

Moving PrEP into Practice

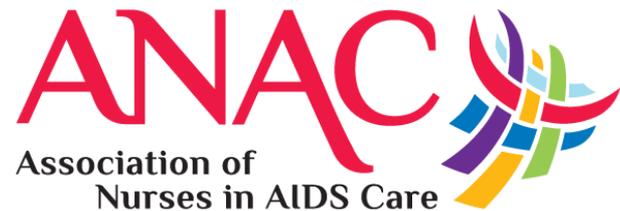
Nursing Advocacy, Strategies and Policies for the Establishment of HIV Pre Exposure Prophylaxis (PrEP) Prevention Programs In Substance Abuse Treatment, Reproductive Health and Primary Care Settings

ANAC 2015 Chicago October 30,2015

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Continuing Nursing Education

Upon full participation in this webinar & completion of an evaluation, participants will be awarded 1.0 contact hours.



The Association of Nurses in AIDS Care (ANAC) is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.



Disclosures

Faculty Conflict of Interest Disclosures

Joanne Phillips, Claire Simeone, Carole Treston have no actual or perceived conflicts of interest related to the content of this program.

Commercial Support Disclosures

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Agenda

- Overview & Resources
- Policy Implications
- PrEP & Women
- PrEP & People Who Use Drugs
- Q&A

Learning Objectives

At the end of this session participants will be able to:

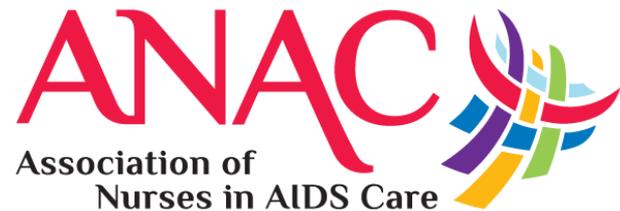
- Describe the various roles of nurses in advocating for and establishing local PrEP programs.
- Discuss innovative nursing strategies for PrEP programs in substance abuse treatment and reproductive health settings.
- Identify local institutional and programmatic policies that are necessary for implementing effective PrEP programs that align with national HIV prevention policies and recommendations.

Moving PrEP into Practice

HIV Pre Exposure Prophylaxis (PrEP) Implementation Resources & Policy Overview

October 30, 2015

Carole Treston, RN MPH ACRN FAAN



Trials Guidelines & Approvals

- Nov 2010 IPREX Study
- **Jan 2011 CDC Interim Guidance MSM**
- July 2011 Partners PrEP TDF2
- **July 2012 FDA Approval of PrEP**
- **Aug 2012 CDC Interim Guidance Hetero M/F**
- **May 2014 USPHS CDC Guidelines**
- July 2014 IPREX Ole
- **Sept 2015 WHO Recommendations**
- **2015 SCALE-UP**

CDC Guidelines

Daily oral PrEP with the fixed-dose combination of tenofovir 300 mgm/FTC 200 mgm (Truvada) has been shown to be safe and effective in reducing the risk of sexual HIV acquisition in adults; therefore PrEP is recommended as one prevention option for:

- sexually-active adult MSM at substantial risk of HIV
- adult heterosexually active men and women at substantial risk of HIV
- **adult injection drug users**
- In sero-discordant couples to protect the uninfected partner during **conception and pregnancy**

U.S. Cities Involved in Demonstration Projects



Demonstration and Implementation projects have a planned enrollment of approximately 8,000 participants.

* NYC = Manhattan, Harlem, Bronx and Brooklyn

Implementation Assistance

PrEPline: Peer to Peer Consultation:

Clinician Consultation Center UCSF, HRSA/HAB, AETC

Mon-Fri 11 a.m. – 6 p.m. EST 855-448-7737

Drug Payment:

MA & Pvt insurance coverage; Prior authorization

Gilead **Medication** Assistance Program

Insured & non-insured at 500% FPL = \$58,344/year

Provider & Lab Costs

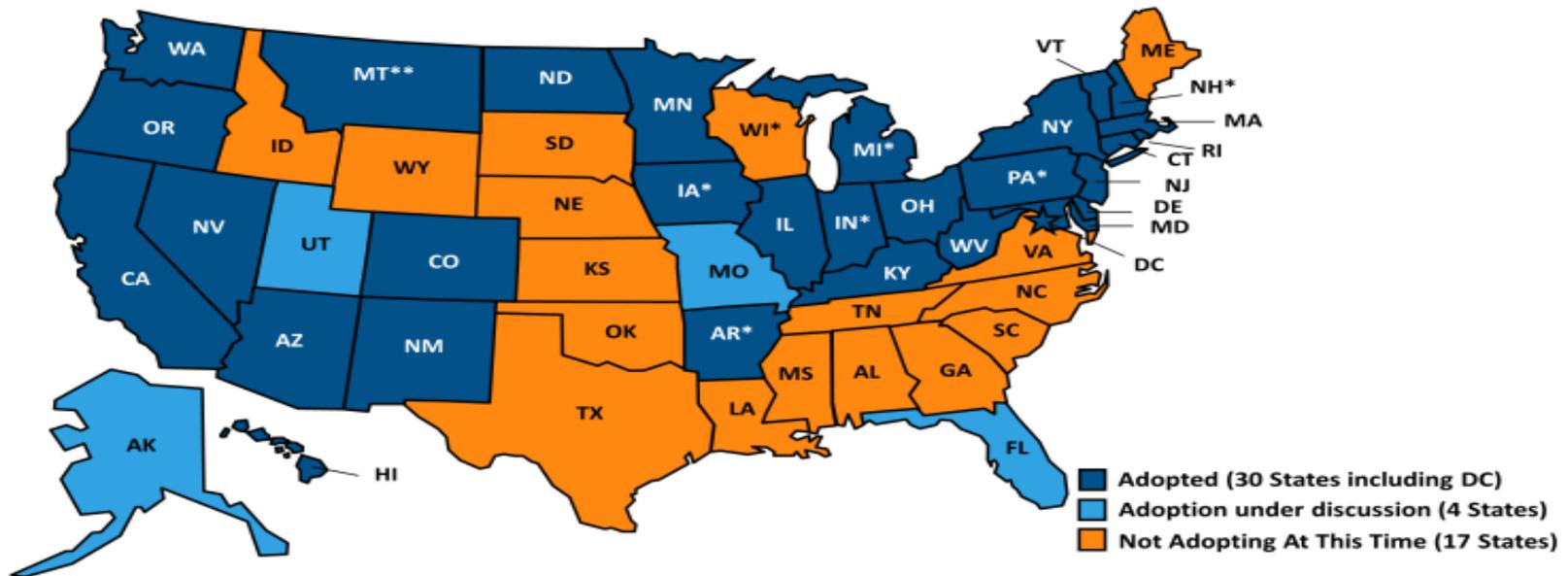
Insured

Uninsured****



Access to PrEP

Current Status of State Medicaid Expansion Decisions



NOTES: Under discussion indicates executive activity supporting adoption of the Medicaid expansion. **MT has passed legislation adopting the expansion; it requires federal waiver approval. *AR, IA, IN, MI, PA and NH have approved Section 1115 waivers. Coverage under the PA waiver went into effect 1/1/15, but it is transitioning coverage to a state plan amendment. Coverage under the IN waiver went into effect 2/1/15. WI covers adults up to 100% FPL in Medicaid, but did not adopt the ACA expansion.

SOURCE: "Status of State Action on the Medicaid Expansion Decision," KFF State Health Facts, updated April 20, 2015.
<http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/>



Other Resources

What is PrEP.org

Patient Video

myprepexperience.com

Patient Experience/

Access

PrEPWatch.org

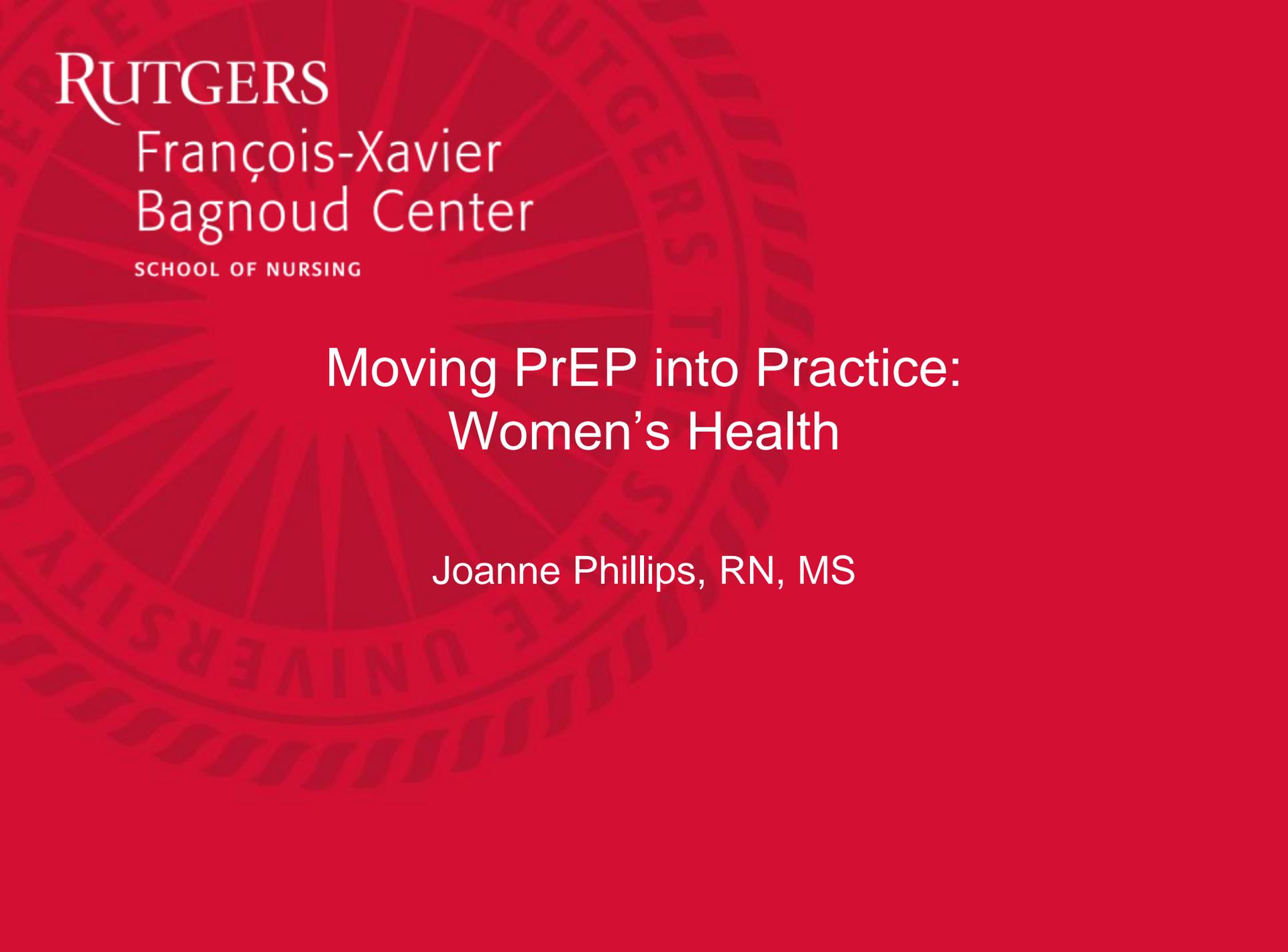
Trials & Global Advocacy

ANAC website

ANAC webinars

PrEPisms

- When ARVs – for treatment or prevention – are taken, they work
- PrEP is a Tool, but it is not forever, it is not for everyone. Useful during “Seasons of Risk”
- PrEP is a Program, not just a prescription
- **Barriers are real, and sometimes they are us**

The background of the slide features a large, faint watermark of the Rutgers University seal. The seal is circular and contains the text "RUTGERS UNIVERSITY" around the perimeter and "1823" at the bottom. The seal is centered and overlaps the text.

RUTGERS

François-Xavier
Bagnoud Center

SCHOOL OF NURSING

Moving PrEP into Practice: Women's Health

Joanne Phillips, RN, MS

PrEP Guidelines

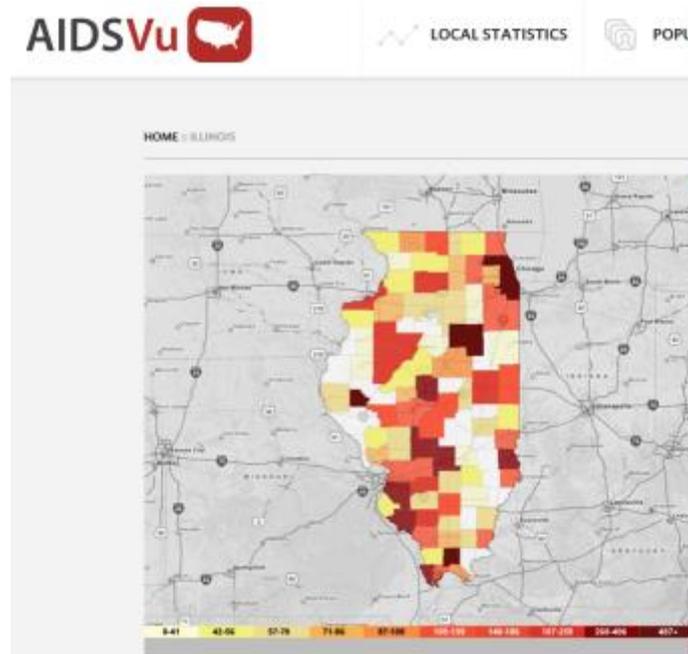
		Heterosexual Women and Men	
Detecting substantial risk of acquiring HIV infection	<ul style="list-style-type: none"> HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work 	<ul style="list-style-type: none"> HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work In high-prevalence area or network 	<ul style="list-style-type: none"> HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible	<ul style="list-style-type: none"> Documented negative HIV test result before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function; no contraindicated medications Documented hepatitis B virus infection and vaccination status 		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply		
Other services	<ul style="list-style-type: none"> Follow-up visits at least every 3 months to provide the following: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment At 3 months and every 6 months thereafter, assess renal function Every 6 months, test for bacterial STIs 		
	Do oral/rectal STI testing	<ul style="list-style-type: none"> Assess pregnancy intent Pregnancy test every 3 months 	Access to clean needles/syringes and drug treatment services

Current Evidence

Among Heterosexual Men and Women					
Partners PrEP	Phase 3	TDF (n = 1589) TDF/FTC (n = 1583)	Placebo (n = 1586)	Minimal	High
TDF2	Phase 2	TDF/FTC (n = 611)	Placebo (n = 608)	High loss to follow-up; modest sample size	Moderate
Among Heterosexual Women					
FEM-PrEP	Phase 3	TDF/FTC (n = 1062)	Placebo (n = 1058)	Stopped at interim analysis, limited follow-up time; very low adherence to drug regimen	Low
West African Trial	Phase 2	TDF (n = 469)	Placebo (n = 467)	Stopped early for operational concerns; small sample size; limited follow-up time on assigned drug	Low
VOICE	Phase 2B	TDF (n = 1007) TDF/FTC (n = 1003)	Placebo (n = 1009)	TDF arm stopped at interim analysis (futility); very low adherence to drug regimen in both TDF and TDF/FTC arms	Low

PrEP Considerations for Women

- Risk
 - Partner status
 - Estimated 140,000 serodifferent couples in the US (Lampe, 2011)
 - Study of 181 WLWH of child bearing age in 2 US clinics in Baltimore:
 - 62% have a negative partner
 - 11% have a partner whose HIV status was unknown (Finocchiaro-Kessler, 2010)
 - Residing in a high-prevalence area



PrEP Considerations for Women

- Plans for conception, especially if partner HIV-positive
 - “Preception” – use of PrEP in preparation for timed condomless sex for the purpose of conception between a serodifferent couple.
 - Barriers identified by the Expert Panel
 - Conducting semen analysis
 - Coordination of couples counseling
 - Access to both partner’s medical records
- Continuation of PrEP during pregnancy or breastfeeding



Accessing PrEP

Primary
Care

Reproductive
health clinic

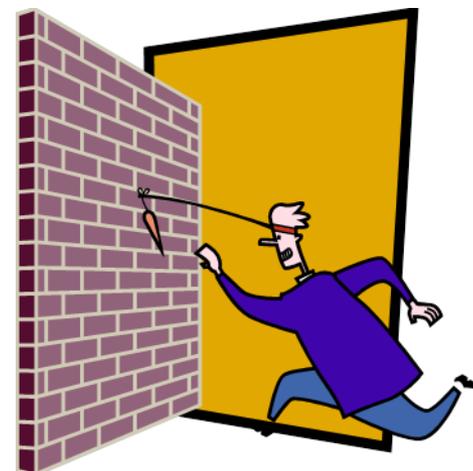
ID clinic

OB/GYN



Barriers

- Lack of clarity on where to access PrEP
- Reaching clients “at-risk” for HIV but otherwise healthy
- Cost
 - Insurance co-pays can be very expensive
 - Time-consuming process for clinic staff and client to obtain insurance approval or complete drug company assistance paperwork
- Stigma
- Lack of provider knowledge
- Lack of Patient knowledge
 - About PrEP
 - About risk for HIV



PrEP Implementation

- Recommendations from the Expert Panel on Reproductive Health and Preconception Care for Persons Living with HIV
 - Work with key clinic stakeholders to obtain buy-in in the clinical setting
 - Develop and train a group of “PrEP Champions”
 - Providers who see PrEP as a priority, feel comfortable prescribing and monitoring those on PrEP
 - Educate patient navigators about PrEP so they can be the ones sharing the information with patients – peer- to-peer
 - Use a team-based approach



PrEP Implementation (Cont.)

- Recommendations from the Expert Panel on Reproductive Health and Preconception Care for Persons Living with HIV
 - Develop models of identifying candidates for PrEP
 - Utilize a reproductive justice framework when training about PrEP
 - Train providers to empower women to decide her level of acceptable risk and take control of PrEP and other reproductive health decisions
 - Educate patient navigators about PrEP so they can be the ones sharing the information with patients – peer- to-peer
 - Identify & fund support staff and/or automated reminder systems for monitoring, assessment and HIV testing and adherence counseling



Moving PrEP into Practice: PrEP for People Who Use Drugs

Claire Simeone, FNP, MSN
ANAC Annual Conference
Chicago, IL
October 30, 2015



CDC Recommendation

Any non-prescription IDU in past 6 months

AND at least one:

Shared equipment in past 6 months

Participated in medication assisted treatment in
past 6 months

Risk of sexual acquisition

What does the research say?

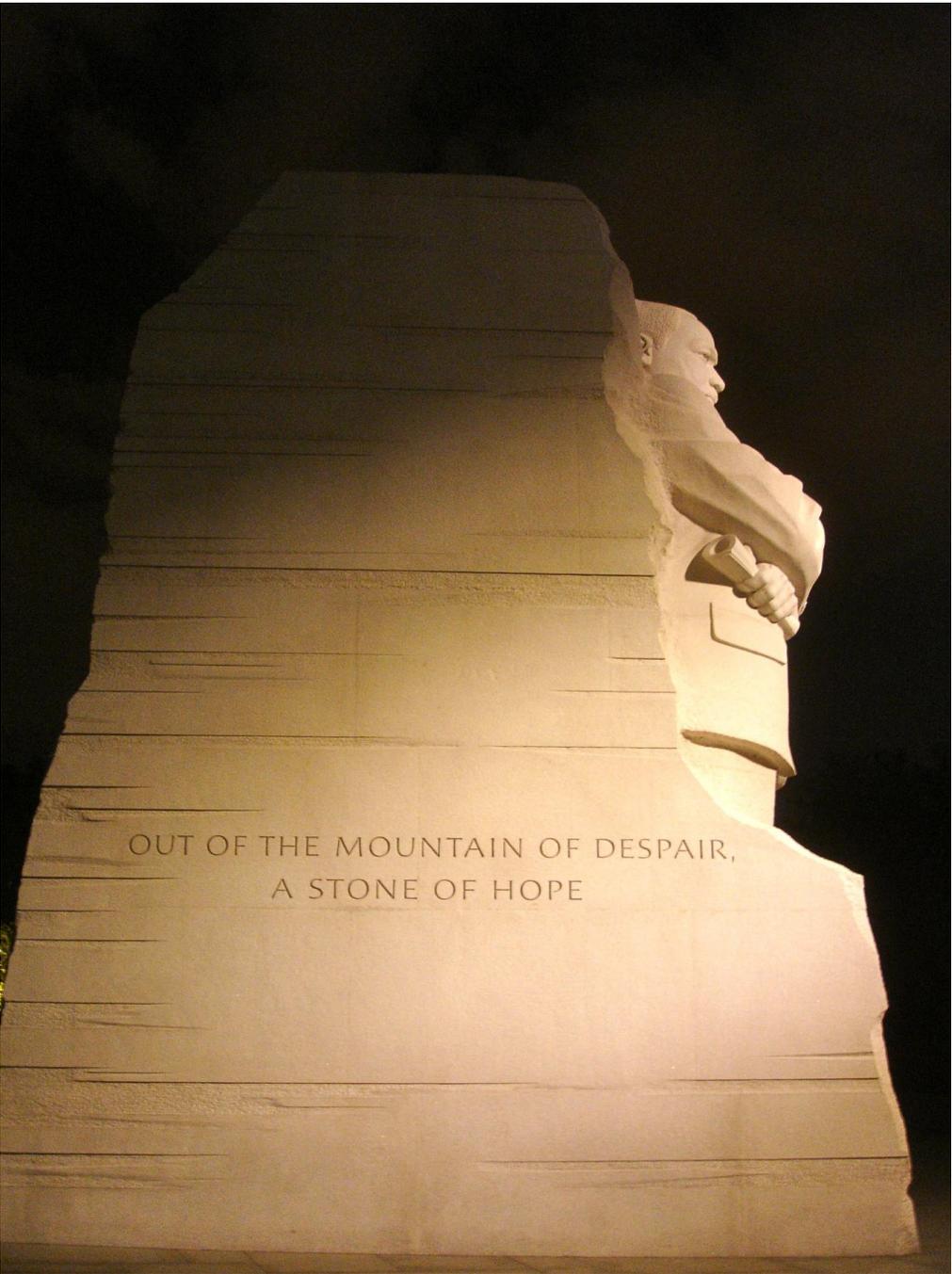
- One RCT: “the Bangkok study”
- Clients attending drug treatment services
- TDF vs placebo
- 17 vs 33 new infections in treatment vs placebo
- 48.9% reduction in HIV incidence, 73.5% if TDF detected

Questions to Answer

- Can we predict adherence?
- What is the added value of PrEP to other risk reduction strategies?
- What is the driver of risk? (paraphernalia or sex)
- Diversion?

Implementation Challenges

- Aligning medical and behavioral health cultures
- Funding
- Staff knowledge/skills
- Leadership support and prioritization
- Work flow
- Confidentiality



OUT OF THE MOUNTAIN OF DESPAIR,
A STONE OF HOPE

References

Centers for Disease Control and Prevention. (2104). Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014: A Clinical Practice Guideline. U.S. Public Health Service, Department of Health and Human Services.

Choopanya,K., Martin,M., Suntharasamai,P., Sangkum,U., Mock,P.A., Leethochawalit,M.,... Vanichseni,S. (2013). Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomized, double-blind, placebo-controlled phase 3 trial. *Lancet*, 381(9883), 2083-2090.

Questions

