behavior during VOICE
- Part 1 (completed) – 88 women after they exited VOICE
- In-depth interviews focused on perceptions and understanding of risk behaviors, e.g., anal sex
- Part 2 – 108 -144 women who were on active product
- Results of their own blood tests (drug levels) to be used as ice-breaker for in-depth interviews and focus group discussions to get to reasons for non-use

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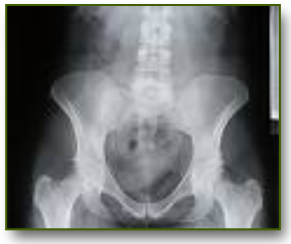
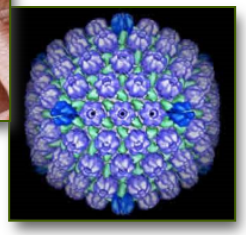
Answering other questions





- More information about who used products
  - Blood samples were tested for drug in only 15% of the participants
  - Now testing *every* sample collected from *all* 5,029 women – 160,000 plasma samples alone
- Effects of oral products on bone health
  - VOICE-B results awaiting additional data on drug levels and product use
- Frequency of drug resistance
- Effects of tenofovir gel on HSV-2 acquisition

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Truvada and women?

- **Effective** in Partners PrEP
  - Women were older (mean age 36)
  - All in committed relationship with a partner they knew was HIV-positive; both partners aware of HIV risk
- **Effective** in TDF2
  - Relatively small study
  - Effect size in women (49.4% in sub-analysis) not statistically significant-- (wide CI: -0.217% to 80.8%)
- **Not effective** in FEM-PrEP
  - Similar population to VOICE - 59% under age 25
  - 70% perceived themselves at little or no risk of HIV
- **Not effective** in VOICE

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Truvada and women?

	Avg # women per arm	Avg # woman yrs follow-up per arm	Women on active product (Truvada)	Women yrs follow-up on active product
Partners PrEP	595	920	873	1,271
TDF2	278	351		
FEM-PrEP	1,060	703	2,066	1,829
VOICE	1,006	1,126		

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A few take-home messages

- Even the most effective product will do no good if it's not used (or not used correctly)
  - The women who need safe and effective HIV prevention methods must also be willing and able to use them – and they must actually use them
- Low adherence in a clinical trial can provide important clues about potential "real world" use
  - Is there stigma with using an ARV product for prevention?
  - Is daily use asking too much?

Summary and Key Points

- Results of VOICE are clear: daily use (gel or tablet) was not right approach for the women in VOICE
- Young, unmarried women used product the least – and acquired HIV the most
- Hope to understand *why* women didn't use products
- VOICE is consistent with FEM-PrEP results for Truvada – together, send very strong message

- Need products women *will* use
  - Exploring long-acting methods:
    ASPIRE and The Ring Study of monthly dapivirine ring
  - Next generation:
    Products that also provide contraception

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More to come….

- Primary results expected to be published soon
- VOICE C results to be reported before end of 2013
- VOICE D expected to be completed by end of 2013 and report results mid 2014
- VOICE B results (bone health) available in 2014
- Complete analysis of all drug plasma levels in VOICE by ????

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Acknowledgements

Women need safe and effective HIV prevention products!

We are grateful to the women who participated in VOICE, to the community and family members who supported their participation, and to everyone who continues to support HIV prevention research so that someday we may all live in an AIDS-free world.

MTN is funded by NIAID (AI068633), NICHD and NIMH, all of the U.S. National Institutes of Health

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PrEP Research Agenda in the HPTN

Sally L. Hodder, MD

SEPTEMBER 16, 2013

National Institute of Allergy and Infectious Diseases

National Institute of Mental Health

National Institutes of Health

U.S. Department of Health and Human Services
National Institutes of Health
NIDA National Institute on Drug Abuse

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ISIS
a women's study

HIV Incidence Among US Women HPTN 064: The Women's HIV SeroIncidence Study (ISIS)

National Institute of Allergy and Infectious Diseases

NIMH National Institute of Mental Health

National Institutes of Health

U.S. Department of Health and Human Services
NATIONAL INSTITUTES OF HEALTH
NIDA NATIONAL INSTITUTE ON DRUG ABUSE

ISIS Objectives

- Accurately estimate new HIV incidence in a group of women at risk for HIV in the US
- Evaluate new lab methods for identification of new HIV infections
- Describe factors in participants lives that impacted HIV risks
  - For example, partner risks, alcohol/ use, financial factors, condom use

ISIS Inclusion Criteria

- Self identifies as a woman ages 18-44 years
- Residence in area with relatively high rates of HIV prevalence and poverty
- Unprotected sex with a man during the previous 6 months
- AND at least one additional risk factor

Study Sites

10 distinct communities within 6 geographic locations
Qualitative data collected in four communities

ISIS Cohort Baseline Characteristics n=2,099

		Number	Percentage[a]
Median Age		29	[23 – 38]
Race	Black	1851	88.2
Hispanic Ethnicity		245	12
Education	< high school graduation	777	37.0
Marital Status	Single/Divorced/Widowed	1258	59.9
	Married/Living with partner	638	30.4
Annual Household Income	<$10,000	932	44.4
	$10,000 - $20,000	225	10.7
	>$20,000	197	9.4
	Unknown	745	35.5
Food Insecurity	Concerns for self and/or family	971	46

[a]Number and percentage shown for all variables except age which shows median,interquartile range.

Reported Characteristics at Baseline (all risk factors within 6 months)

FACTOR	%
≥ Monthly binge drinking ≥ 4 drinks on one occasion	39
Intravenous drug use	4
Exchange sex for commodities	37
Unknown HIV status of last vaginal sex partner	41
Anal sex	40
Condom at last vaginal sex	18
Condom at last anal sex	18

HIV Prevalence and Incidence in Context

- Thirty-two women (1.5%) entered the study unaware of their HIV infection, suggesting that testing programs must improve coverage

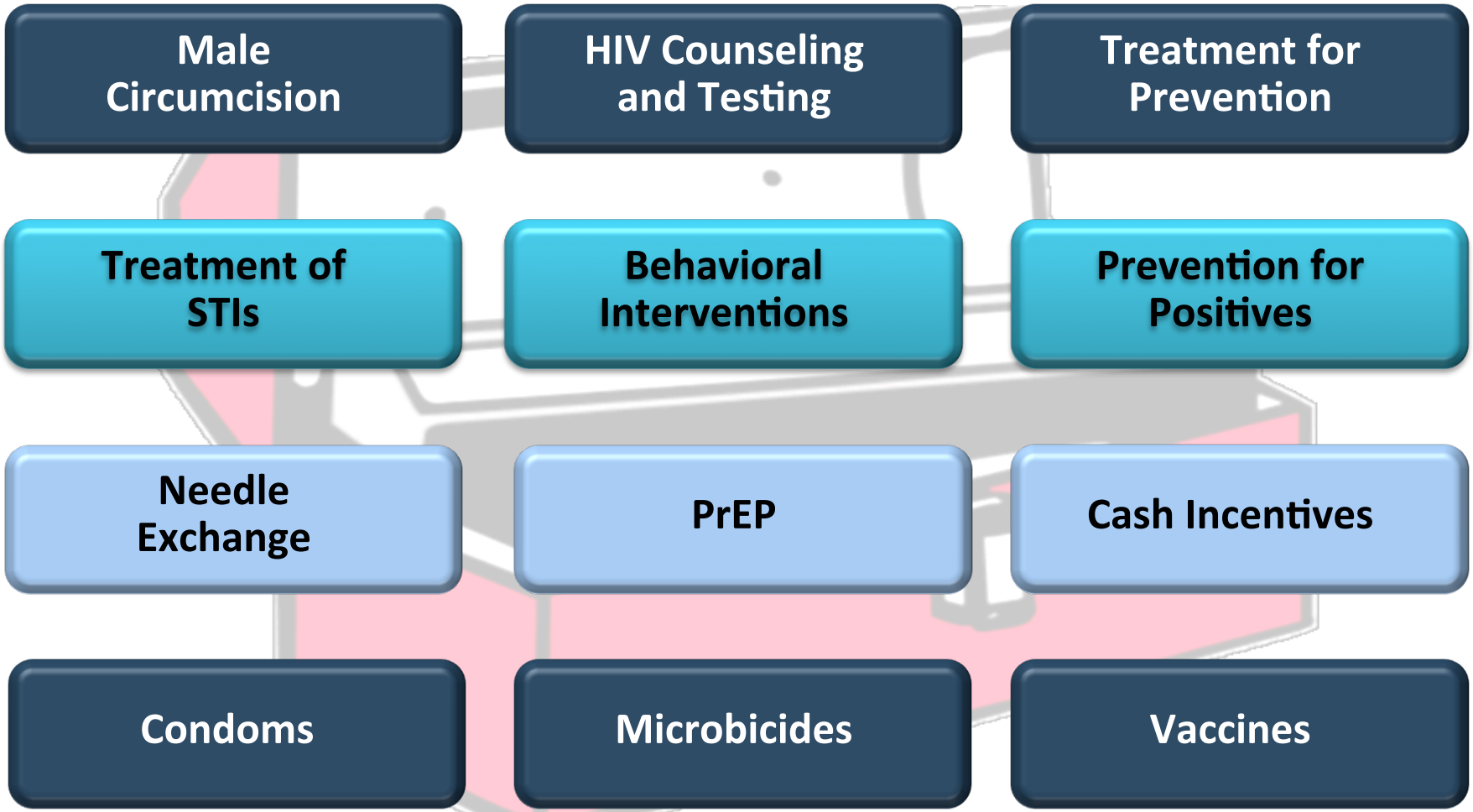
- Annual incidence of 0.32% is more than 6 times the CDC estimated national incidence for similarly aged black women

Univariate Analysis of Potential Factors Associated with HIV Infection

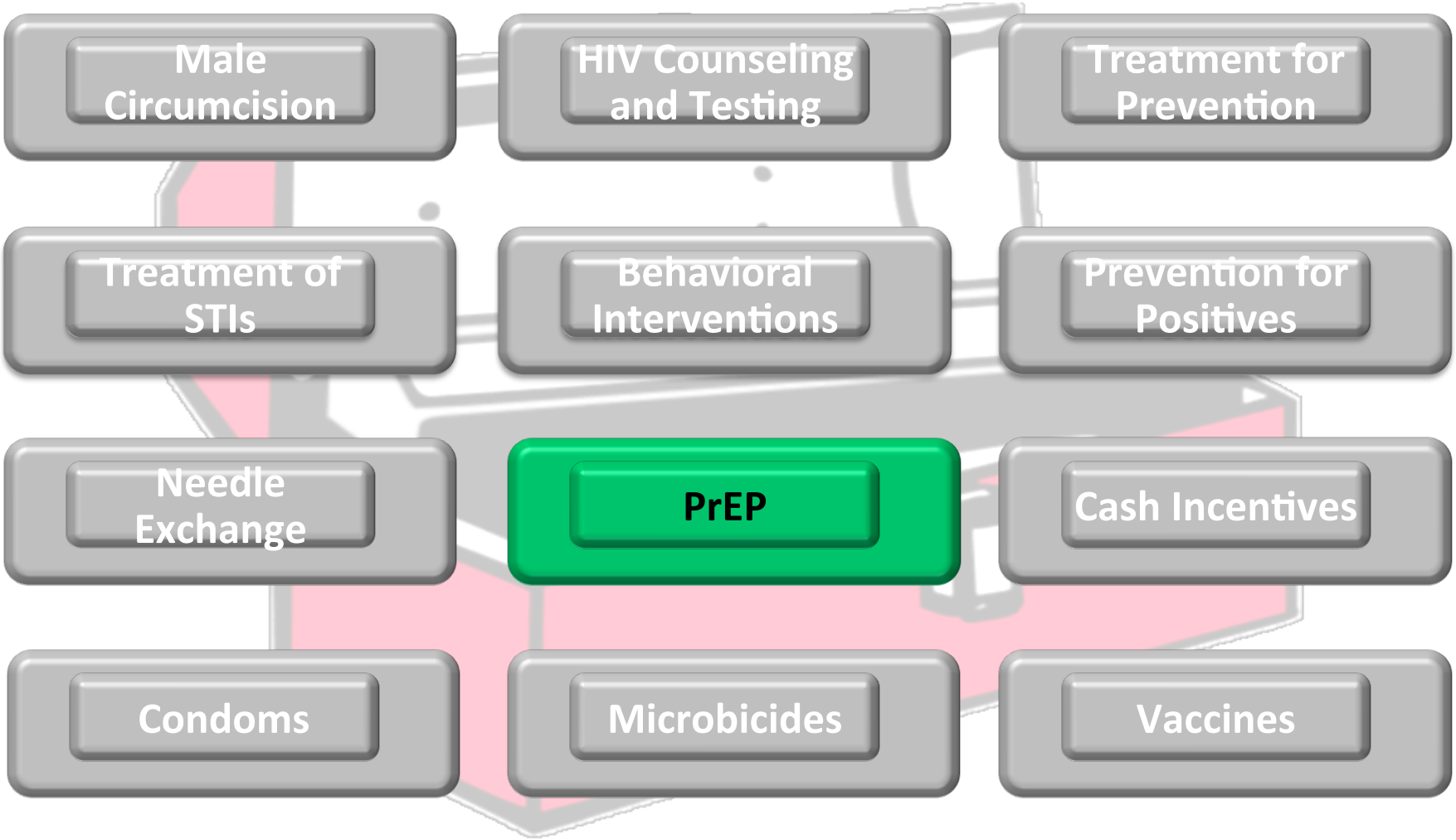
Participant Risk Factors	Prevalent HIV (n=30)	Incident HIV (n=8)
Substance Use[a]	**2.52 (1.22, 5.21)[b]**	0.57 (0.06, 3.18)
Age (27-33 vs. 18-26)	**5.83 (1.22, 27.96)[b]**	0.84 (0.08, 5.89)
Age (34+ vs. 18-26)	**11.54 (2.71, 49.05)[b]**	0.57 (0.05, 3.94)
HIV Diagnosis of partner	**8.19 (2.64, 25.42)[b]**	0.0 (0.0, 47.90)

[a] Within the previous 6 months. [b] $p<0.05$

HIV Combination Prevention



HIV Combination Prevention



US Women are Being Prescribed PrEP

- Between January 2011 and March 2013, pharmacy data from ~55% US pharmacies assessed for PrEP prescriptions
- Total of 1,774 subjects were identified as starting TVD for PrEP.
  - 47.7% women

Mera RM et al. ICAAC 2013, Poster H-663a

HPTN PrEP Agenda

- Evaluate the efficacy of an ARV regimen containing new oral drugs (such as maraviroc (MVC) for PrEP
- Develop new agents and new formulations for PrEP including long lasting injectables
- Develop pharmacostatistical models to define the role of new agents for PrEP

HPTN Pre- Exposure Prophylaxis (PrEP) Studies

HIV Prevention Trials Network

HPTN 067

The ADAPT Study:

Alternative Dosing to Augment PrEP pill-Taking

HIV Prevention Trials Network

Main Study Questions

- How does taking oral Truvada® tablets intermittently compare to taking the tablets daily? Will participants in the intermittent groups:
  - have the same coverage of sex events,
  - need fewer tablets for coverage, and
  - report fewer side effects compared to participants who take their tablets daily?

Study Groups

Truvada taken:

1. Daily
2. Event-driven (before and after sex)
3. Time-driven (2 times a week and a booster after sex)

No more than

- 2 tablets in a 24-hour period
- 7 tablets in a week.

Daily

180 Participants

- 120 MSM
- 60 Women

Time Driven

180 Participants

- 120 MSM
- 60 Women

Event Driven

180 Participants

- 120 MSM
- 60 Women

HPTN 069/ACTG 5305
NEXT-PREP:
Novel Exploration of Therapeutics for PREP

HIV Prevention Trials Network

HPTN 069 Study Groups

- There are 3 active drugs:
  - maraviroc (MVC)
  - emtricitabine (FTC)
  - tenofovir (TDF)

- Study Regimens (3 pills/arm):
  - **maraviroc** + FTC placebo + TDF placebo
  - **maraviroc + emtricitabine** + TDF placebo
  - **maraviroc + tenofovir** + FTC placebo
  - **tenofovir + emtricitabine** + MVC placebo

HPTN 069 Endpoints

Primary Endpoint:

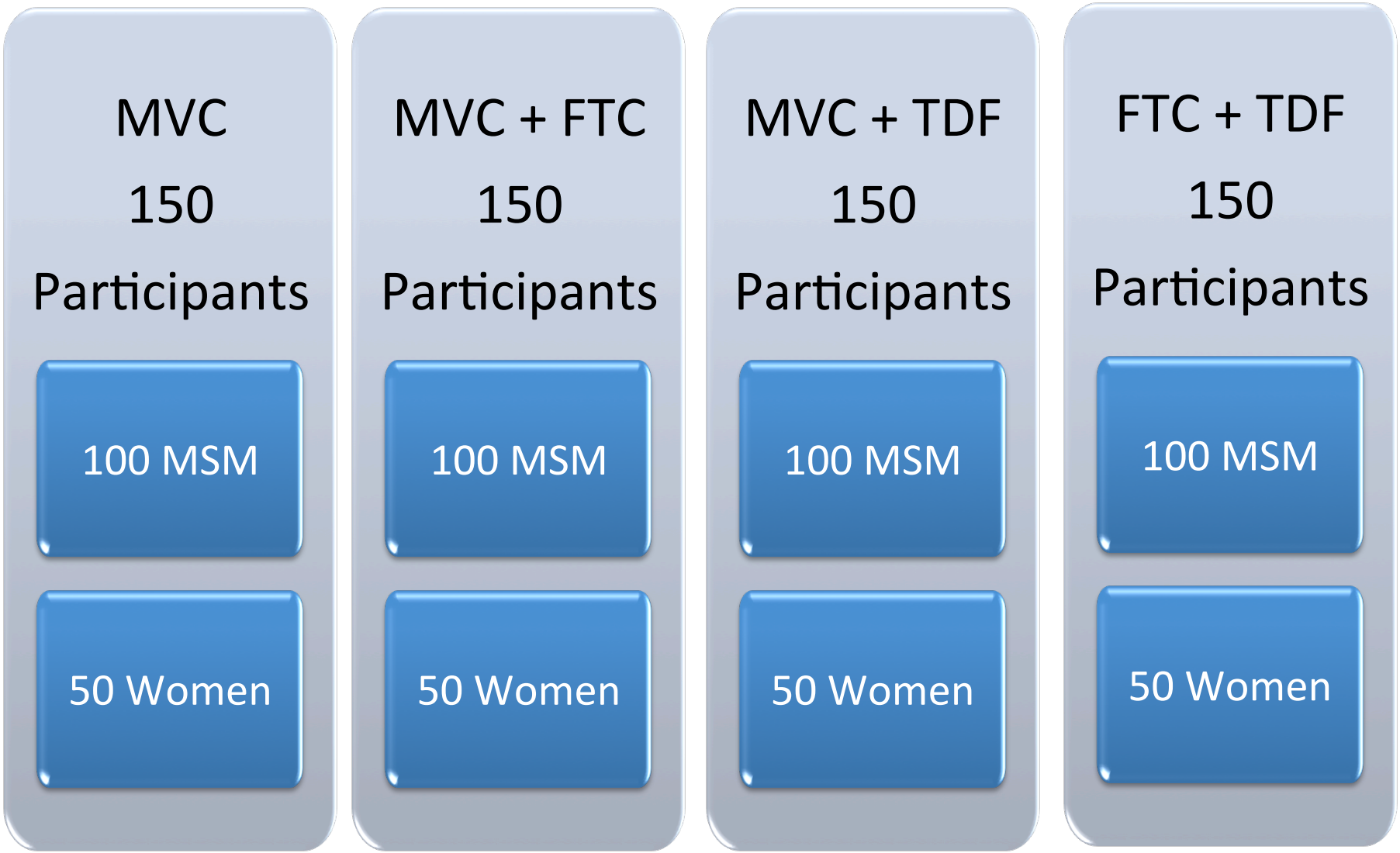
- Grade ≥3 toxicities; time to study treatment discontinuation

Secondary Endpoints:

- Assess changes in bone mineral density
- Evaluate drug concentrations of in plasma, peripheral blood mononuclear cells (PBMC), rectal tissue and fluid, and cervical tissue and cervicovaginal fluid, in a subset of participants
- Assess adherence as measured by an electronic drug monitoring device (EDM)
- Assess and characterize sexual behavior over time as measured by computer-assisted self-interview (CASI).
- Evaluate the association of drug concentrations with other adherence measures

Exploratory Objective

- Determine whether oral PrEP is associated with suppression of HIV replication in colorectal and cervical explants (*ex vivo* HIV challenge, Tissue Subset).


MVC
150
Participants
100 MSM
50 Women
MVC + FTC
150
Participants
100 MSM
50 Women
MVC + TDF
150
Participants
100 MSM
50 Women
FTC + TDF
150
Participants
100 MSM
50 Women

HPTN 073: PrEP Adherence and Uptake Among BMSM in Three US Cities

HIV Prevention Trials Network

HPTN 073 Study Design

- Demonstration project
- Once daily oral emtricitabine 200 mg / tenofovir disoproxil fumarate 300 mg (FTC/TDF)
- Client-centered care coordination (C4)

Main Study Questions

- How willing BMSM are to take PrEP
- How consistently the men who do decide to take PrEP, take it as prescribed
- How the men evaluate the experience of using PrEP, and
- Is it acceptable for local health care facilities to administer client-centered care coordination (C4) along with PrEP to BMSM

Chapel Hill, NC

75 Participants

- 5 PrEP Uptake Interviews
- 5 PrEP Non-Initiator Interviews
- Site Staff C4 Focus Group

Los Angeles, CA

75 Participants

- 5 PrEP Uptake Interviews
- 5 PrEP Non-Initiator Interviews
- Site Staff C4 Focus Group

Washington, DC

75 Participants

- 5 PrEP Uptake Interviews
- 5 PrEP Non-Initiator Interviews
- Site Staff C4 Focus Group

HPTN 076: Injectable Pre-Exposure Prophylaxis (PrEP)

HIV Prevention Trials Network

HPTN 076 Main Study Questions

- Is injectable rilpivirine PrEP safe for women?
- Will women find injectable PrEP acceptable for use?
- Is injectable PrEP tolerable for women?

Study in Development

- Total of 132 participants participants at 4 sites
  - 48 at each international site
  - 18 at each US site
- Injectable PrEP vs injectable placebo

Conclusions

- Existing data suggest that US women are at risk and are actively being prescribed antiretroviral therapy for prophylaxis
- HPTN research agenda assesses novel PrEP agents and administration strategies
- Data to be generated from the HPTN addresses the need for increased PrEP options

HIV Prevention Trials Network

THANK YOU

Wafaa El-Sadr, MD, MPH
Jonathan Lucas, MPH
Niru Sista, PhD
Sponsors
HPTN Investigators and Study Staff
Participants of past and current HPTN studies

National Institute of Allergy and Infectious Diseases

NIMH National Institute of Mental Health

National Institutes of Health

U.S. Department of Health and Human Services
National Institutes of Health
NIDA National Institute on Drug Abuse

PrEP Update:
The science, new tools, and next steps

Dawn K. Smith MD, MS, MPH
Division of HIV/AIDS Prevention, CDC
US Women & PrEP WG Webinar
16 September 2013

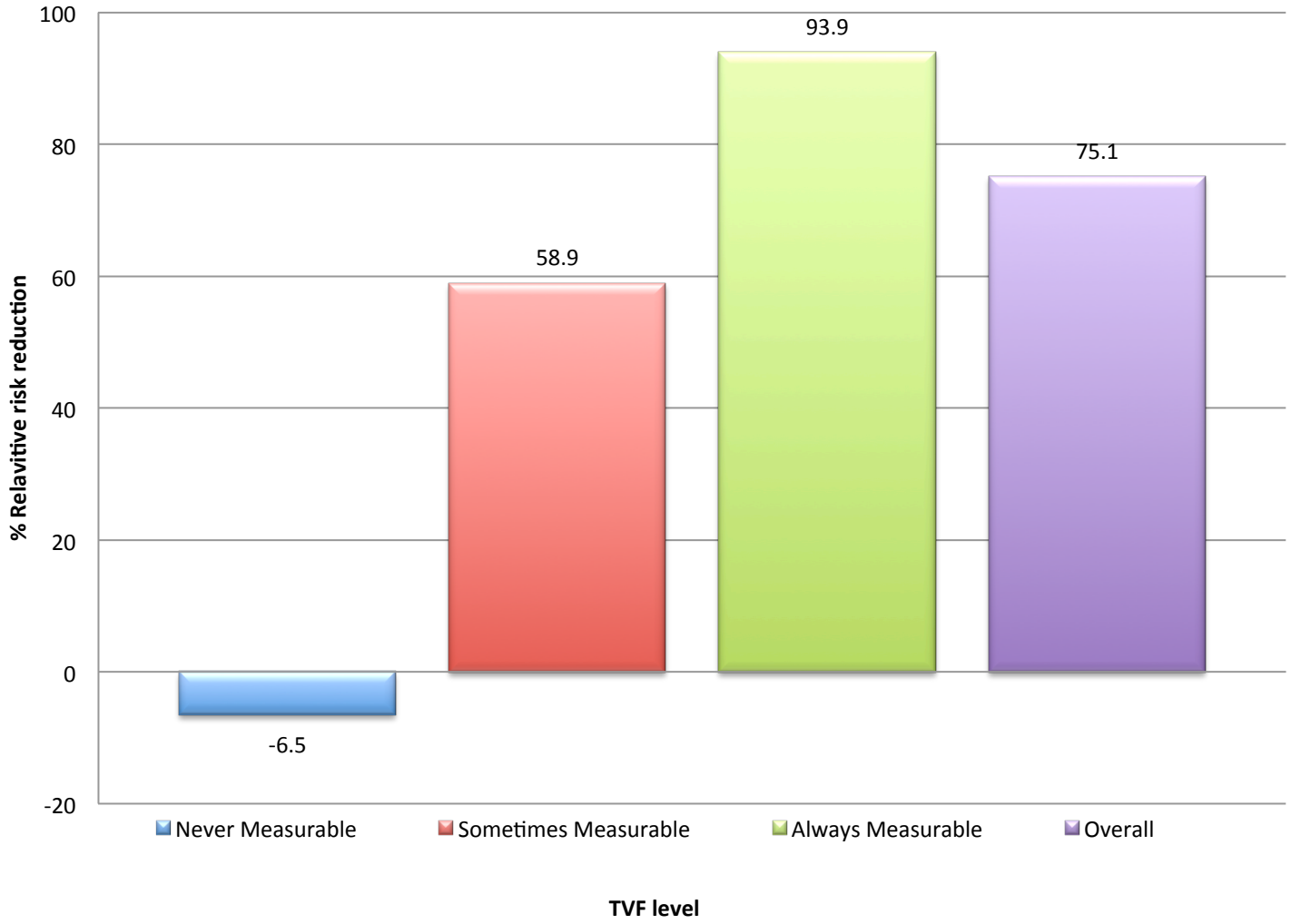
"The findings and conclusions in this presentation have not been formally disseminated by the CDC and should not be construed to represent any agency determination or policy"

PrEP Efficacy by Adherence

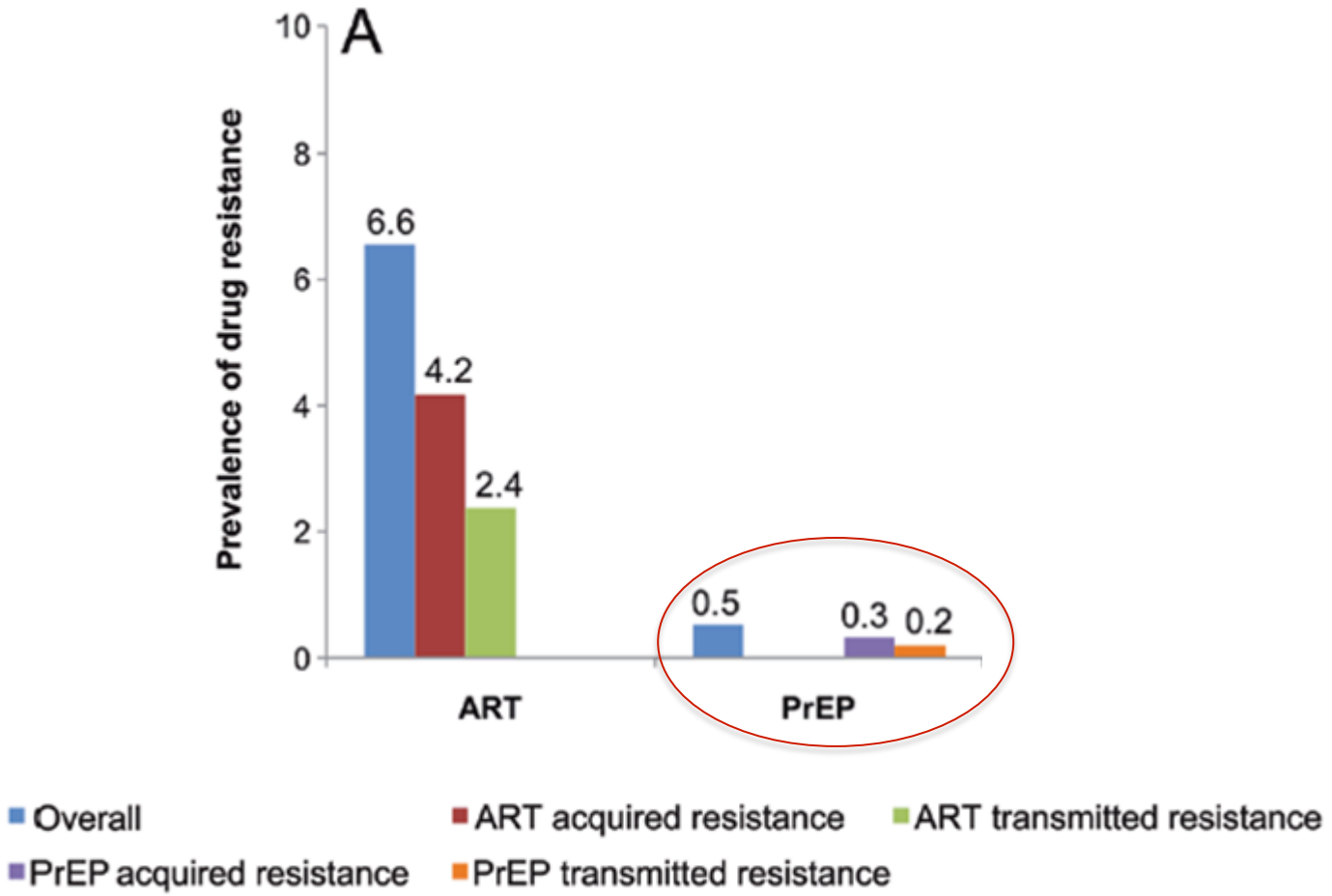
Intervention	mITT	Self-report, diary, or pill count		Drug detected
Male condom (HET)	-	80% (always vs never)	<10% (sometimes vs never)	-
PrEP – TDF/FTC (iPrEx, MSM)	44%	73% (>90% self-report+pill count)	50% (>50% self report+ pill count)	92%
PrEP – TDF/FTC (Partners PrEP, HET)	75%	100% (>80% pill count)	-	90%
PrEP – TDF (BTS)	49%	56% (>71% diary)	-	70%

Sources: Weller S, Davis K. Condom effectiveness in reducing heterosexual HIV transmission. *Cochrane Database Syst Rev.* 2002(1):CD003255.
Grant RM et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *NEJM.* 2010;363(27):2587-2599.
Baeten JM et al. Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women. *NEJM.* 2012;367(5):399-410.
Choopanya K et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand. *Lancet* 2013;381(9883):2083-2090.

Relative risk reduction in acquiring HIV infection (compared with placebo) based on plasma TFV concentrations (Partners PrEP)



Resistance, ART, and PrEP



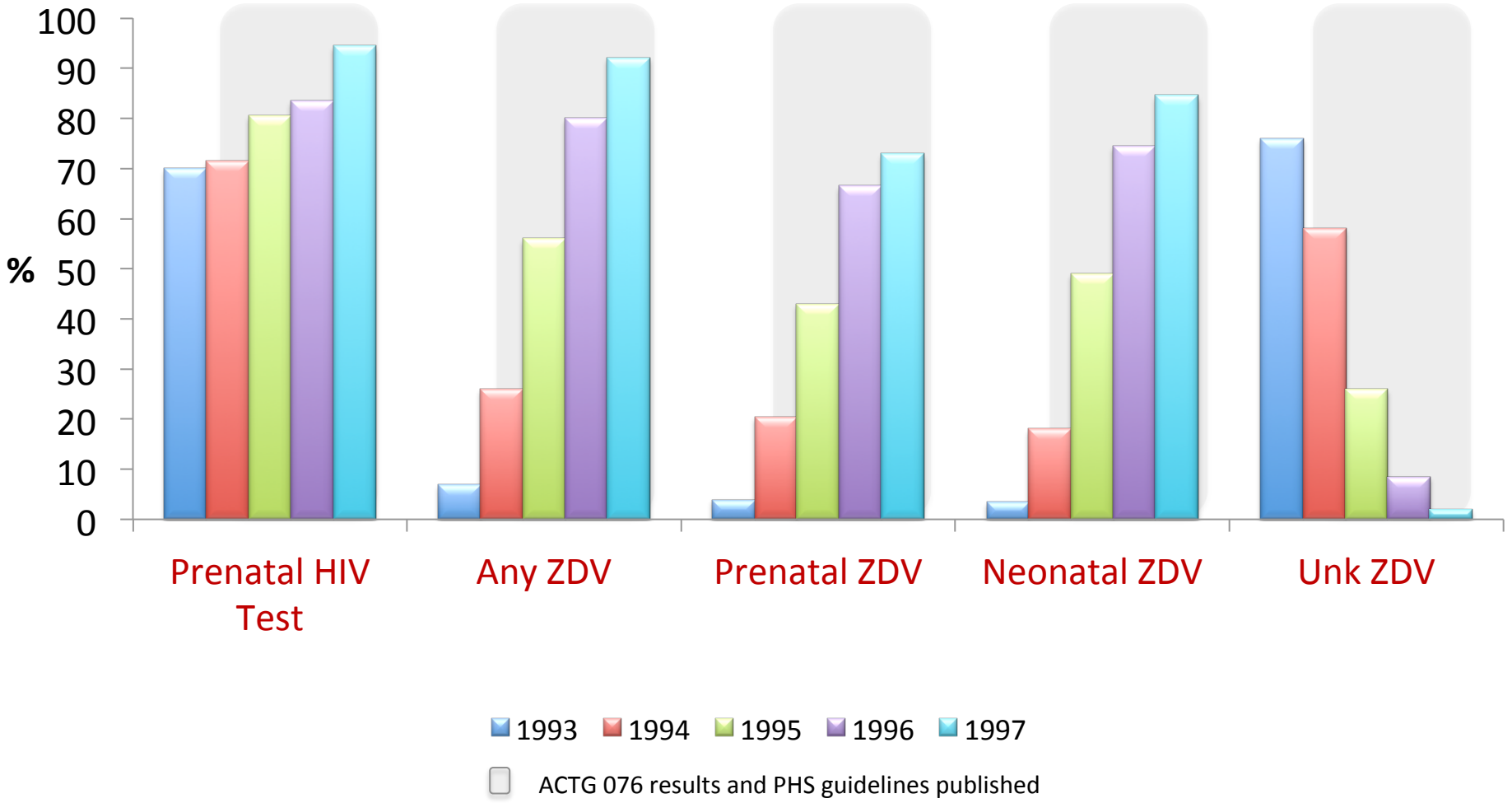
Source: Abbas UL et al. JID 2013;208:224–34.

Implementation Science

- Adoption
- Diffusion (passive)
- Implementation (active)
- Institutionalization (sustainability)

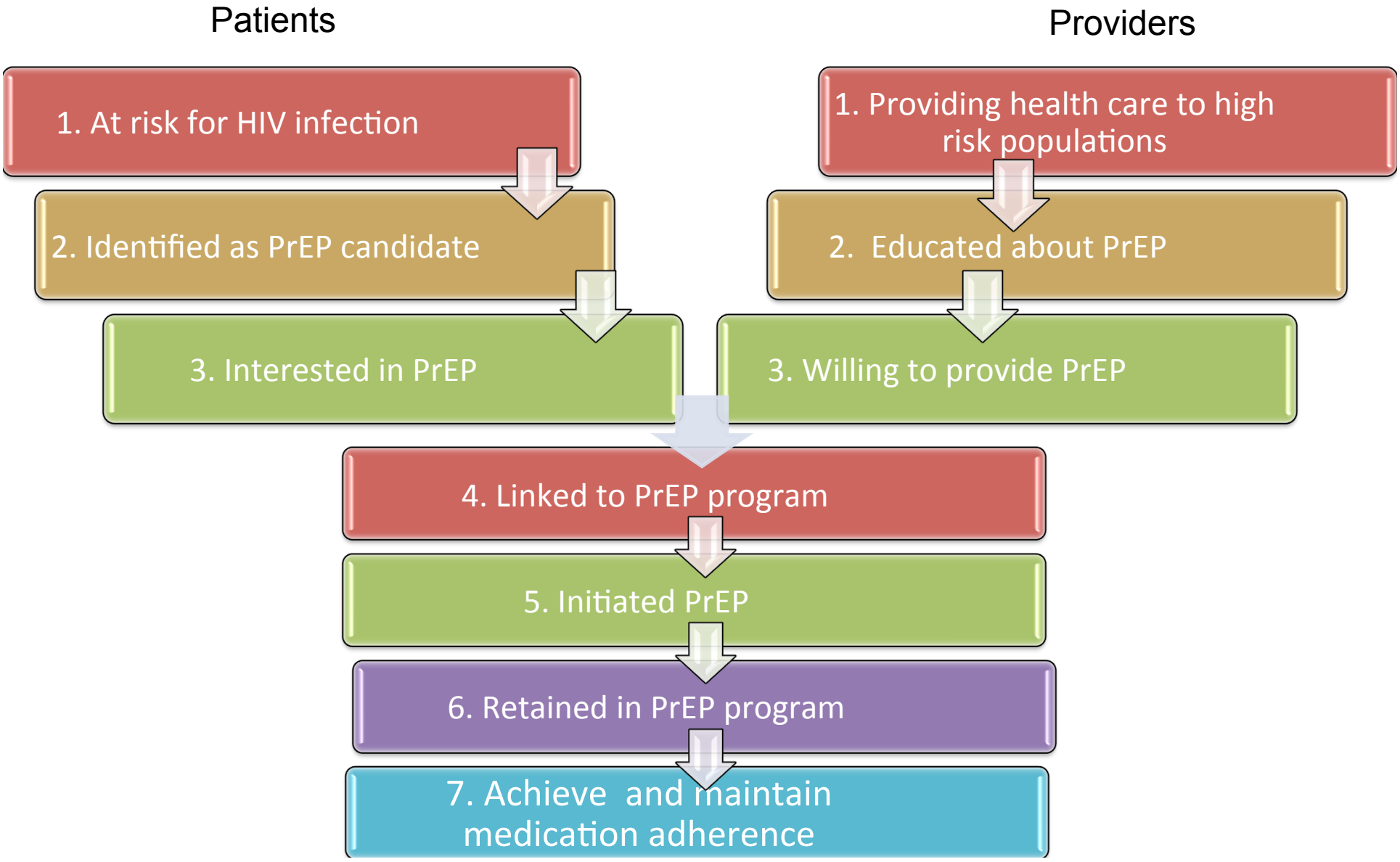
Uptake of ZDV for perinatal prevention

(in 18 states with HIV surveillance)



Source: Lindegren et al., JAMA 1999; 282-531-38

PrEP Cascade



Evidence of PrEP Use
HIV Care Providers, mid-2011

- 78% had read Interim Guidance for MSM
- 43% had patients who requested PrEP
- **19% had prescribed PrEP, of those**
  - 78% for MSM 31% for MSW 28% for WSM
  - 83% prescribed TDF/FTC
  - 92% documented initial HIV-negative status
  - 25% did not test for acute HIV infection-if symptomatic
  - 17% did not confirm ongoing risk behaviors

N=189, web survey of members of AAHIVM

Source: Maznavi et al., IDSA, 2011

Estimating PrEP Uptake

- 3,000+ patients in US PrEP post-approval studies 2013-2014
- Gilead analysis:
  - Retail prescriptions for ~ 55% of US pharmacies, claims data
  - PrEP prescribers in ~700 US cities, 49 states
    - 31% family practice and internal medicine
    - 17% non-physician prescribers (NP and PA)
    - 14% emergency medicine
    - 12% infectious disease
    - 37% also prescribed Truvada for HIV treatment
  - Prescriptions increasing 2011-2013
    - 13.6% were for persons under age 25 years
    - 47.7% were for women
  - In 2013, anticipated as many as 2545 PrEP prescriptions

Source: Levin J, et al. ICAAC 2013

Tools for implementation of PrEP in clinical practice

- PrEP Guidelines
  - Interim guidance
  - PHS guidelines
  - Local protocols
- Risk screening tools (for MSM, IDU, HRH, and HDC)
- Local prevalence data
  - Health department reports
  - www.AIDSvue.org
- Brief risk counseling protocols
- Billing codes for PrEP-related care

PrEP Patient Assistance Program

3 Statement of Medical Necessity

Statement of Medical Necessity for Financially Needy Applicants. To the best of my knowledge, this applicant has no coverage (including Medicaid or other public programs) for TRUVADA. I certify that the medication(s) listed above are medically indicated for this applicant and that I will be supervising the applicant's treatment. I certify that I am prescribing TRUVADA for PrEP as part of a risk reduction strategy for HIV prevention for this applicant. I certify that the applicant has been tested for HIV infection and found to be HIV negative, and regular HIV testing will be conducted as part of the applicant's care plan. As part of my applicant's eligibility, I agree to periodically verify continued use of Gilead medication and resubmit current prescriptions.

SIGN HERE **Prescriber Signature:**_____ **Date:**_____

Applications are considered complete only if they include all of the following:

- Front and Back Pages of Enrollment Form
- Applicant as well as Prescriber Signatures and Dates
- Documentation of Income Sources and Residency
- Copy of Prescription

When complete, **FAX** application and documentation to: **1-855-330-5478**

Gilead Sciences, Inc.
Medication Assistance Program
P.O. Box 13185

Social Security #: ___ ___ ___ – ___ ___ – ___ ___ ___ ___	Date of Birth: MM ___ / DD ___ / YYYY ____	Gender: M ☐ F ☐	Resides in U.S/U.S. territories: YES ☐ NO ☐

Primary Contact:_____ Relationship:_____ Phone Number: _____

Applicant Financial Information

Current Annual Household Income: $_____ Number in Household (circle one): **1 2 3 4 5 6** _____
Please include current documentation for all sources of income (eg, tax return, W2, last 2 pay stubs, etc).

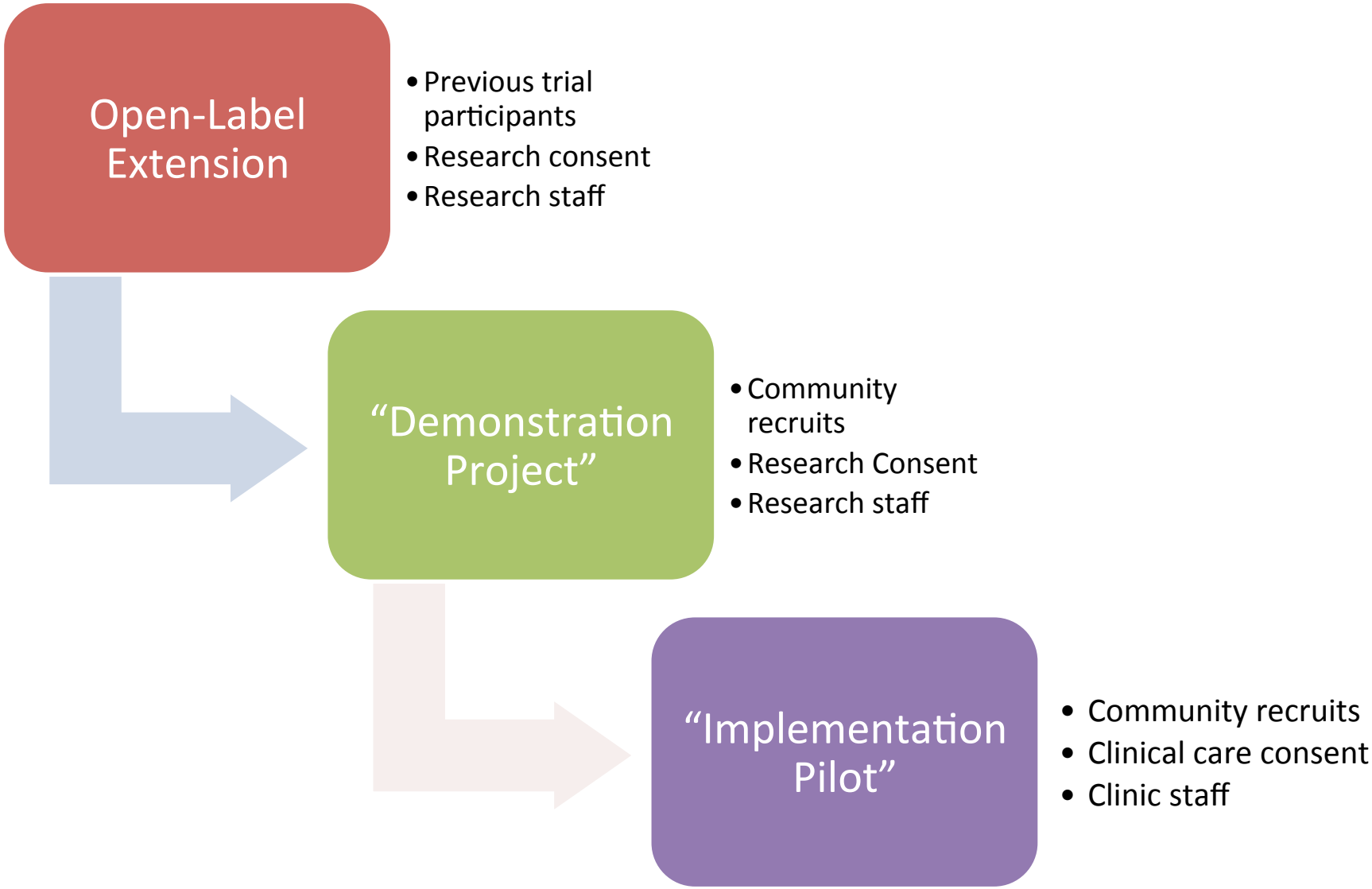
☐ **Applicant is insured** (Please fill out all the applicable insurance information below. Attach copy (front and back) of applicant insurance card.)

☐ **Applicant is uninsured** (No health insurance through any public or private payer.) Complete **"Additional Insurance Information"** below.

Next Steps

- With what we know now:
  - Increase awareness and linkage to clinical care for persons who might benefit from PrEP use
  - Increase awareness and training for providers interested in offering PrEP to their patients
  - Increase systematic monitoring of PrEP use and its health impact
- With what we will learn soon:
  - Incorporate lessons learned from OLE and demonstration projects
  - Continue implementation research
  - Continue clinical research

Post-Trial PrEP Studies



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"The findings and conclusions in this presentation have not all been formally disseminated by the CDC and should not be construed to represent any agency determination or policy"