François-Xavier Bagnoud Center
School of Nursing, University of Medicine & Dentistry of New Jersey

CDC's Interim Guidance on the Use of PrEP in Heterosexually Active Adults: Implications for Clinical Practice

Welcome!

The webinar will begin at
1:00 p.m. ET/12 p.m. CT/11 a.m. MT/10 a.m. PT

To join by phone: 1-888-205-5513
Enter participant Code: 654543#

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This teleconference was made possible by the Cooperative Agreement #1U65PS003776-01 from the U.S. Centers for Disease Control and Prevention

Special thanks to our AETC, Title X, and National HIV/AIDS Clinicians' Consultation Center partners

Navigating the Webinar

- Participant phone lines will be muted during the presentations.
- You may type a question in the **CHAT BOX** on the lower right side of your screen at any time. Presenters will address questions during the Q&A sessions after each presentation.
- Throughout the webinar we will ask **POLL** questions
  - A separate window will show the poll questions
  - Choose your response
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Navigating the Webinar

- This webinar will be recorded and will be available for later viewing:
  - http://www.aids-etc.org
  - http://www.fxbcenter.org

- Please complete the webinar evaluation:
  - https://www.surveymonkey.com/s/PrEPGuidanceWebinar

Agenda

1:00* Welcome

1:05 Overview of CDC's Interim Guidelines on the Use of PrEP in Heterosexually Active Adults

- *Dawn Smith, MD, MS, MPH*

1:25 Implications for Clinical Practice: Case Studies

- *Deborah Cohan, MD, MPH*

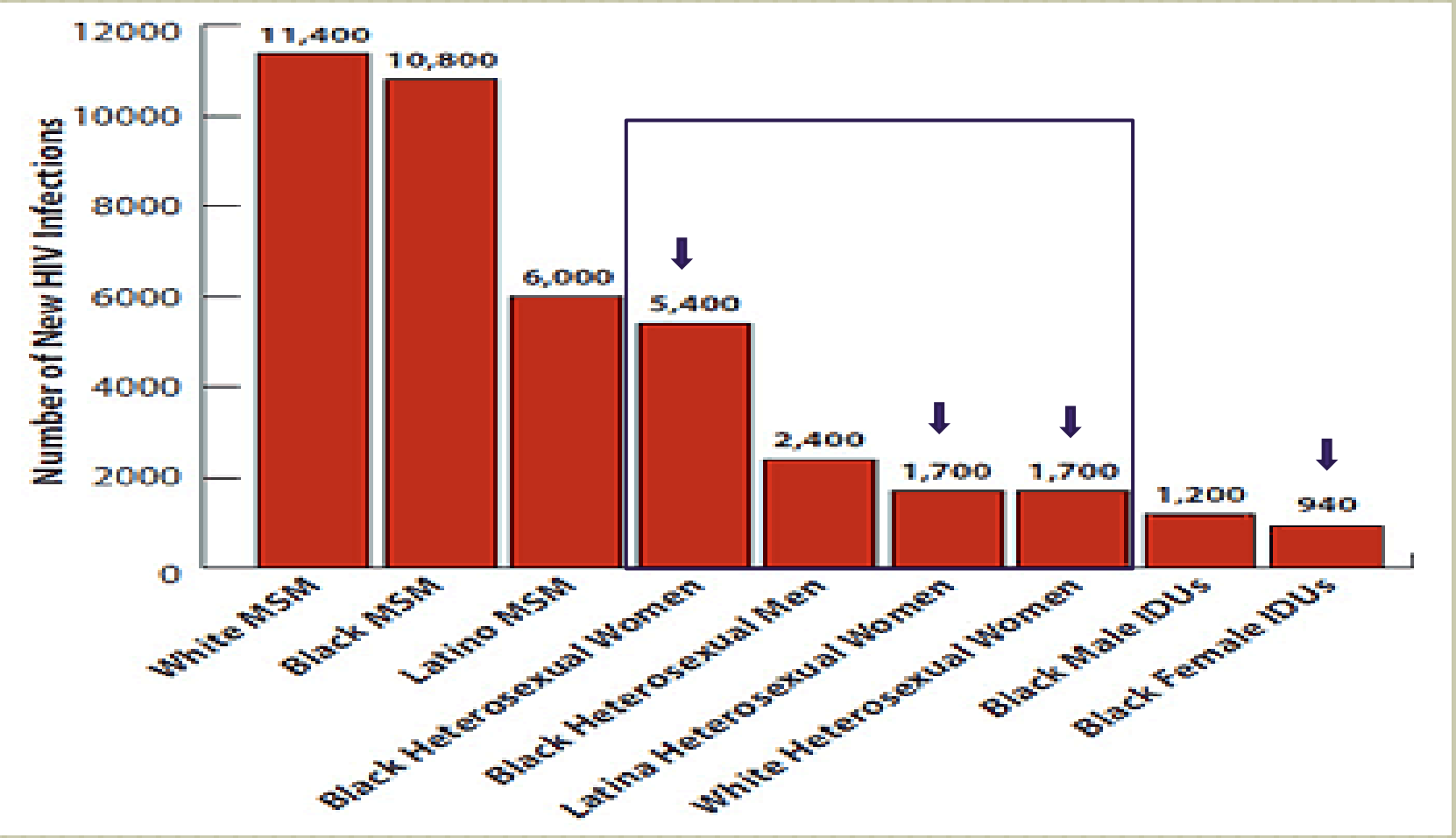
1:50 Questions and Answers

*all times listed are ET

PrEP for Heterosexually-Active Women and Men in the U.S.

Dawn K. Smith, MD, MS, MPH
Division of HIV/AIDS Prevention
Centers for Disease Control and Prevention

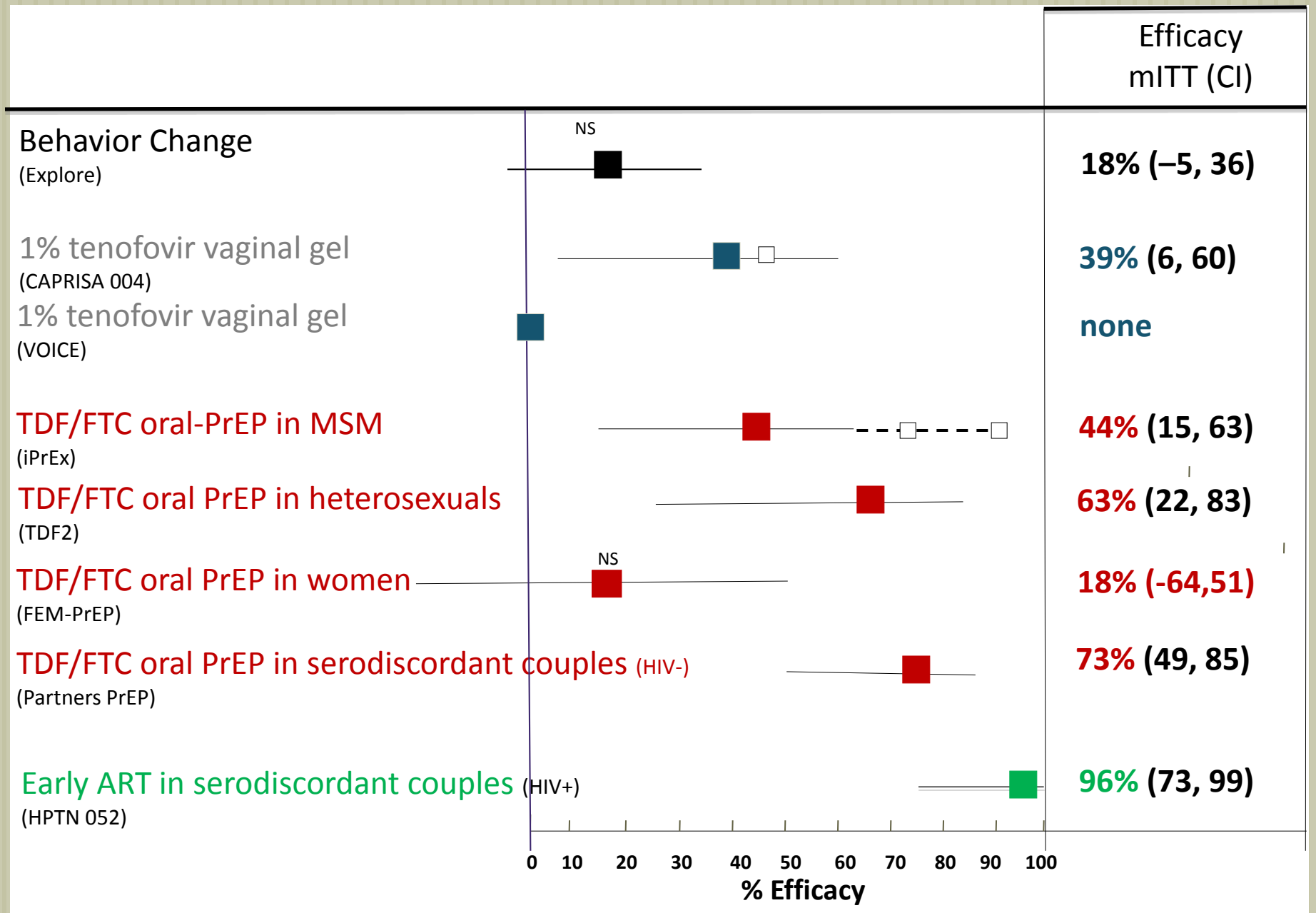
HIV Incidence in the US, 2009



Why consider PrEP?

- Need more than condoms and counseling
- Effective microbicides and vaccines still years away
- Not coitally-dependent
- Will be used with, and can enhance, existing prevention modalities
- Significantly reduces HIV acquisition for both women and men
  - Women get HIV infection from male partners
  - Men get HIV infection from female partners
  - All HIV transmission occurs in discordant partnerships (however brief)

Key Prevention Trials



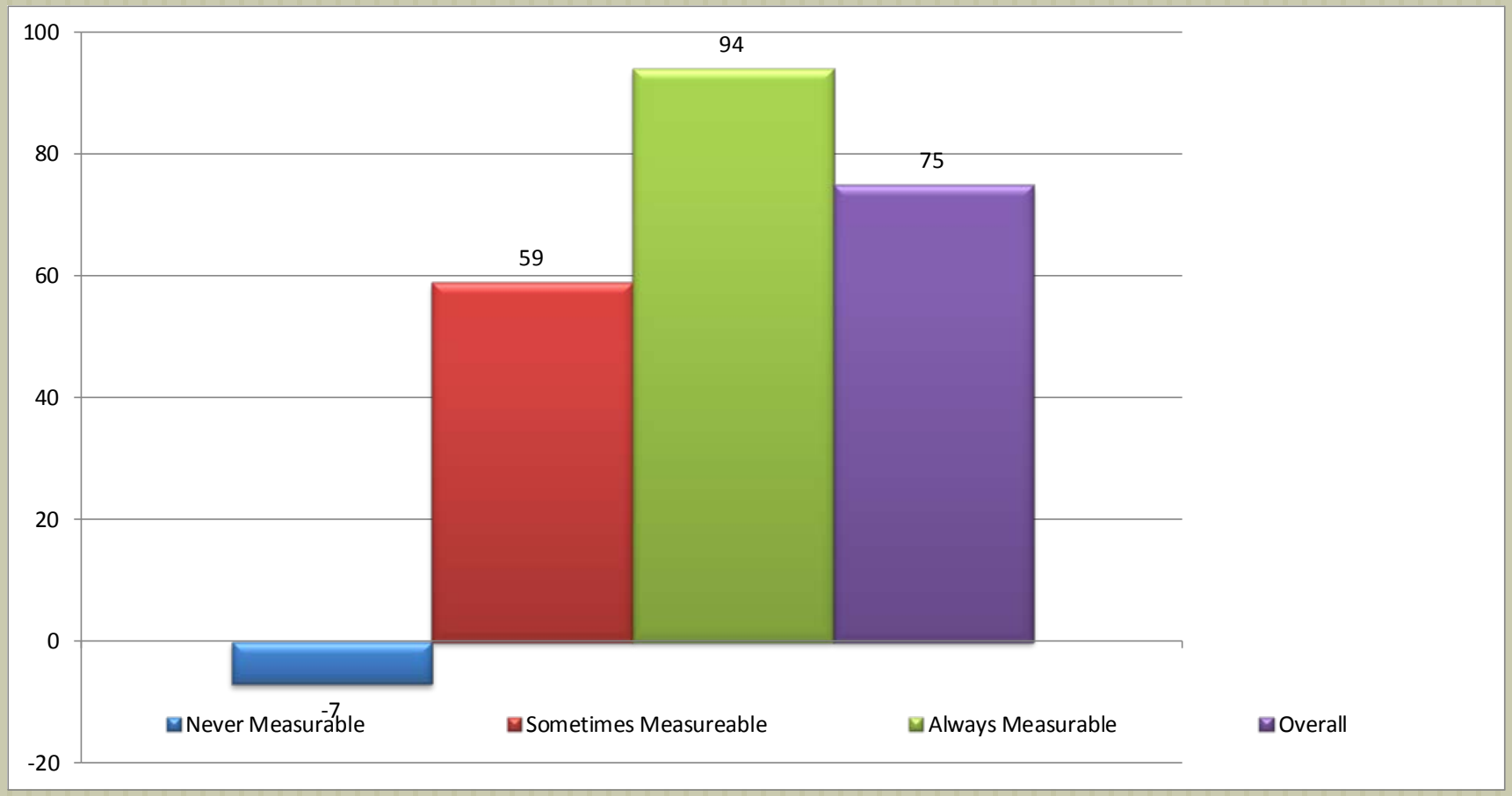
PrEP: Benefits and risks (so far)

- Primary care benefits
  - hepatitis vaccination, reproductive health care
- Cost-effective
  - Yes, if targeted to those with high incidence
- Resistance
  - Uncommon if screening for acute infection
- Toxicities/side effects
  - Few, mild, and transient
- Adherence
  - Poor in some trials, high in others
- Risk compensation
  - Not seen (yet), models suggest unlikely to exceed benefit

Key Concerns for the Safe and Effective Use of PrEP

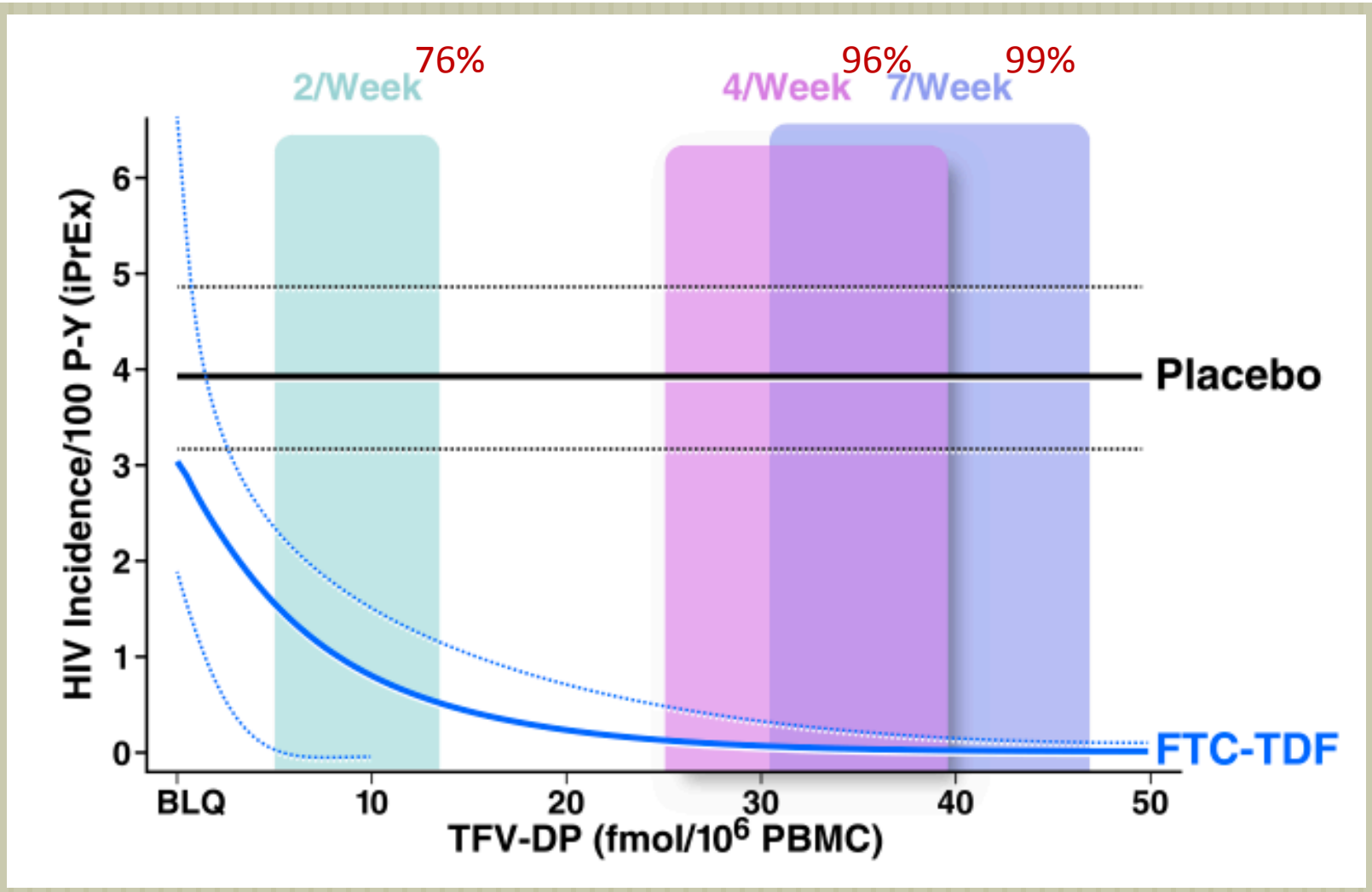
- Risk Compensation
  - Condom substitution
  - Increased risk behaviors
- Medication Adherence
  - Daily dosing
- Viral Resistance
  - Exclusion of acute HIV infection
  - Repeated HIV testing

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

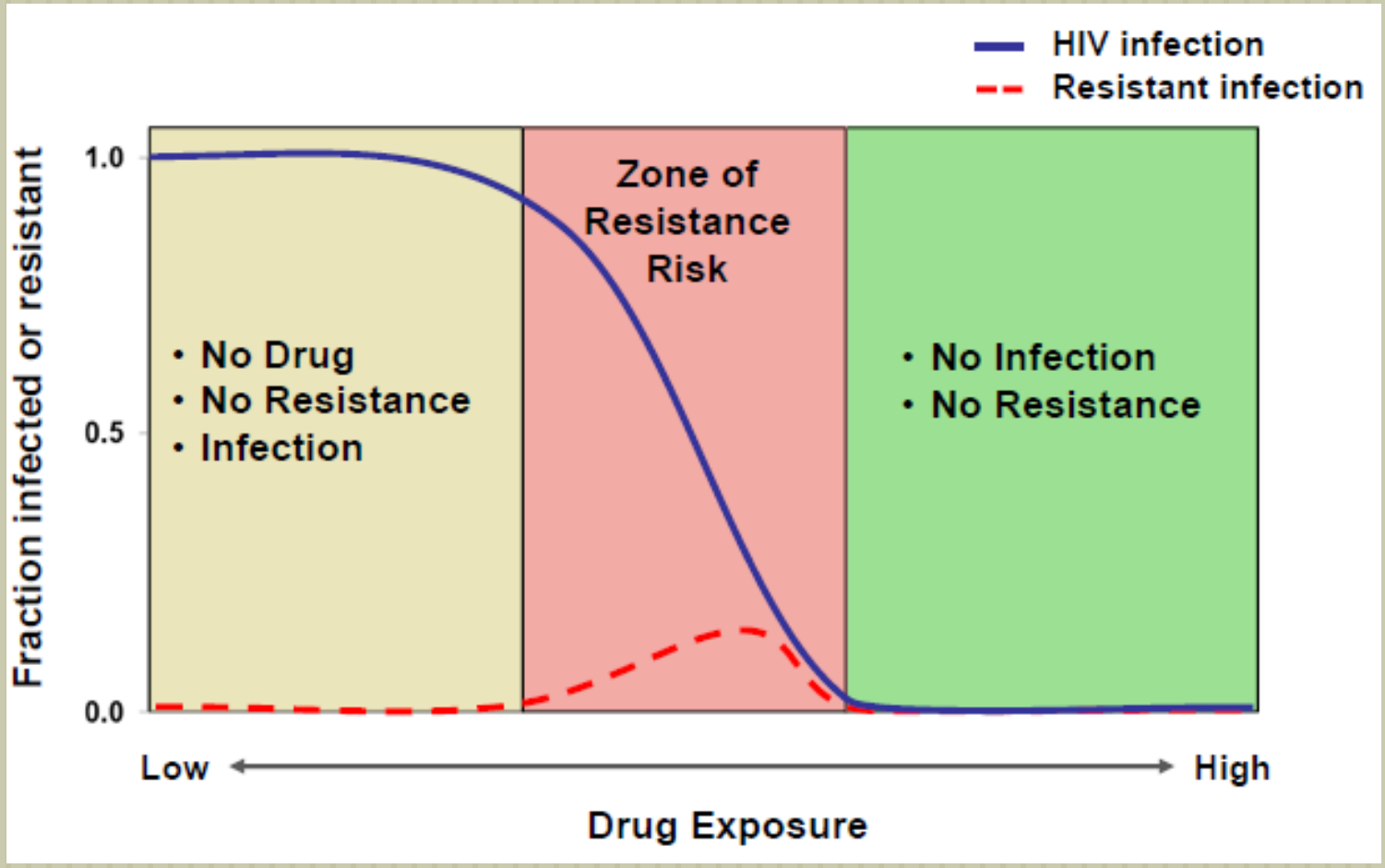


*compared with placebo

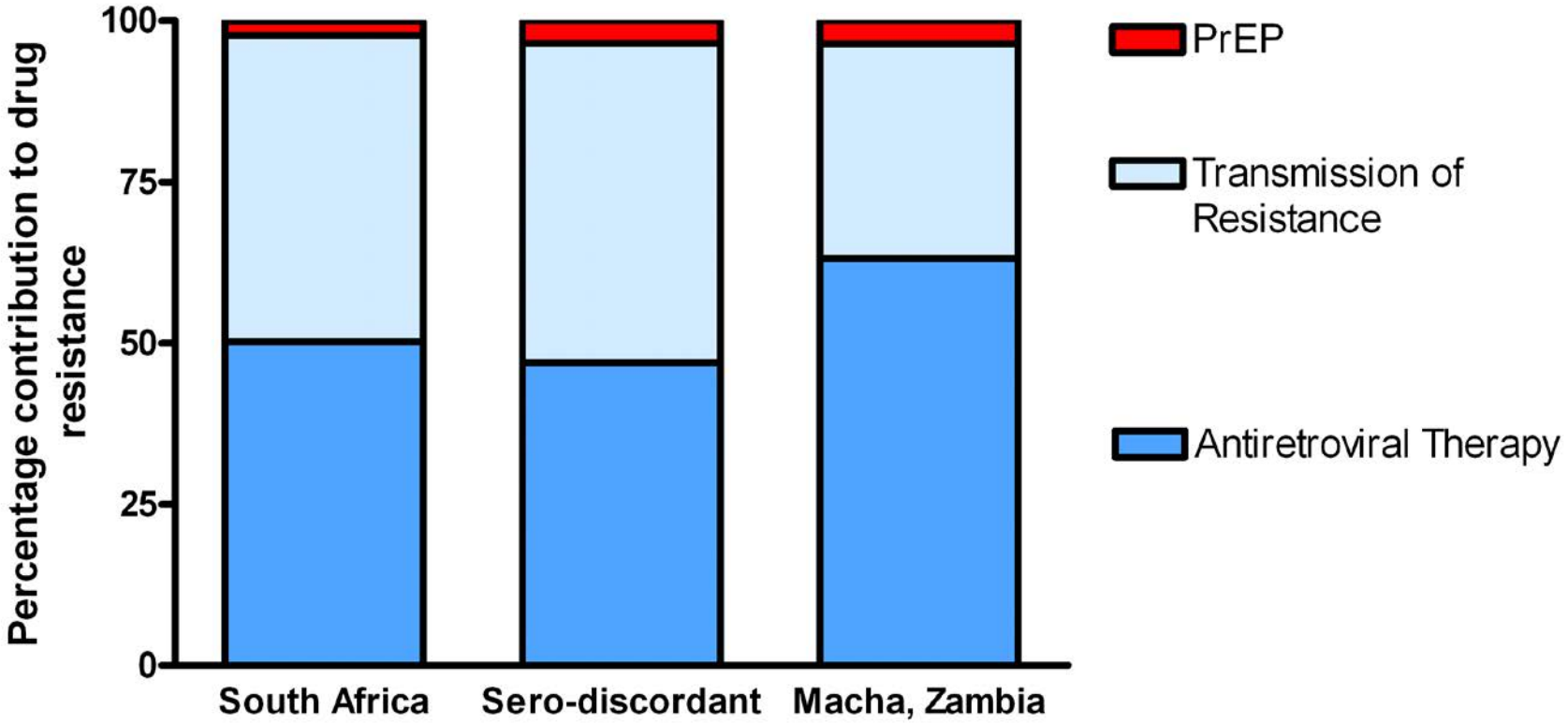
Adherence “forgiveness”



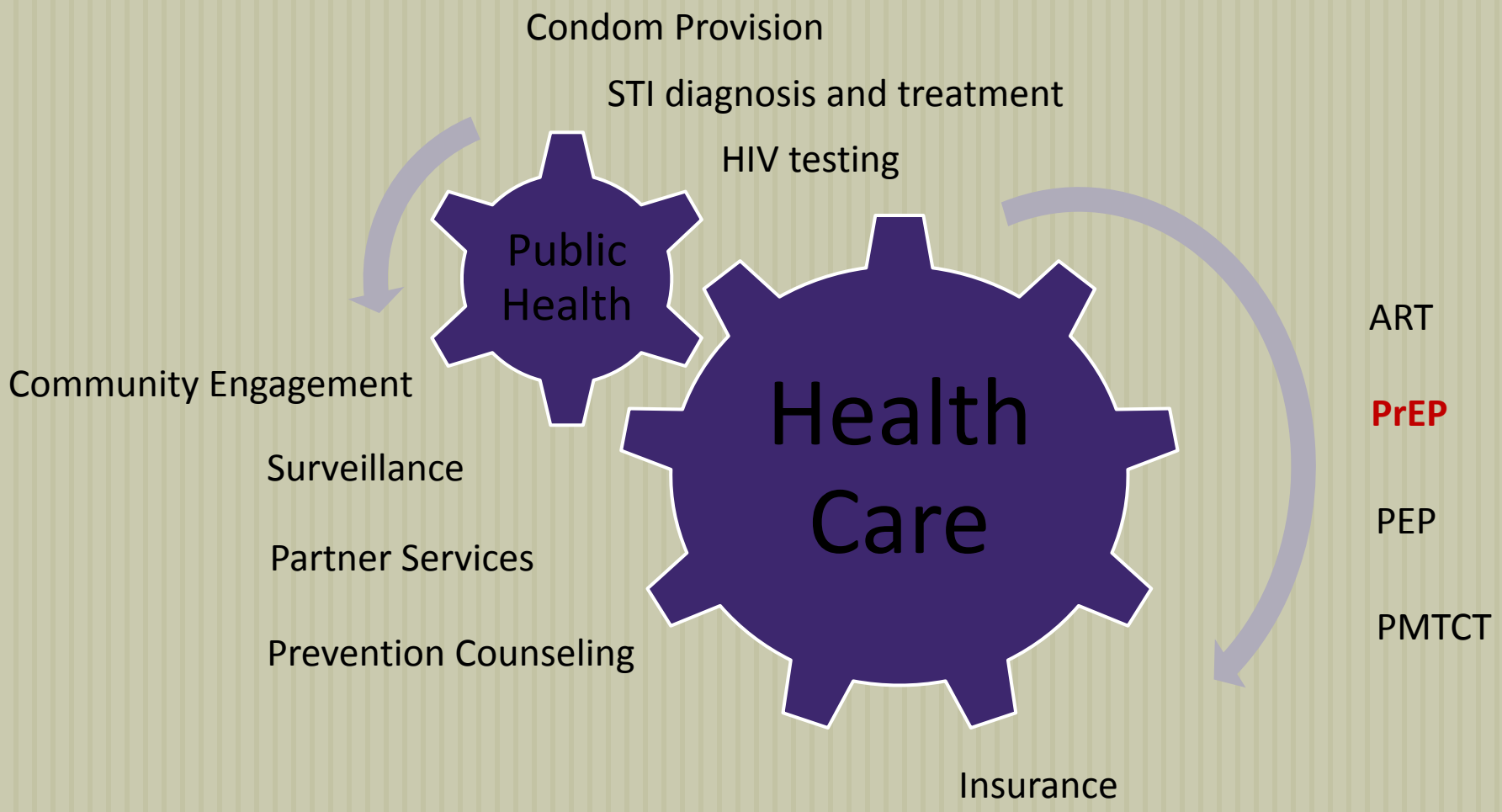
Adherence and Resistance



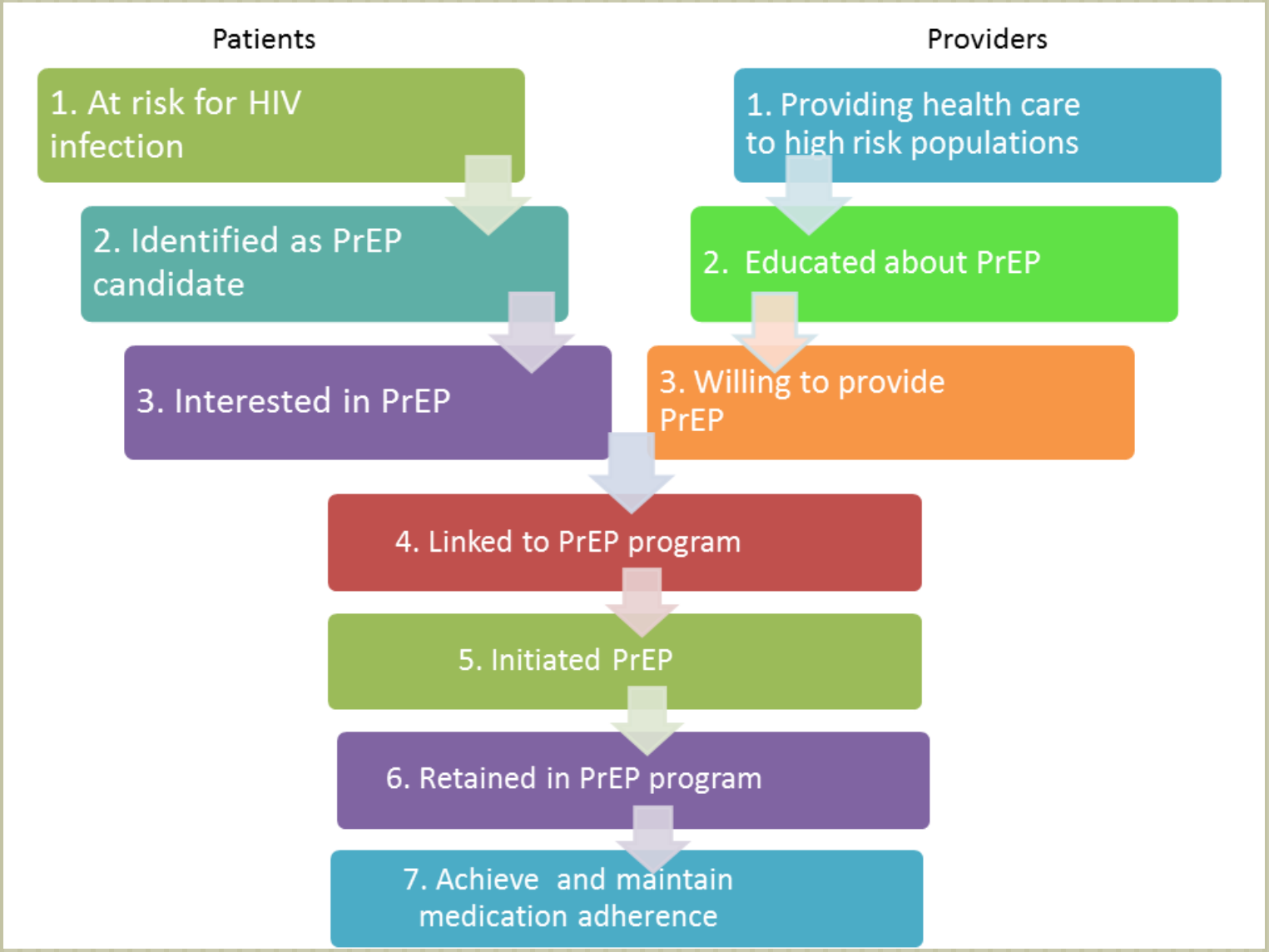
Processes contributing to resistance after 20 years



Integrating and Leveraging Biomedical HIV Prevention



PrEP Implementation Cascade



Who are the PrEP providers?

- Those who provide medical care to HIV-uninfected persons at risk of acquisition
  - Primary care
  - STD care
  - Family planning
- Those familiar with antiretrovirals
  - HIV care providers who also see uninfected patients
- Coordination of care and special issues for HIV discordant couples

Source of HIV Tests and Positive Results

- 38%-44% of adults age 18-64 have been tested
- 16-22 million persons age 18-64 tested annually in U.S.

	HIV tests*	HIV+ tests**
Private doctor/HMO	44%	17%
Hospital, ED, Outpatient	22%	27%
Community clinic (public)	9%	21%
HIV counseling/testing	5%	9%
Correctional facility	0.6%	5%
STD treatment	0.1%	6%
Drug treatment clinic	0.7%	2%

* National Health Interview Survey, 2002 ** Suppl. To HIV/AIDS Surveillance, 2000-2003

Acceptability?

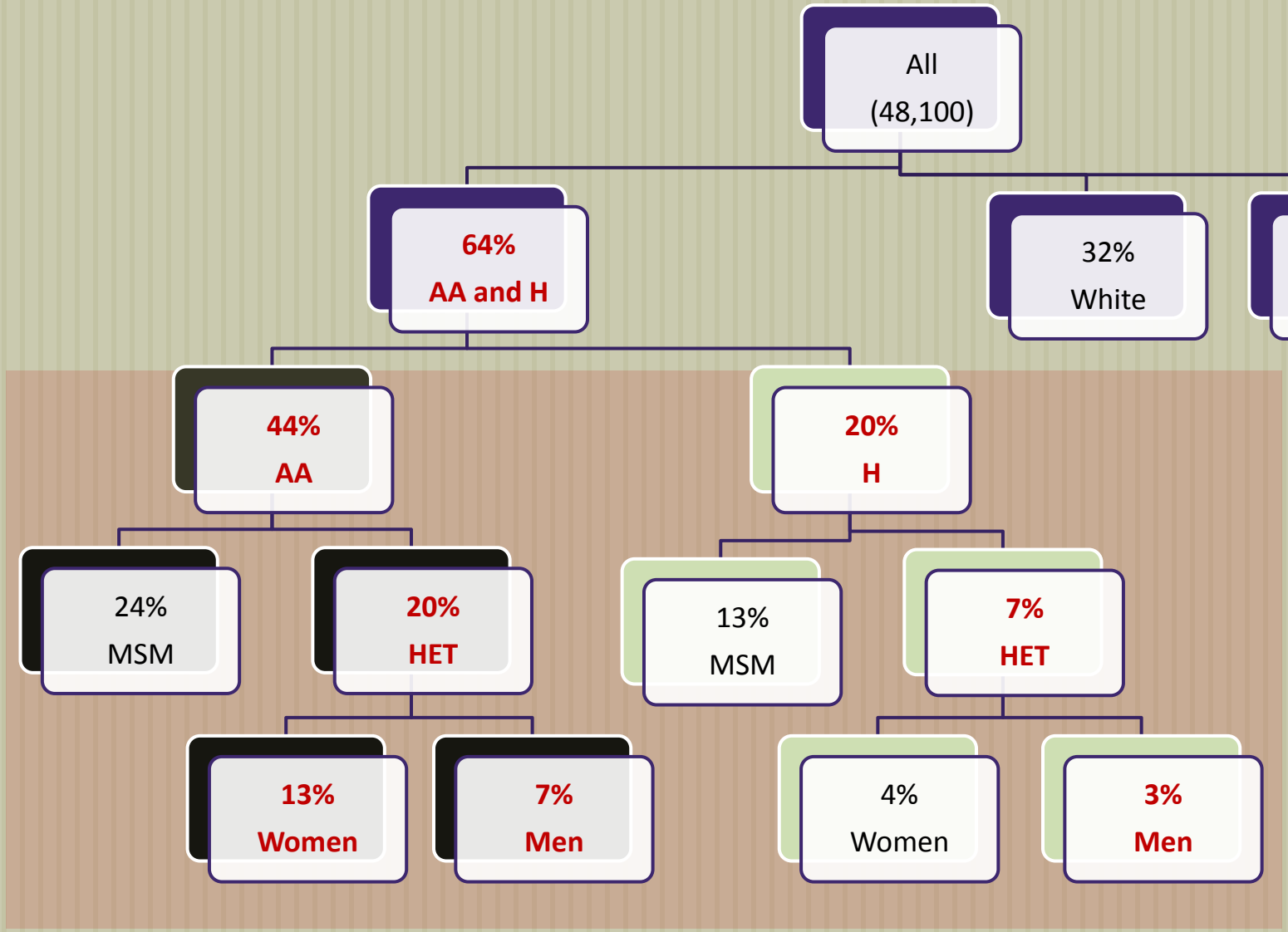
- Nearly all awareness and acceptability studies in the US have been done with MSM
  - Whiteside et al, South Carolina
    - <8 % of women had ever heard of PrEP
  - DocStyles and HealthStyles 2009

	Had heard of PrEP	Support use or prescription of PrEP				Support public funding of PrEP
		MSM	IDU	STD clients	Discordant couples	
Physicians and nurses	23%	68%	67%	39%	78%	61%
General population	5%	47%	45%	48%	70%	68%

Which Heterosexual Women and Men?

- Those with:
  - High risk of encountering HIV+ partners
    - local/network HIV prevalence
    - Known HIV+ partner (with detectable viral load?)
    - Surrogate markers (e.g., incarceration hx, poverty)
  - Inconsistent or never use of condoms during sex
    - Self-report
    - Surrogate markers (STI hx, unintended pregnancy)

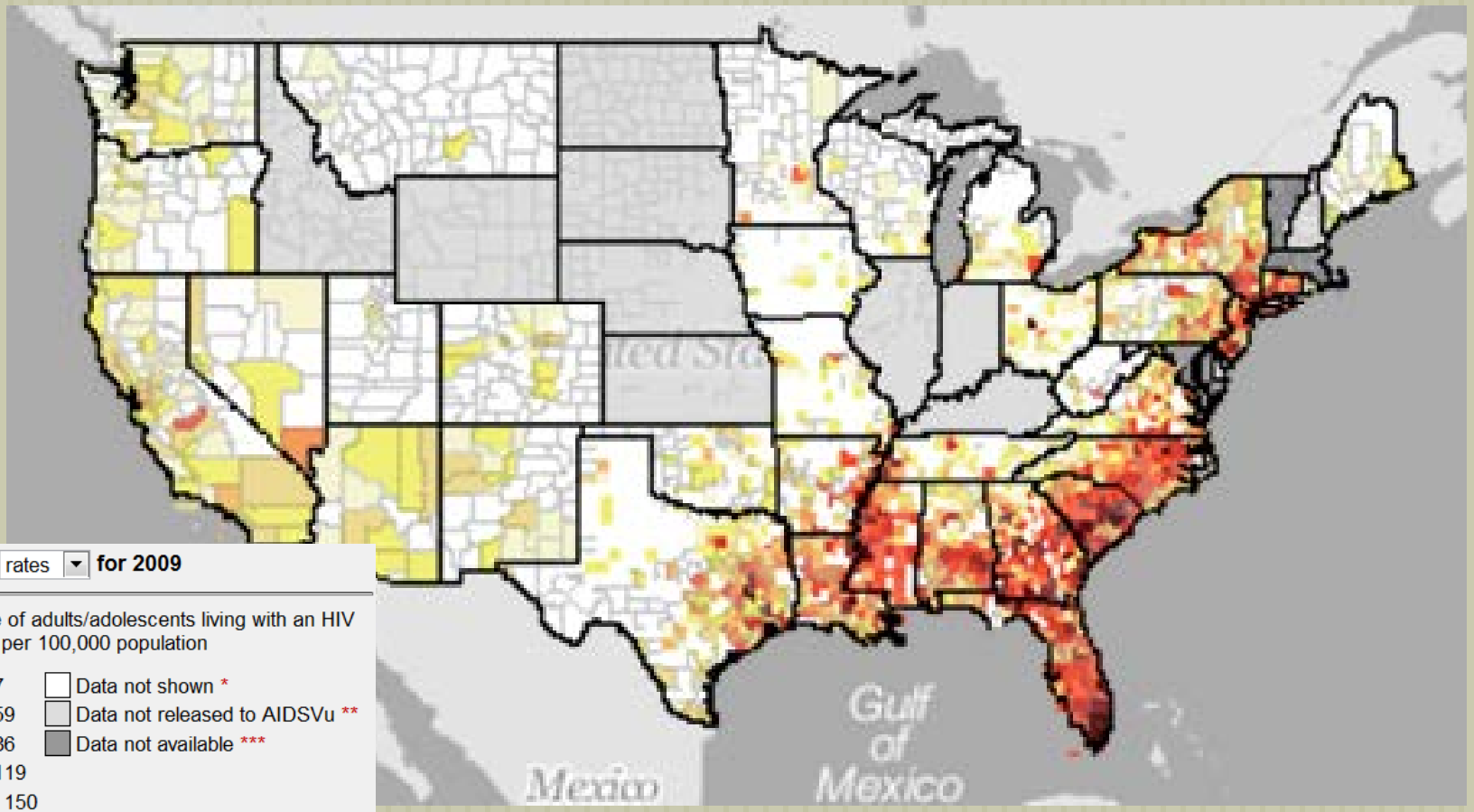
Of all estimated new HIV infections in 2009*….



*MSM and HET include those with reported injection drug use

http://www.cdc.gov/nchhstp/newsroom/docs/HIV-Infections-2006-2009.pdf

AIDSVu



Display rates **for 2009**

2009 Rate of adults/adolescents living with an HIV diagnosis per 100,000 population

- 0 to 37
- 38 to 59
- 60 to 86
- 87 to 119
- 120 to 150
- 151 to 197
- 198 to 249
- 250 to 344
- 345 to 517
- 518+

- Data not shown *
- Data not released to AIDSVu **
- Data not available ***

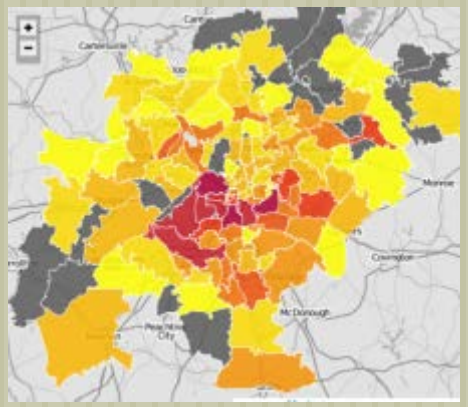
Overall / Race / Age / Sex

Female

Atlanta, Epi

PLWHA in 2009, by zipcode

Women



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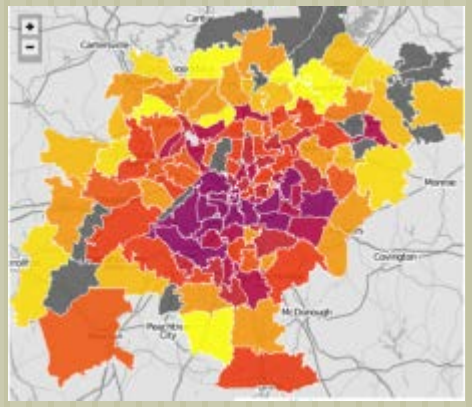
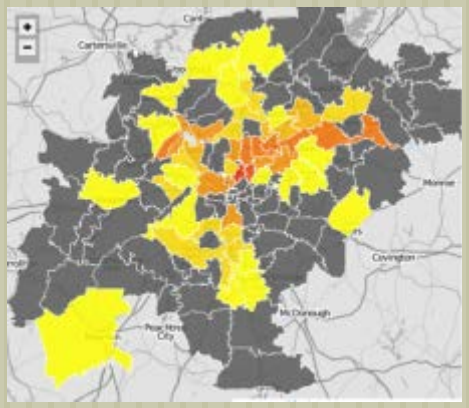
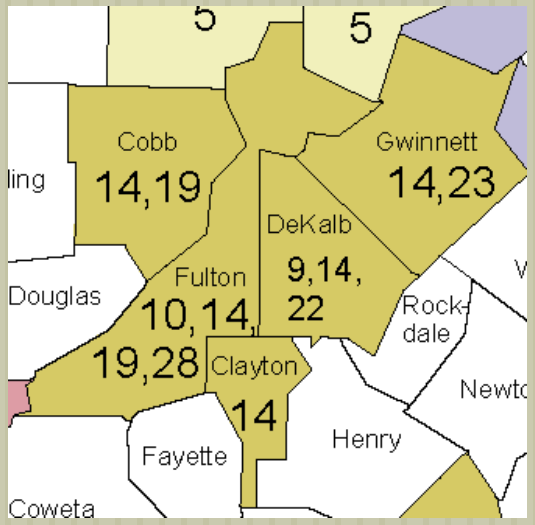


Hispanic





FQHCs, by county

Data to consider: STI and RH in women

- Women and STIs (NSFG 2002[1])
  - >15 lifetime male sex partners (Ages 25-44): 11.2%
- Young women and STIs (NHANES 2004[2])
  - Of sexually-experienced women ages14-19, >40% had an STI
- Women and RH (NSFG 2002[1])
  - Ages 15-44: expect no births in their lifetimes: 8.7%
  - Ages 40-44: have had no children: 15.0%
  - Ages 15-44: ever used contraception: 98.2%
  - In 5 years before 2002 interview, % of pregnancies that were:
    - Intended: 64.9%
    - Mistimed (too soon): 20.8%
    - Unwanted (did not want ever): 14.1%

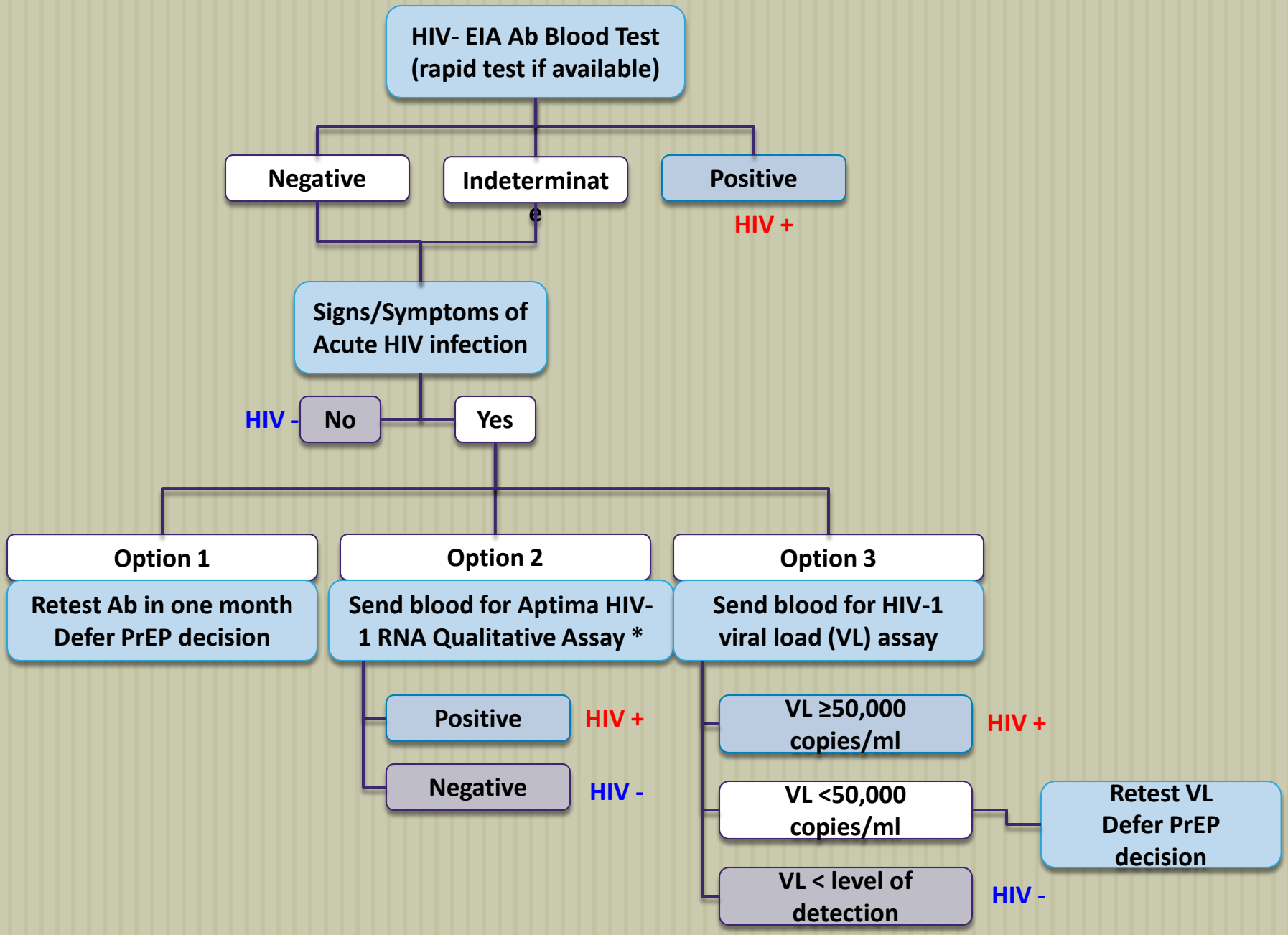
[1] *National Survey of Family Growth http://www.cdc.gov/nchs/nsfg/abc_list.htm*

[2] *Forhan et al. 2008 National STD Prevention conference http://cdc.confex.com/cdc/std2008/webprogram/Session8871.html*

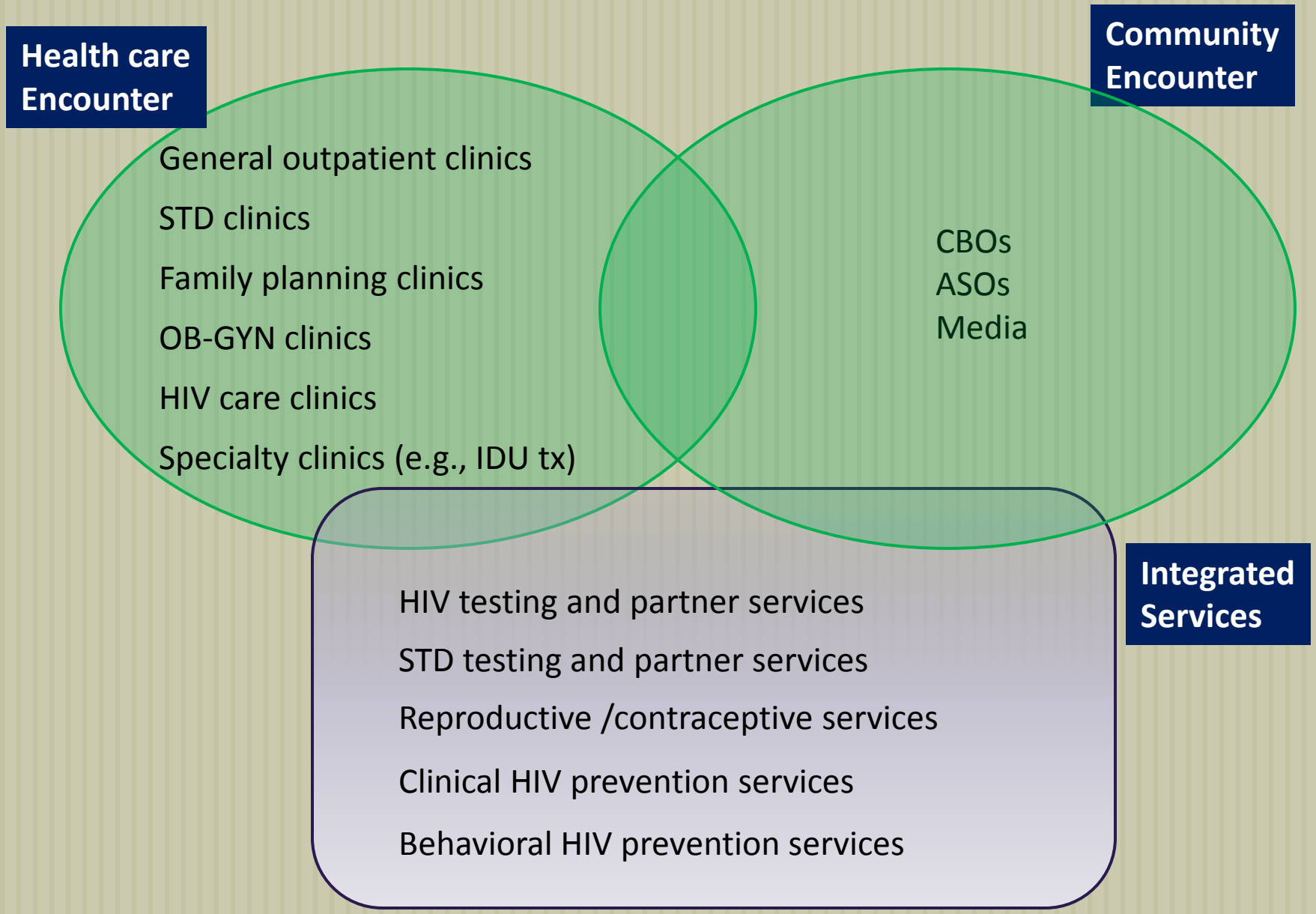
Interim Guidance* For PrEP Use With HIV-Uninfected Sexually-Active Adults

	MSM	HRH
At Very High Risk of Acquiring HIV Infection	HIV+ partner STI history, high number of sex partners History of inconsistent or no condom use Commercial sex work	
		In high prevalence area or network
Clinically Eligible	Documented negative HIV test before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function, no contraindicated medications Documented hepatitis B virus infection/vaccination status	
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada®), ≤ 90 day supply	
Other services	• Follow-up visits at least every 3 months to provide: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment • At 3 months and every 6 months after, assess renal function • Every 6 months test for bacterial STIs	
	Do oral/rectal STI testing	Assess pregnancy intentions Every 3 months do pregnancy test Consider use for safer conception Consider continuing during pregnancy

***Main points only. See source documents:**
CDC. *MMWR.* 2011;60(3):65-68 and
CDC. *MMWR.*2012;61(31):586-590.


HIV- EIA Ab Blood Test
(rapid test if available)
Negative
Indeterminate
Positive
HIV +
Signs/Symptoms of
Acute HIV infection
HIV -
No
Yes
Option 1
Retest Ab in one month
Defer PrEP decision
Option 2
Send blood for Aptima HIV-
1 RNA Qualitative Assay *
Option 3
Send blood for HIV-1
viral load (VL) assay
Positive
HIV +
Negative
HIV -
VL ≥50,000
copies/ml
HIV +
VL <50,000
copies/ml
Retest VL
Defer PrEP
decision
VL < level of
detection
HIV -

A systematic approach to consider



Dr. Dawn K. Smith
dsmith1@cdc.gov
404.429.0904

"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"

Deborah Cohan, MD, MPH
Associate Professor
University of California San Francisco

Clinical Director, National Perinatal HIV Hotline
Medical Director, Bay Area Perinatal AIDS Center
cohand@obgyn.ucsf.edu

BAPAC
Bay Area Perinatal AIDS CENTER

UCSF
University of California San Francisco
advancing health worldwide

Let's be in touch!

- National Perinatal HIV Hotline & Clinicians Network
  - 1-888-448-8765
  - 24 hour/day coverage
- Reproductive Infectious Disease pager (24/7)
  - 415-443-8726
- ReproID_HIV listserv: sweber@nccc.ucsf.edu

Poll…

My goal by the end of this talk

- HIV clinicians
  - Open practice to HIV-negative, at-risk adults (testing, prevention counseling, PrEP)
  - Ensure linkage if unable to provide services on-site
- Family planning/women's health clinicians
  - Prescribe PrEP and manage HIV-negative, at-risk women
    - Even if never prescribed ARVs before (and scared to do so)
  - Ensure linkage to PrEP if unable to provide services on-site
  - Ensure linkage to care for HIV+ partners

What are reproductive rights?

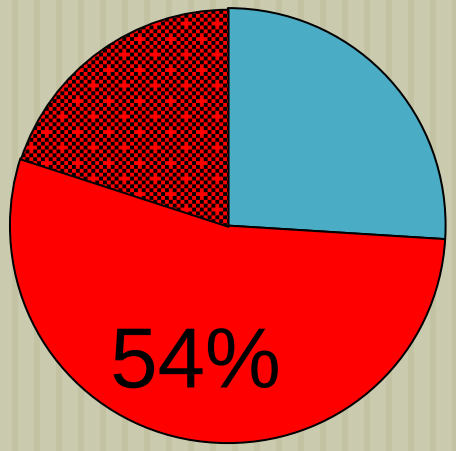
- The basic right of all couples and individuals to decide freely and responsibly the number, spacing and timing of their children and to have the information and means to do so, and ***the right to attain the highest standard of sexual and reproductive health.***

World Health Organization

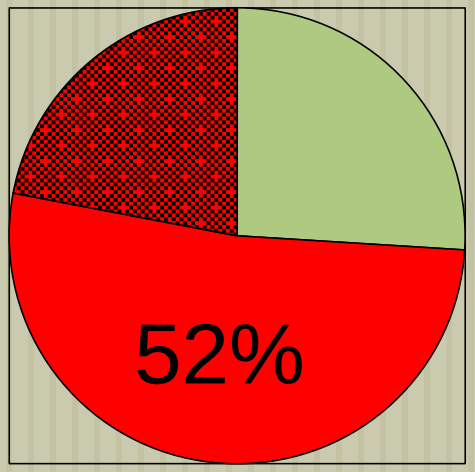
Epidemiology of HIV Heterosexual Serodifference

- HIV Cost and Services Utilization Study (1996)
- Probability sample, n=1421 (34,833 ♀, 53,177 ♂)
  - Currently married or with heterosexual partner

HIV + WOMEN



HIV+ MEN



Chen et al. Family Planning Perspectives, 2001

Every new case of sexual HIV acquisition in a woman represents

- An HIV-negative woman having sex without a condom with:
  - An HIV+ man not yet tested for HIV
  - An HIV+ man not linked to or engaged in care
  - An HIV+ man not prescribed, declining or non-adherent to ARVs
- An at-risk, HIV-negative woman not prescribed (or adherent to) PrEP

Every new case of sexual HIV acquisition in a woman represents

- An HIV-negative woman having sex without a condom with:
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  - An HIV+ man not prescribed, declining or non-adherent to ARVs
- An at-risk, HIV-negative woman not prescribed (or adherent to) PrEP

Oral PrEP likely works if taken, but…

- Who is a good candidate? Only serodifferent couples?
- Who will prescribe, monitor?
  - HIV clinics not equipped to manage HIV-neg pts
  - Women's health clinics not equipped to manage PrEP
- Who will pay (public, private sector)?
- How to optimize adherence in clinical setting?
- Are there any alternative PrEP formulations?
  - Just like contraception, we are starting with a once daily pill
  - RAL vaginal gel, Injectable rilpivirine, Dapivarine ring

Heterosexual HIV Transmission

- Partners in Prevention Study (ACV vs plac.)
  - 3297 couples with 86 linked transmissions
  - Unadjusted risk per-unprotected act
    - Male-to-female 0.0019
    - Female-to-male 0.0010
  - Each log ↑ viral load: 2.9-fold ↑ risk per-act
  - Condom use: 78% ↓ risk per-act

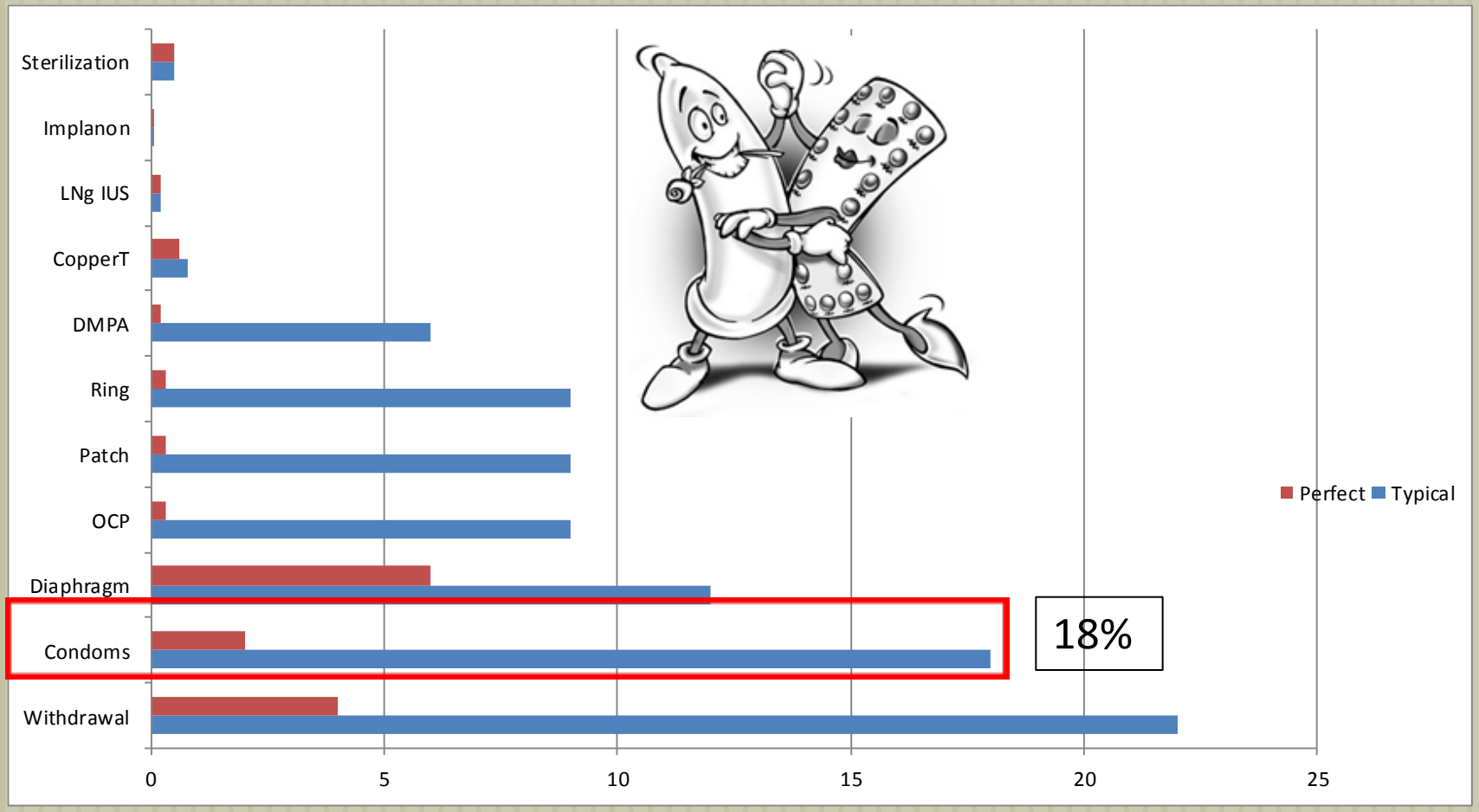
Hughes et al, JID 2012

Poll…

Condoms

- The one method that protects against STIs and provides contraception
- How do your clients (and their partners) feel about using male condoms? Female condoms?

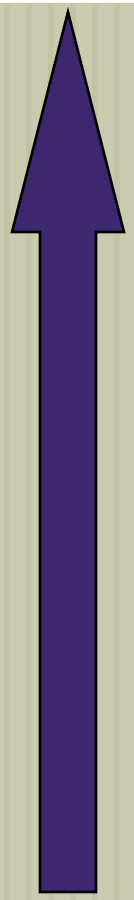
Contraceptive Failure (1st year)



Adapted from J. Trussell Glob. Libr. Women's Med 2011

Counseling: Frequency of Intervention

- Permanent: sterilization
- Every 10 years: Copper T IUD
- Every 5 years: Mirena IUD
- Every 3 years: Implanon
- Every 3 Months: DMPA
- Monthly: vaginal ring
- Weekly: patch
- Daily: pill, natural family planning (NFP)
- Episodic: condoms, NFP



Increasing efficacy

Comprehensive prevention counseling for HIV+ patients

- Sexual transmission risk and viral load/ARVs
- ARV adherence
- Disclosure of HIV status to partners
- Partner HIV testing
- Sexual practices and condoms
- Reproductive health intentions
- PrEP and PEP

Are HIV providers discussing reproductive intentions?

- Women Living Positive Survey (n=700, ARVs for 3+ yr)
  - 48% previously pregnant or considering pregnancy never asked about pregnancy intentions
  - 57% currently/previously pregnant or considering pregnancy had not discussed treatment options
- Baltimore cohort (n=181)
  - 67% reported a general discussion about pregnancy and HIV
    - 80% satisfaction with primary HIV-provider communication
  - 31% reported a personalized discussion about fertility desires/intentions (64% patient-initiated)

Squires AIDS Patient Care STDs 2011, Finocchario-Kessler AIDS Patient Care STDs 2010

Fertility desires among HIV+

US reproductive-aged women		**35%**
Cross-sectional, n=118	Rochester	20% yes, 15% unsure 12% tubal regret (4% tubal regret in US)
Cross-sectional, n=182	British Columbia	25.8%
Cross-sectional, n=181	Baltimore	59%
HCSUS probability sample, n=1421	US, HCSUS	29% women (51% if SDC) 28% men (46% if SDC)

[1]Chen Fam Plann Persp 2001, [2]Stanwood Contraception 2007, [3]Ogilvie AIDS 2007, [4]Oladapo J Natl Med Assoc 2005, Finocchario-Kessler AIDS Behav 2010

Cases…

Case #1: A young woman asks for help

- 19 y/o perinatally-infected male with a new girlfriend
  - Sequential monotherapy, intermittent adherence, resistance
  - CD4 count: 110, HIV viral load 8,900 last month
  - On TDF/FTC, DRV/r, RAL x 6 months
- 19 year old girlfriend without medical problems
  - HIV negative test when had abortion 8 months ago
- Sexually active x 4 months, last sex 2 weeks ago
- Neither likes to use condoms (especially him).
- When he goes to use the restroom during the visit, she asks, “Is there is anything I can do to not get HIV?”

Poll…

Comprehensive prevention counseling and care for H+M/H-F couples

- Ideally, counsel couples together
- For this couple:
  - Provide positive feedback about couples visits, disclosure, engagement in care and open communication with providers
  - Discuss fertility intentions
  - Counsel on condom use: http://www.effectiveinterventions.org/en/HighImpactPrevention/Interventions.aspx
  - Counsel on contraception

Comprehensive prevention counseling and care for H+M/H-F couples …for HIM

- Counsel and support ARV adherence
  - Impact on his health and to reduce risk of transmission
  - http://www.effectiveinterventions.org/en/HighImpactPrevention/BiomedicalInterventions/MedicationAdherence.aspx
- Optimize ARV treatment
  - Resistance testing, ARV intensification/switch
- Screen for STIs
- Monitor viral load frequently

Comprehensive prevention counseling and care for H+M/H-F couples…for HER

- Counseling
  - HIV transmission risk
  - Pre-Exposure Prophylaxis
    - Adherence (TDF/FTC once daily)
    - Symptoms of acute HIV
    - Benefits, Risks (side effects)
    - Resistance
    - Condoms
- Testing
  - Pregnancy test
  - STI screening; repeat at 6 months
  - HIV antibody [and HIV RNA PCR/viral load because recent sex]
  - Baseline labs (Cr, HBV → vax prn)
  - Serial HIV testing

Case #2: A pregnant woman with placenta previa

- 32 year old G4P2 presenting for consult at 20 weeks. Prenatal HIV antibody screen negative.
- Male partner HIV+, CD4 750, viral load 6200, on methadone maintenance, in HIV care, not yet on ARVs
- 18 week ultrasound revealed placenta previa; Instructed to avoid vaginal penetration.
- Couple engages in anal sex without a condom.
- How to proceed?

Poll…

Comprehensive prevention counseling and care for H+M/H-F pregnant couples

- Ideally counsel couples together
- For this couple:
  - Provide positive feedback about couples visits, disclosure, engagement in care and open communication with providers
  - Counsel on use of condoms: http://www.effectiveinterventions.org/en/HighImpactPrevention/Interventions.aspx

Comprehensive prevention counseling and care for H+M/H-F pregnant couples …. for HIM

- Discuss pros/cons of ARV initiation
  - DHHS Guidelines now recommend ARVs regardless of CD4 count
  - Sexual transmission benefit
- Release of medical information → contact his provider
  - ARV initiation
  - Monthly viral loads during pregnancy
  - ARV adherence
    - http://www.effectiveinterventions.org/en/HighImpactPrevention/BiomedicalInterventions/MedicationAdherence.aspx
  - STI screening

Comprehensive prevention counseling and care for H+M/H-F pregnant couples …. for HER

- HIV transmission risk (sexual and during pregnancy/breastfeeding)
- Pre-Exposure Prophylaxis
  - Adherence (TDF/FTC once daily)
  - Symptoms of acute HIV
  - Benefits
  - Risks (maternal side effects; fetal toxicity): Antiretroviral Pregnancy Registry
  - Resistance
  - Condoms
- Testing
  - STI screening
  - HIV antibody [and HIV viral load if recent sex or sxs of acute HIV]
  - Baseline labs (Cr, HBV → vax prn)
  - Serial HIV testing (consider monthly viral loads during pregnancy)
  - Repeat STI screening at 6months

Antiretroviral Pregnancy Registry

- www.apregistry.com
- Collects data on ARV use during pregnancy
  - Treatment or prophylaxis
- Congenital anomalies among 1st trimester prospective reports
  - TDF: 31/1370 2.3% (1.5%, 3.2%)
  - FTC: 21/899 2.3% (1.4%, 3.5%)
  - MACDP (CDC surveillance system, metropolitan Atlanta region) 2.72 per 100 live births

PrEP and Breastfeeding

- High risk of transmission with acute HIV during breastfeeding
- Limited breastfeeding safety data on TDF/FTC
- Limited data re: transfer into milk compartment
  - Insignificant TDF levels; sub-therapeutic FTC levels
- Alternatives in resource-rich setting
  - Formula, human milk bank (https://www.hmbana.org/)
- If on-going risk of HIV acquisition, are benefits of breast milk sufficient to justify breastfeeding?
- Harm reduction if woman set on breastfeeding?

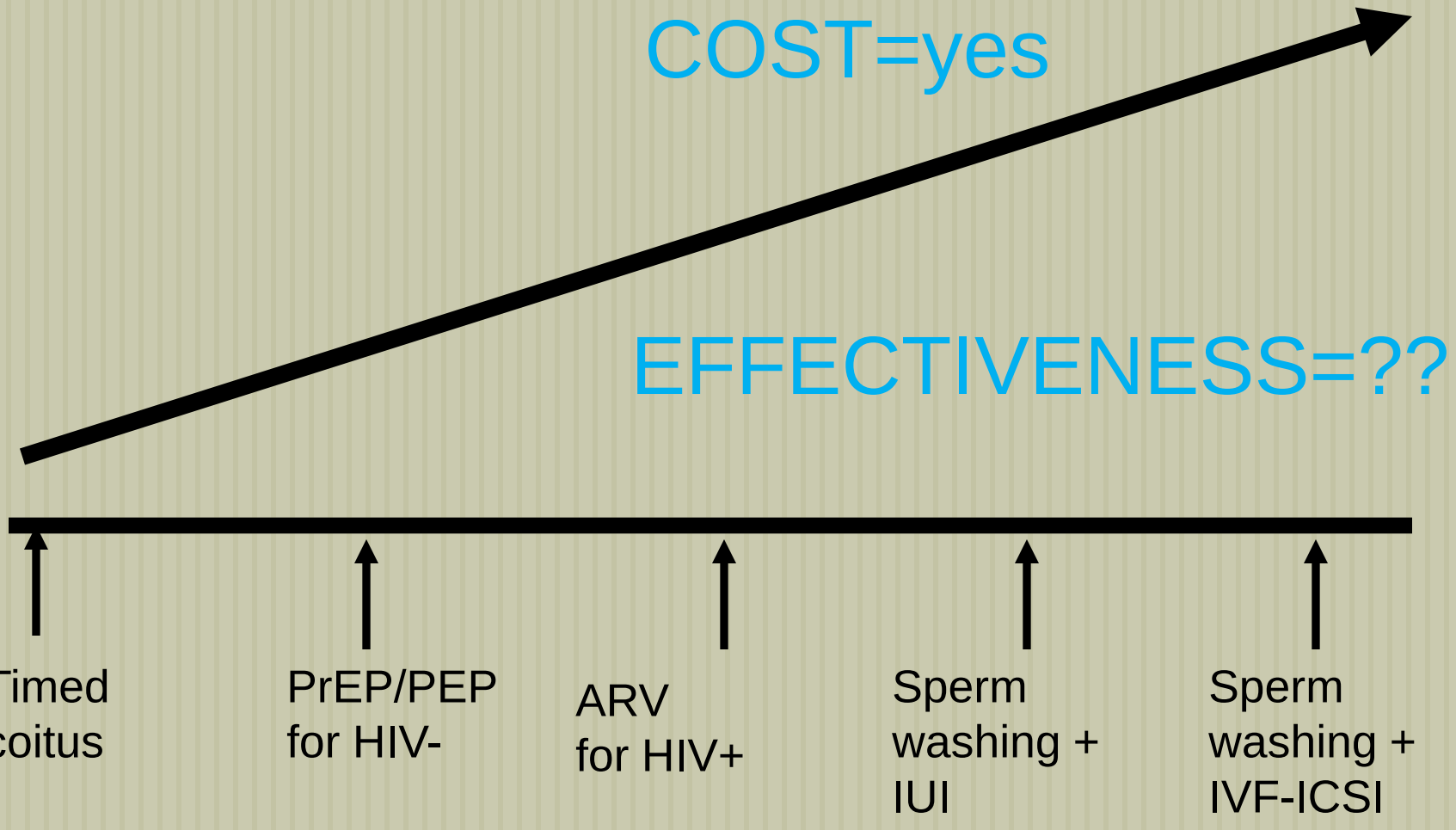
Benaboud, AAC 2011

Case #3: A couple desires pregnancy

- 38 year old man with hemophilia and HIV
  - CD4: 320, HIV viral load undetectable for many years on TDF/FTC/EFV
- Married for 5 years to 34 year old HIV- woman
- 100% condom use but now want to have child

Poll…

Options for safe conception



Adoption, sperm donation, not having children

Timed Coitus

- Sex without a condom during ovulation
  - Ovulation prediction: BBT, spinnbarkeit, urine kit
- French cohort
  - 104 pregnancies among 92 HIV- (1986-1996)
  - ARV use in 21 men
- Monthly HIV testing during pregnancy
  - 1/3 inconsistent or no condom use
  - 4 conversions (all inconsistent condom use)
    - Two at 7 months gestation
    - Two postpartum
- Data pre-HAART

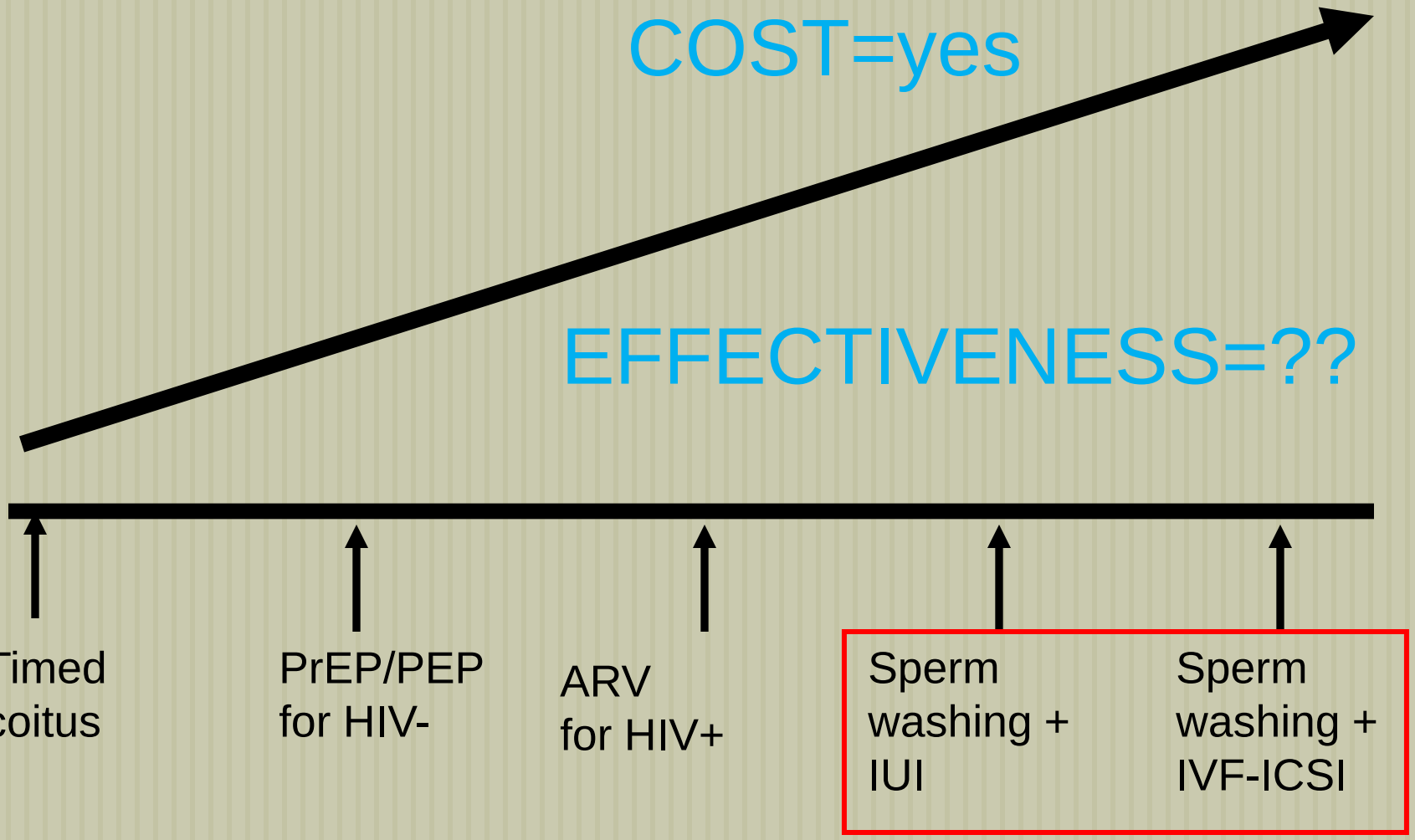
Mandelbrot Lancet 1997

Timed Coitus in the era of ARVs

- 62 HIV serodifferent pregnant couples
- 22 H+F/H-M and 40 H+M/H-F
- All receiving suppressive ART
- No cases of sexual HIV transmission

Barriero, A. Duerr, K. Beckerman et al, 2006

Options for safe conception?



Adoption, sperm donation, not having children

Semen and HIV

Components	HIV present?
Spermatozoa	NO
Seminal fluid	possible
Non-sperm cells (wbc)	possible

- Spermatozoa
  - No CD4, CCR5 and CXCR4 receptors
  - Electron microscopy suggesting HIV viral particles in sperm not replicated

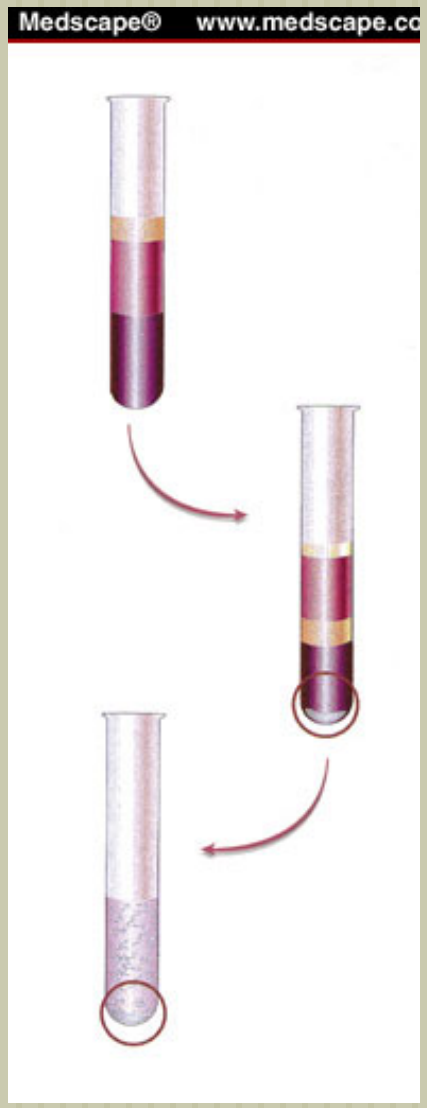
Baccetti J Cell Biol 1994

Sperm Washing

Gradient centrifugation separates out 3 components

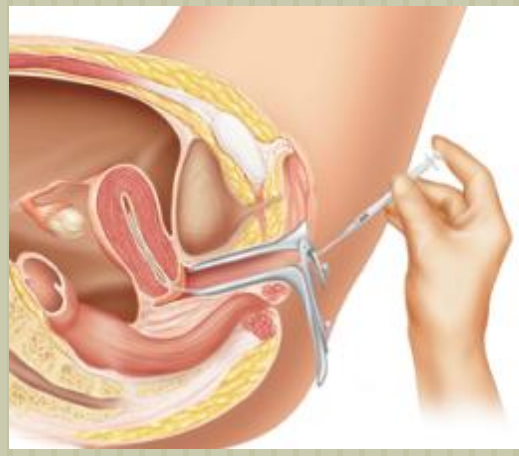
Sperm washed x 2

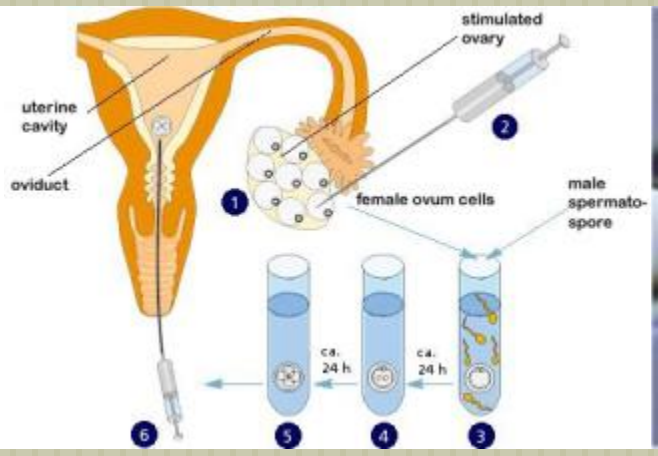
Use in setting of HIV pioneered by Deborah Anderson & Augusto Enrico Semprini



What is done with washed sperm?

- Intrauterine insemination (IUI)
  - Europe/Israel (CREAThE), South America
  - MA, CO, OR, MO, TX, CA, NY, TN, NV, ID
- In-vitro fertilization (IVF)
- Intracytoplasmic sperm injection (ICSI)





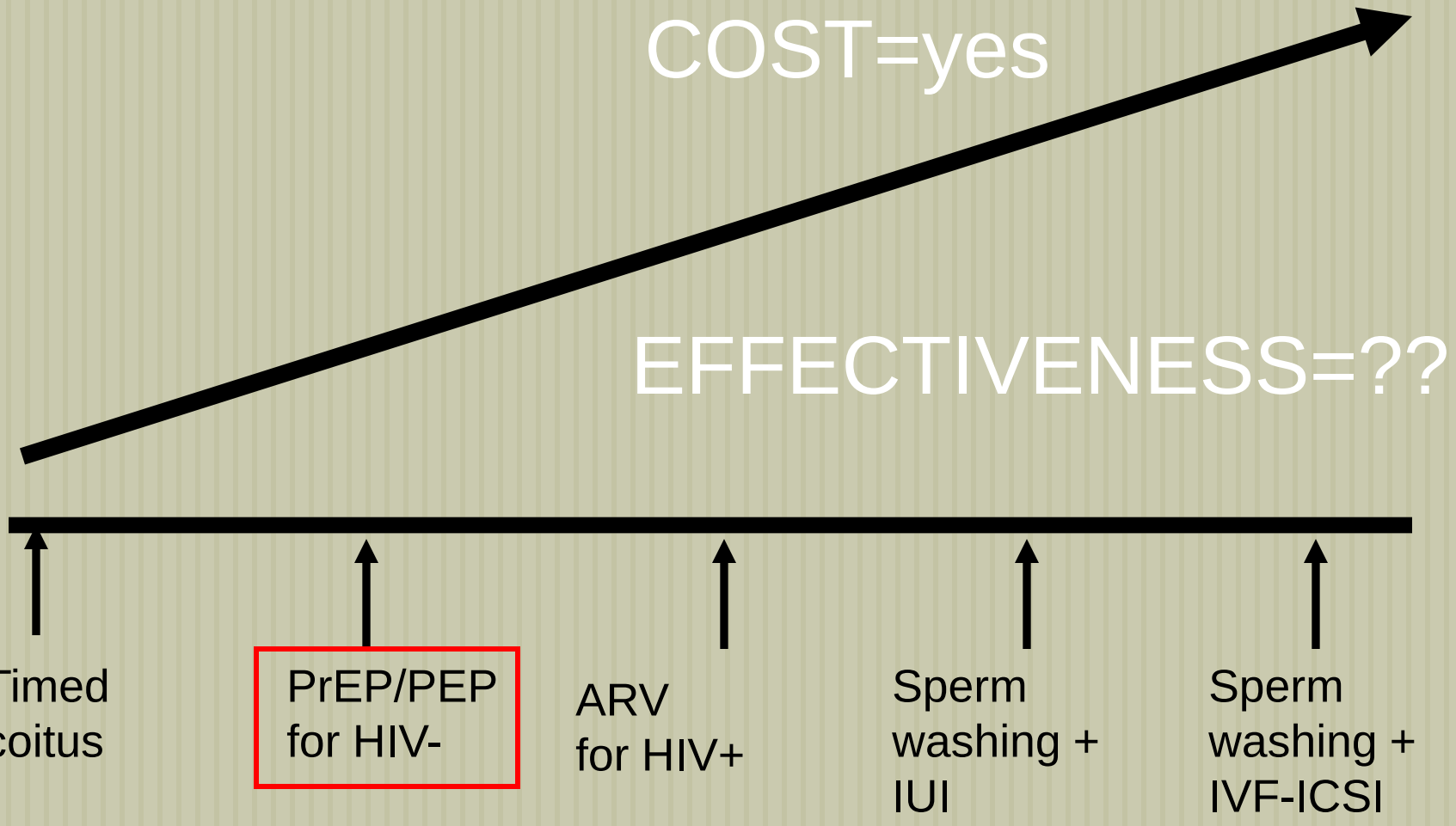
Results of Assisted Reproduction

- Single case of seroconversion with sperm washing/IUI (1990)
  - No density gradient, no semen VL prior to IUI
  - CDC recommends against insemination with semen from HIV+ men

		Pregnancy/ cycle	Cumulative pregnancy	Spont. Abortion
IUI	3900 cycles 1184 couples 11 studies	18%	50%	15.6%
IVF/ ICSI	738 cycles 579 couples 10 studies	38.1%	52.9%	20.6%
No seroconversions at birth, 3 months, 6 months				

Vitorino Fert Ster 2011; Sauer Hum Reprod. 2007, Savasi Hum Repro 2007, Politch, Repro Immun, 2002

Options for safe conception?



Adoption, sperm donation, not having children

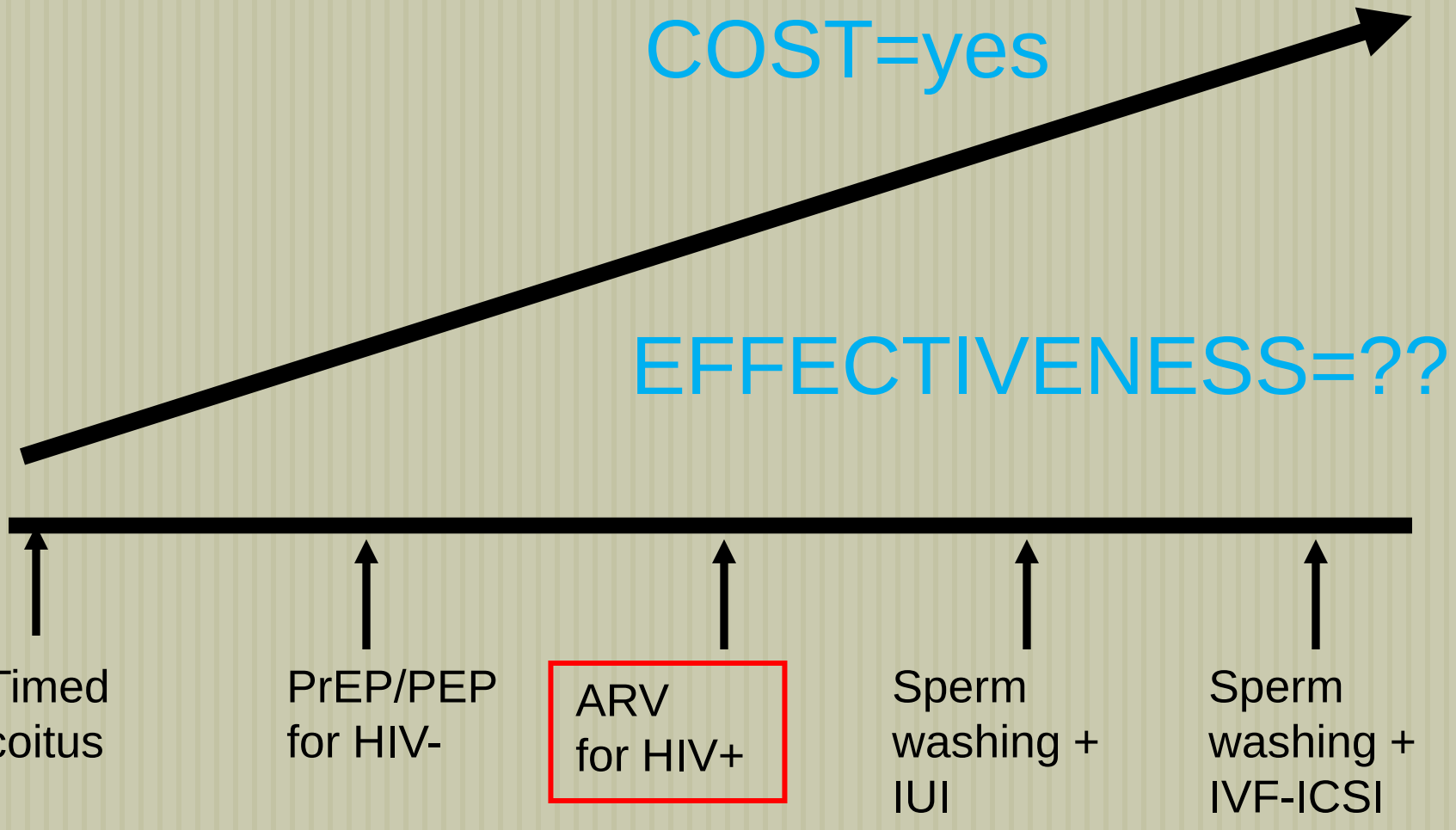
PrEP for Conception: "PrEPception"

- Observational cohort
  - HIV+ men on ARVs; HIV-RNA <50 copies/ml for >3 mos
  - HIV-RNA in semen undetectable at baseline
  - Ovulation predictor kit
  - TDF 36 hrs and 12 hours before sex

- Outcomes:
  - March 2004-March 2007
  - 53 H-F/H+M couples, 46 opted for PrEP
  - Pregnancy rate per # attempts
    - 1 attempt – 26%
    - 5 attempts – 66%
    - 12 attempts – 75%
  - No seroconversions or adverse events

Vernazza AIDS 2011

Options for safe conception?



Adoption, sperm donation, not having children

Antiretrovirals = Enough?

			Transmission	↓
Barriero, 2006	Cohort	62 SDC	0	
Attia, 2009	Meta-analysis	11 cohorts 5021 SDC	0 (HAART and VL <400)	
Donnell Partners in Prevention, 2010	RCT ACV vs. placebo	3381 SDC 349 initiated ARVs	1 case/273 P-Y w/in 18 days of ARV initiation (vs. 102/4558 P-Y)	92%
HPTN 052, 2011	RCT immediate vs. delayed ARV (CD4 350-500)	1763 SDC	Delayed: 3.1% Immediate: 0.1%	96%

Barriero JAIDS 2006; Attia AIDS 2009; Donnell Lancet 2010; Cohen NEJM 2011

Swiss Federal Commission for HIV/AIDS

- HIV-positive people with no other STIs and on effective antiretroviral therapy do not transmit HIV sexually
  - Antiretroviral therapy is taken consistently.
  - Viral load has been undetectable for at least six months

January 2008

The future is now.

Numerous methods to decrease HIV transmission while trying to conceive.

PrEP may be the most feasible option for couples who want some intervention beyond ARVs for HIV+ partner.

Case #3 continued

- They live in northern California and can't afford assisted reproduction (only IVF currently available in No. CA; IUI available in So. CA).
- They are too worried to try timed coitus and don't want adoption or sperm bank.
- After lengthy discussion of pros/cons of all options, they request periconceptional PrEP.

Periconceptional PrEP (PrEPception)

- Is there a standard of care in the US? (No)
  - 2-dose peri-ovulatory TDF (36 &12h prior to sex)
  - Daily TDF/FTC (efficacy data)
    - Initiation: at menses onset vs 1 wk s/p LMP vs 36h before sex
    - Continuation: No PEP component vs 28 days after last sex vs continue until pregnant vs continue through pregnancy if sex without condom
- Early embryonic exposure
  - No known risks but data limited
- Antiretroviral Pregnancy Registry

Vernazza AIDS 2011; Matthews Curr Opin HIV AIDS. 2012

What do the DHHS Perinatal HIV Guidelines say about PrEPception?

- Periconception administration of antiretroviral pre-exposure prophylaxis (PrEP) for HIV-uninfected partners may offer an additional tool to reduce the risk of sexual transmission **(CIII)**.

- The utility of PrEP of the uninfected partner when the infected partner is receiving ART has not been studied.

Perinatal HIV Guidelines: July 2012: www.aidsinfo.nih.gov

Periconceptional PrEP: Other management issues

- For her:
  - STI screening
  - Fertility evaluation prn
  - Preconception counseling/interventions
    - e.g. PNV, immunizations, diet/exercise, smoking cessation, medication review
- For him:
  - STI screening
  - *Consider* routine semen analysis prior to PrEP
  - Confirm viral suppression and optimal ARV adherence
  - Frequent HIV plasma viral load
- For them:
  - Condom promotion when not attempting conception

Prescribing Issues

- Private insurance: No obstacles identified
- Truvada® for Pre-Exposure Prophylaxis (PrEP) Medication Assistance Program
  - 1-855-330-5479
  - 4 page application
    - http://www.ohioaidscoalition.org/wp-content/uploads/Medication_Assistance_Program.pdf
  - Patient and prescriber signatures
  - Documentation of income and residency
- Pharmacists to prescribe?

Bruno and Saberi, Int J Clin Pharm 34(6):803-6 (2012)

Unanswered questions

- How do we find women who could benefit?
- How do we optimize adherence to PrEP?
- Who will prescribe PrEP and follow patients?
- Will alternative formulations be effective?

We have the tools …

How can we NOT come together and defeat HIV?

Resources

- CDC PrEP website
  - http://www.cdc.gov/hiv/prep/
- ACOG
  - HIV information for OB-GYNs and their patients
  - http://www.womenandhiv.org
- National Perinatal HIV Hotline/NCCC
  - 1-888-448-8765
  - http://www.nccc.ucsf.edu/about_nccc/perinatal_hotline/

Resources

- Bay Area Perinatal AIDS Center (BAPAC)
  - PRO-Men; ovulation prediction videos, PrEP handout
  - http://hiv.ucsf.edu/care/perinatal.html
- AETC-National Resource Center
  - Trainer and clinician resources
  - http://www.aids-etc.org/
- FXB Center
  - Clinician support tools, including the *HIV and Preconception Care Toolkit*
  - http://www.fxbcenter.org/resources.html

Resources

- AVAC
  - A global source for updates, advocacy and information on biomedical HIV prevention.
  - http://www.avac.org/
- Sister Love
  - A reproductive justice organization for women, with an emphasis on HIV/AIDS.
  - http://sisterlove.org/
- The Well Project
  - Health resources for women diagnosed with HIV and AIDS.
  - http://www.thewellproject.org/en_US/
- WORLD
  - Women organized to respond to life-threatening disease
  - http://www.womenhiv.org/