DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

26 JULY 2017

MEMORANDUM FOR SGO5I
ATTN: LT COL JASON OKULICZ

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Review of HIV Pre-exposure Prophylaxis (Prep) and Example of HIV Prep Toolkit** presented at/published to **AF Team Aerospace Operational Solutions Meeting, Tempe, AZ on 28 Aug 2017**
2. **October 8-11 2017** in accordance with MDWI 41-108, has been approved and assigned local file #**17287.**

3. Pertinent biographic information (name of author(s) title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

4. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.

5. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
   a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]

   b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.

2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.

3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.

4. Attach a copy of your abstract, paper, poster and other supporting documentation.

5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.

6. On page 2, have either your unit commander, program director or immediate supervisor:
   a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.

7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). **This should be accomplished no later than 30 days before final clearance is required to publish/present your materials.** If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.

8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.

9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.

10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers,* for additional information.

11. The Joint Ethics Regulation (JER) DoD 5500.07-R, *Standards of Conduct*, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. **If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review.** To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

    For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

    If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

    If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

    If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

    If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

    If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:
"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:
"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP :
"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol)	3. GME/GHSE STUDENT:	4. PROTOCOL NUMBER:
	Jason Okulicz, Lt Col, O-5, 959 MDOS/SGO5I	☐ YES ☒ NO	N/A

5. PROTOCOL TITLE: (**NOTE:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)

N/A

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:

Review of HIV Pre-exposure prophylaxis (PrEP) and example of HIV PrEP Toolkit

7. FUNDING RECEIVED FOR THIS STUDY? ☐ YES ☒ NO FUNDING SOURCE:

8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: ☐ YES ☒ NO

9. IS THIS MATERIAL CLASSIFIED? ☐ YES ☒ NO

10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.?
☐ YES ☒ NO **NOTE:** If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.

11. MATERIAL IS FOR: ☒ DOMESTIC RELEASE ☐ FOREIGN RELEASE
CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.

☐ 11a. PUBLICATION/JOURNAL (List intended publication/journal.)

☐ 11b. PUBLISHED ABSTRACT (List intended journal.)

☐ 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)

☒ 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meting.)
AF Team Aerospace Operational Solutions Meeting, Tempe, AZ on 28 Aug 2017

☐ 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)

12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED?
☐ YES ☒ NO ASSIGNED FILE # _____ DATE _____

13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC
NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).

DATE	
August 01, 2017	

14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)	15. DUTY PHONE/PAGER NUMBER
Lt Col Jason F Okulicz, jason.f.okulicz.mil@mail.mil	210-916-5554

16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Okulicz, Jason F	O-5, Lt Col	959 MDOS/SGO5I	
b.			
c.			
d.			
e.			

17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? ☐ YES ☒ NO

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.

18. AUTHOR'S PRINTED NAME, RANK, GRADE	19. AUTHOR'S SIGNATURE	20. DATE
Lt Col Jason Okulicz	OKULICZ.JASON.F.1029369697 Digitally signed by OKULICZ.JASON.F.1029369697 Date: 2017.07.14 09:54:32 -05'00'	14Jul17
21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE	**22. APPROVING AUTHORITY'S SIGNATURE**	**23. DATE**
Maj Alice Barsoumian, Acting Asst Chief Infectious Disease	BARSOUMIAN.ALICE.E.1281168920 Digitally signed by BARSOUMIAN.ALICE.E.1281168920 Date: 2017.07.21 11:28:49 -05'00'	July 21, 2017

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1st ENDORSEMENT (59 MDW/SGVU Use Only)

TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	24. DATE RECEIVED July 14, 2017	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17287

26. DATE REVIEWED	27. DATE FORWARDED TO 502 ISG/JAC
21 Jul 2017	

28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: ☒ NO ☐ YES If yes, give date. _____ ☐ N/A

29. COMMENTS ☒ APPROVED ☐ DISAPPROVED

The presentation is approved.

30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	31. REVIEWER SIGNATURE	32. DATE
Rocky Calcote, PhD, Clinical Research Administrator	CALCOTE.ROCKY.D.1178245844 Digitally signed by CALCOTE.ROCKY.D.1178245844 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=CALCOTE.ROCKY.D.1178245844 Date: 2017.07.21 12:41:04 -05'00'	

2nd ENDORSEMENT (502 ISG/JAC Use Only)

33. DATE RECEIVED	34. DATE FORWARDED TO 59 MDW/PA

35. COMMENTS ☐ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

36. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	37. REVIEWER SIGNATURE	38. DATE

3rd ENDORSEMENT (59 MDW/PA Use Only)

39. DATE RECEIVED	40. DATE FORWARDED TO 59 MDW/SGVU
July 21, 2017	July 24, 2017

41. COMMENTS ☒ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	43. REVIEWER SIGNATURE	44. DATE
Kevin Iinuma, SSgt/E-5, 59 MDW Public Affairs	IINUMA.KEVIN.MITSUGU.1296227613 Digitally signed by IINUMA.KEVIN.MITSUGU.1296227613 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=IINUMA.KEVIN.MITSUGU.1296227613 Date: 2017.07.24 14:13:45 -05'00'	July 24, 2017

4th ENDORSEMENT (59 MDW/SGVU Use Only)

45. DATE RECEIVED	46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL ☐ YES ☐ NO ☐ COULD NOT BE REACHED ☐ LEFT MESSAGE

47. COMMENTS ☐ APPROVED ☐ DISAPPROVED

48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	49. REVIEWER SIGNATURE	50. DATE

HIV Prevention in the USAF: Focus on Pre-exposure Prophylaxis (PrEP)

Lt Col Jason F. Okulicz, MD
Chief, Infectious Disease Service
HIV Medical Evaluation Unit Director
San Antonio Military Medical Center

Disclosures

- Nothing to disclose

- The views expressed in this presentation are my own and do not necessarily reflect the official policy or position of the Department of the Air Force, Department of the Army, Department of Defense, nor the US government

Objectives

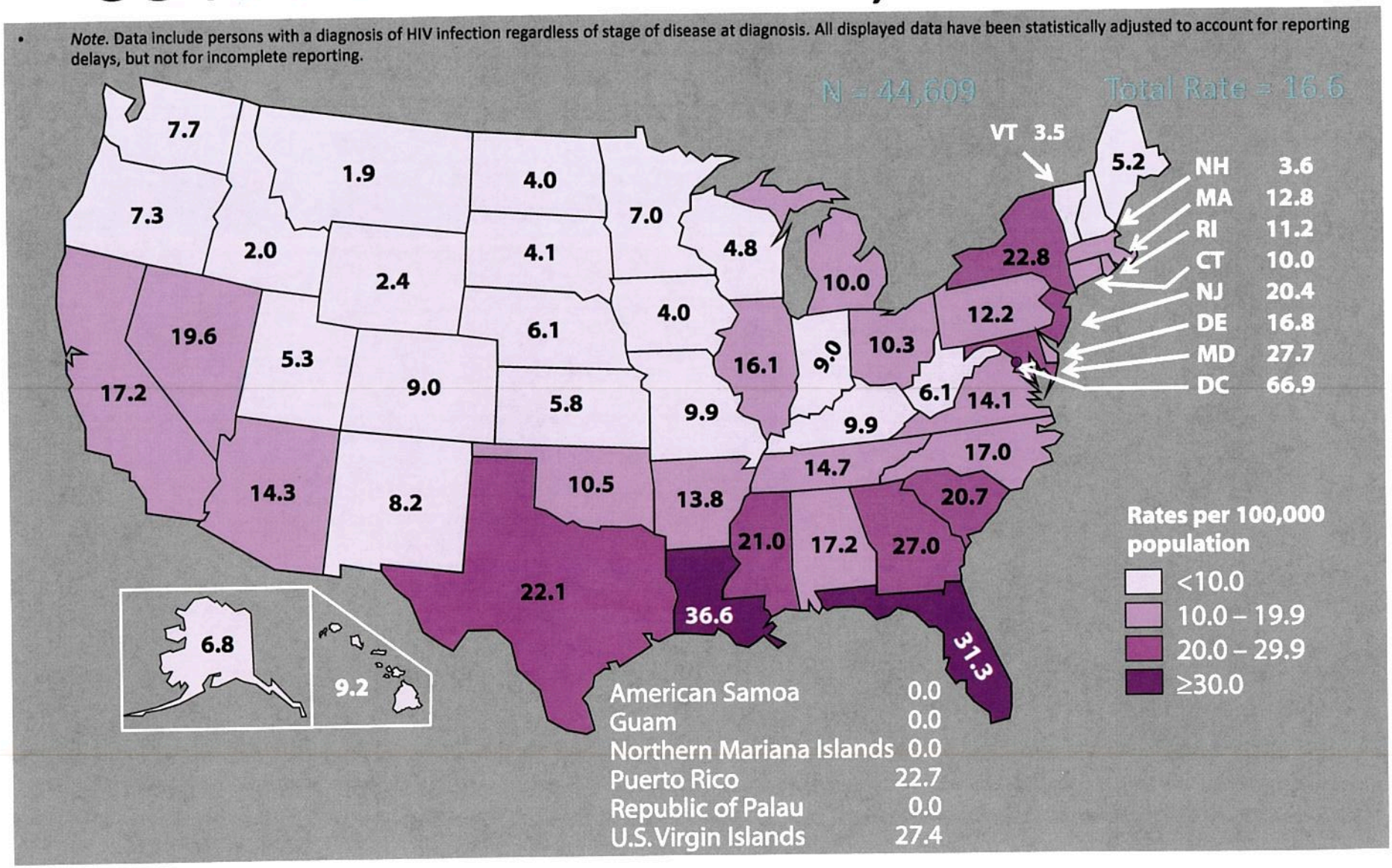
- Provide an overview of HIV in the active duty USAF members
- Describe how HIV PrEP can be a part of a comprehensive HIV/STI reduction strategy
- Detail how to utilize HIV PrEP in USAF healthcare settings
- Describe issues and challenges regarding HIV PrEP

HIV in the USA, 2014 Data

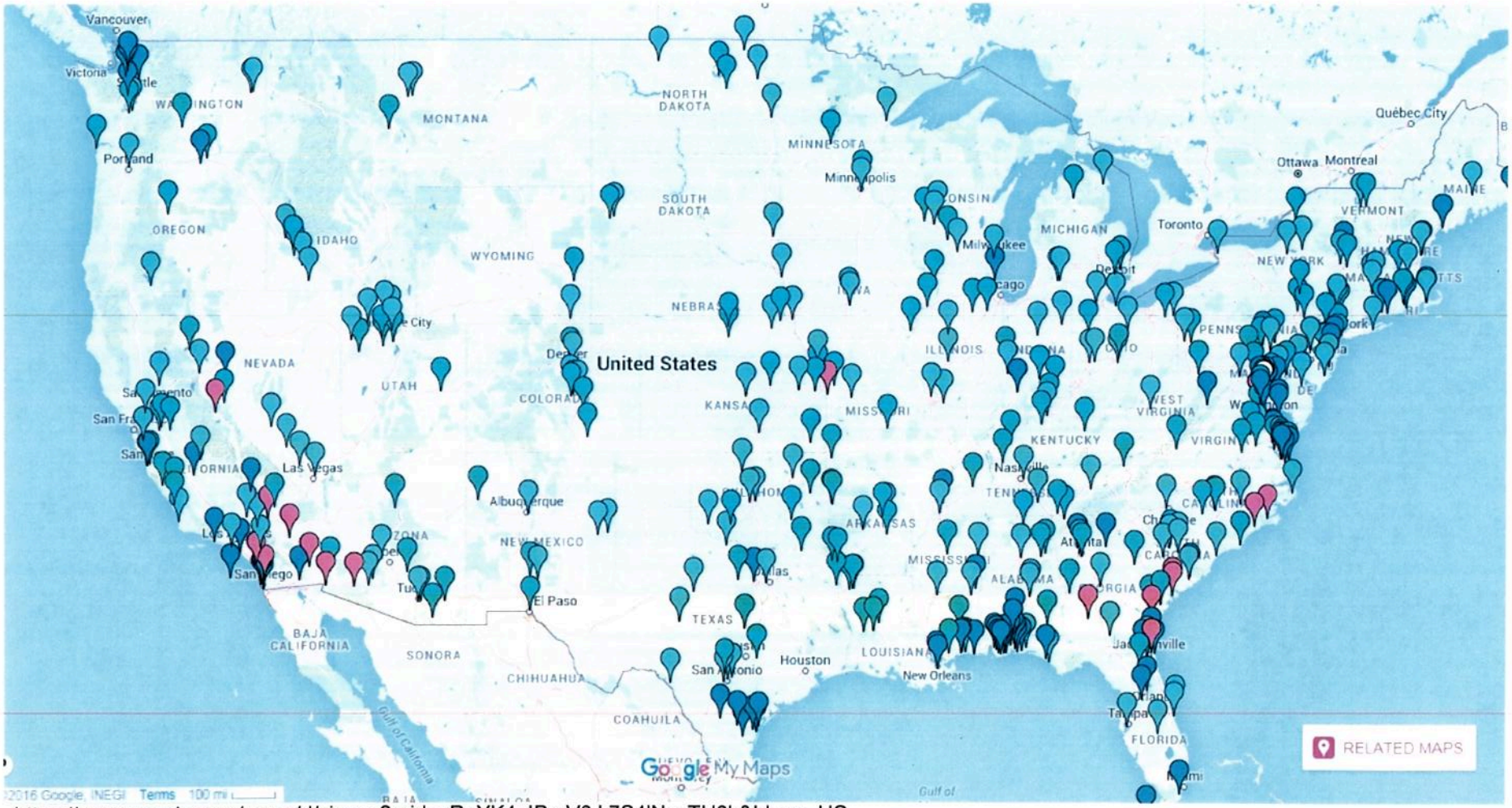
- 40K new infections (stable rates [13-14/100K], 2010-2014)
  - Males account for 81% of all new diagnoses
  - 70% of new diagnoses in MSM, 24% heterosexual
    - Increasing MSM rates (20%) over past 6-8yrs
  - Rates increasing and highest in 25-29y/o (35.8/100K)
  - Second highest in 20-24y/o (34.3/100K)
- African Americans (49.4)>>Hispanics (18.4)>Caucasians (6.1)
- 1.2 million > 13y/o living with HIV infection
  - 156,300 (12.8%) persons undiagnosed

CDC. Diagnoses of HIV infection in the United States and dependent areas, 2014. HIV surveillance report 2015;26. Available at http://www.cdc.gov/hiv/pdf/g-l/hiv_surveillance_report_vol_26.pdf

US HIV Infection Rates, 2014



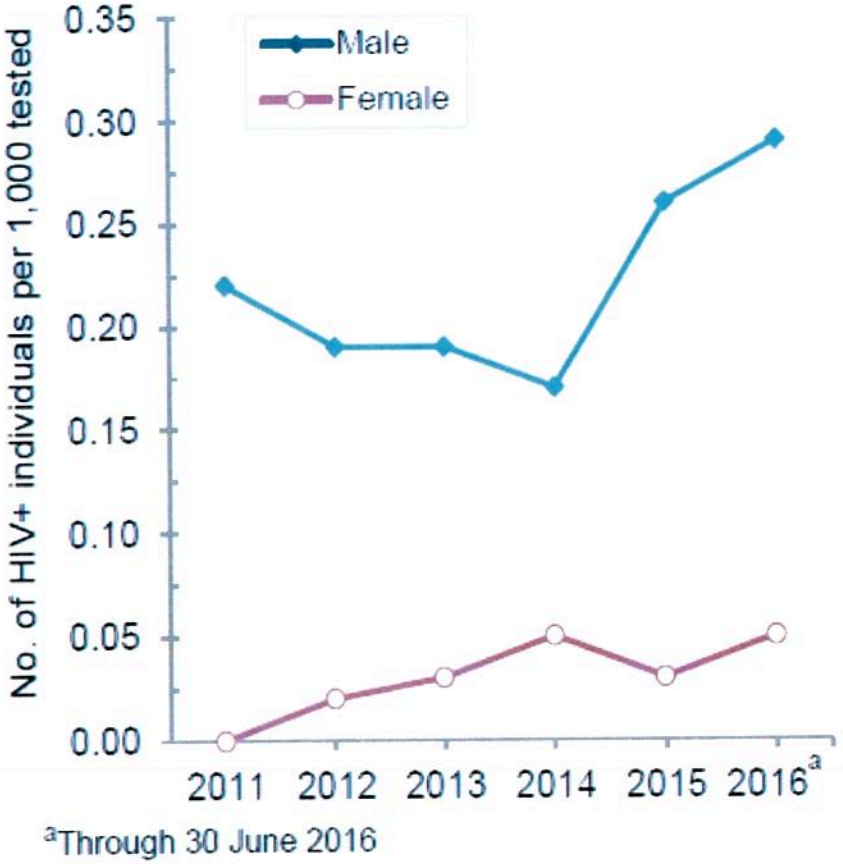
US Military Installations



https://www.google.com/maps/d/viewer?mid=zRnYK4gIPmV0.k7S4lNscTH6k&hl=en_US

USAF HIV Diagnoses By Gender

FIGURE 6. New diagnoses of HIV infections by sex, active component, U.S. Air Force, January 2011–June 2016



[a]Through 30 June 2016

MSMR 2016, Vol 23, No 9

Case-Control Study of HIV Cases in the USAF

Table 1. Frequencies and incidence rates of HIV among United States Air Force personnel in service at any time from 1996 through 2011*.

Characteristic	No. HIV Positive	Incidence Rate per 100,000 Person Years	Incidence Rate Ratio (IRR)	95% CI Around IRR	P-value
		Active Component Only			
Sex					
Male	463	10.14	10.79	(5.77–20.18)	<0.001
Female	10	0.94	Referent	-	-
Race**					
White	215	5.15	Referent	-	-
Black	223	26.6	5.17	(4.28–6.23)	<0.001
Other	35	13.38	2.6	(1.82–3.72)	<0.001

Characteristic	Cases (n = 473)	Controls (n = 2315)	Unadjusted Odds Ratio	95% Confidence Interval	P-Value
Region of assignment					<0.0001
America—South	268	953	1.70	(1.32–2.18)	<0.0001
Americas—West	104	621	Referent	-	-
Europe	29	218	0.80	(0.52–1.25)	0.3323
Non-US—Americas	6	31	1.05	(0.43–2.60)	0.9112
Pacific	18	131	0.85	(0.50–1.44)	0.5420
US—other	42	300	0.81	(0.55–1.19)	0.2772
Missing	6	61	-	-	-

Hakre S, Scott PT, Okulicz JF. Plos One 2015

HIV Risk in the US Military

- Among HIV-infected USAF personnel screened for gonorrhea and *Chlamydia trachomatis*, 2010-2014 (n=316)[1]
  - 79% reported same sex contact
    - 71% MSM and 8% bisexual men vs 18% heterosexual men and women
- Sexual risk behaviors of HIV seroconverters in the US Army, 2012–2014 (n=181)[2]
  - 92% believed HIV exposure was through sexual contact
  - 64% indicated male-male sexual contact
    - 78% had sex with men only, and 22% with both men and women
- Survey of male HIV seroconverters in the US Navy and Marine Corps, 2005-2010 (n=64)[3]
  - 55% reported having sex with men only and 30% with both men and women

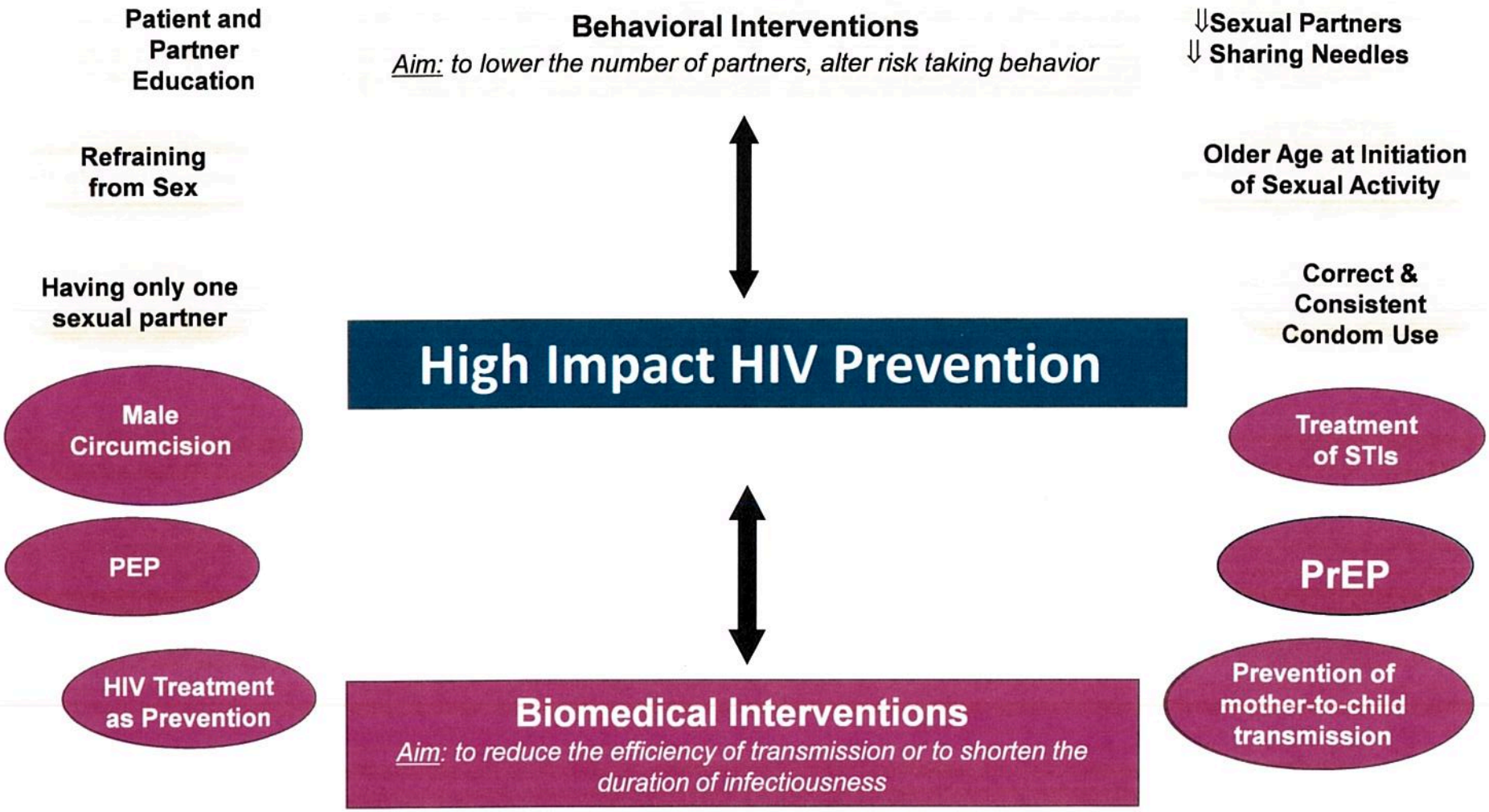
1-Patterson SB. MSMR 2014;21:7; 2-Hakre S, JAIDS 2015;70:456; 3-Hakre S, JAIDS 2012;61(2):125

Who Should We Target for Prevention?

Highest Risk for HIV Infection:

1. MSM > heterosexual men/women
2. Age ranges 18 – 34 years old
3. African American >>Hispanics>Caucasian
4. Geographic regions of US with high rates of HIV infection

HIV Prevention Opportunities



PrEP Continues to Gain Widespread Support

July 16, 2012:

FDA approves TRUVADA for PrEP

May 2014:

DHHS released the first federal PrEP guidelines and now recommends TVD for PrEP for people at substantial risk

March 2015:

CDC announcement: "Scale Up Use of Most Effective HIV Prevention Strategies including PrEP"

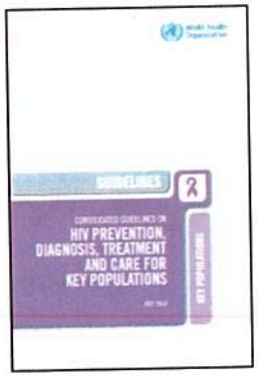
May-June 2015:

New York state announces a comprehensive plan to end AIDS epidemic including facilitating access to PrEP

September 2015:

WHO Guidelines strong recommendation: Oral PrEP (containing TDF) Offered to people at substantial risk of HIV based (>3% prevalence) on individual assessment, rather than risk group

2012 **2013** **2014** **2015**



July 2014:

- WHO released guidelines outlining steps for countries to reduce new HIV infections… and strongly recommends MSM consider taking PrEP with condoms
- IAS-USA released guidelines on HIV prevention in clinical care settings, it emphasized the need to utilize a combination of behavioral and biomedical approaches to prevent HIV

December 2014:

- San Francisco announces their "Getting to Zero" plan which calls for the expansion of PrEP
- Washington state announces a "StopAIDSWashington" Program, one of the items was to increase access to PrEP

July 2015:

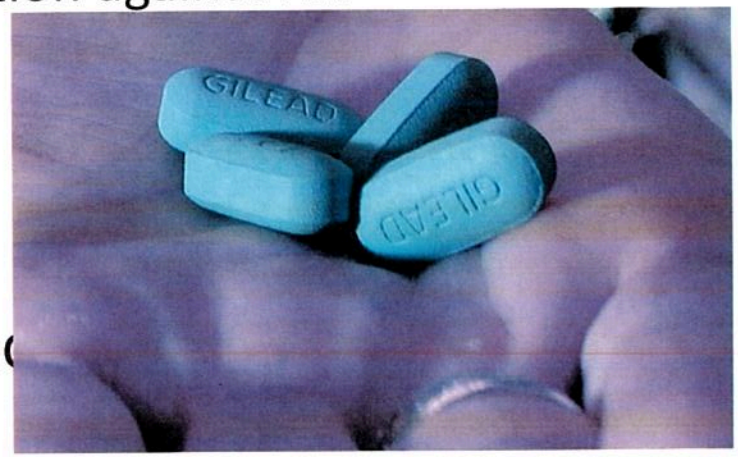
The Updated National HIV/AIDS Strategy was released—PrEP was described as a much needed HIV/AIDS prevention tool

August 2015:

The California Department of Public Health, Office of AIDS issues a "Dear Colleague" letter in support of the use of PrEP as a critical first-line intervention for individuals at greatest risk of HIV exposure

HIV PrEP

- Pre-Exposure Prophylaxis
- Truvada (FTC/TDF)
  - Emtricitabine 200mg/tenofovir 300mg
  - Backbone of current first-line HIV treatment regimens
  - FDA-approved for PrEP July 2012
- Taken daily, provides high level of protection against HIV
  - 92% risk reduction
- Not a substitute for condoms
- Requires regular monitoring
  - HIV status, adherence, side effe



Truvada (FTC/TDF)

- Prescribed as part of comprehensive prevention strategy
- Protection strongly correlated with adherence
- Max concentrations:
  - Blood/vaginal tissue at 20 days
  - Rectal tissue at 7 days
- Adverse reactions: renal, bone toxicity
- Black Box warnings: known HIV infection, lactic acidosis, hepatosteatosis, hepatitis B flares
- Side effects: headache, abdominal pain, nausea (2%)

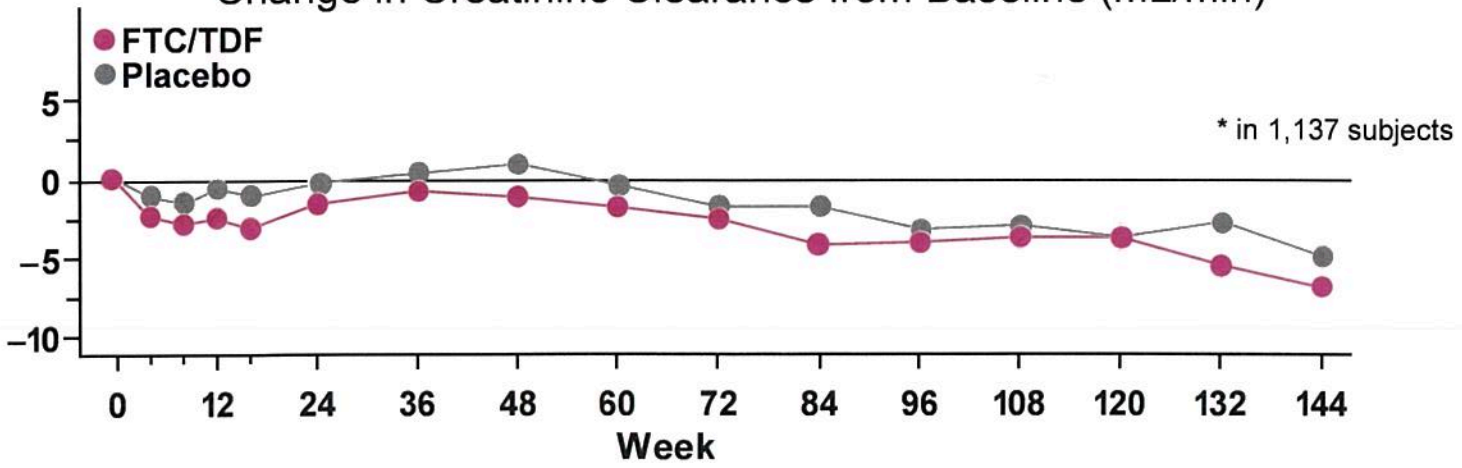
Renal Safety

Renal safety assessment of 2499 HIV-negative subjects in iPrEx study

- A mild, non-progressive decrease in creatinine clearance (Cockcroft-Gault), that was reversible and readily managed with routine monitoring
  - Did not vary by race, age, or HTN history
  - Affected by NSAID use
    - -3.4 mL/min (+NSAID) vs. -0.3 mL/min (no NSAID), $P = 0.04$

Mean Change in CrCL (mL/min)			
	TVD	**Placebo**	**P-value**
Wk 4	-2.4	-1.1	0.02
At Stop	+0.3	+1.8	0.02
Post-stop	-0.1	0.0	0.83

Change in Creatinine Clearance from Baseline (mL/min)*



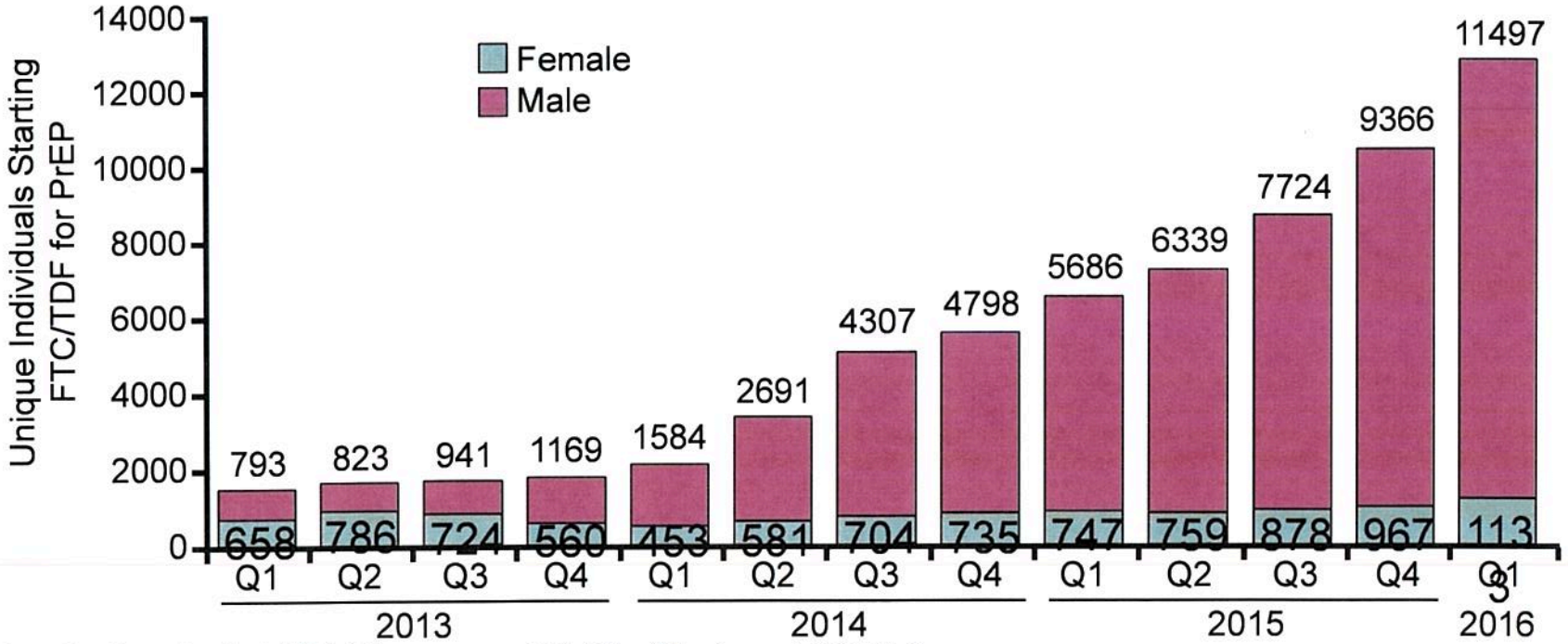
Solomon M. AIDS 2014;28(6):851-9

Estimated Percentages and Numbers of Adults with Indications for PrEP, by Transmission Risk Group — US, 2015

Transmission risk group	% with PrEP indications*	Estimated no.	(95% CI)
Men who have sex with men, aged 18–59 yrs[†]	24.7	492,000	(212,000–772,000)
Adults who inject drugs, aged ≥18 yrs[§]	18.5	115,000	(45,000–185,000)
Heterosexually active adults, aged 18–59 yrs[¶]	0.4	624,000	(404,000–846,000)
Men**	0.2	157,000	(62,000–252,000)
Women	0.6	468,000	(274,000–662,000)
Total	—	**1,232,000**	**(661,000–1,803,000)**

Sex Disparities in US PrEP Use Expansion From 2013 to 2016

- Electronic patient-level data from 82% of US retail pharmacies with FTC/TDF dispensed for PrEP January 2013 to March 2016
- N = 67,403 individuals initiated FTC/TDF PrEP; quarter-by-quarter growth in utilization 870% overall, 172% among women, 1450% among men



Bush S, et al. HIV Glasgow 2016. Abstract O314.

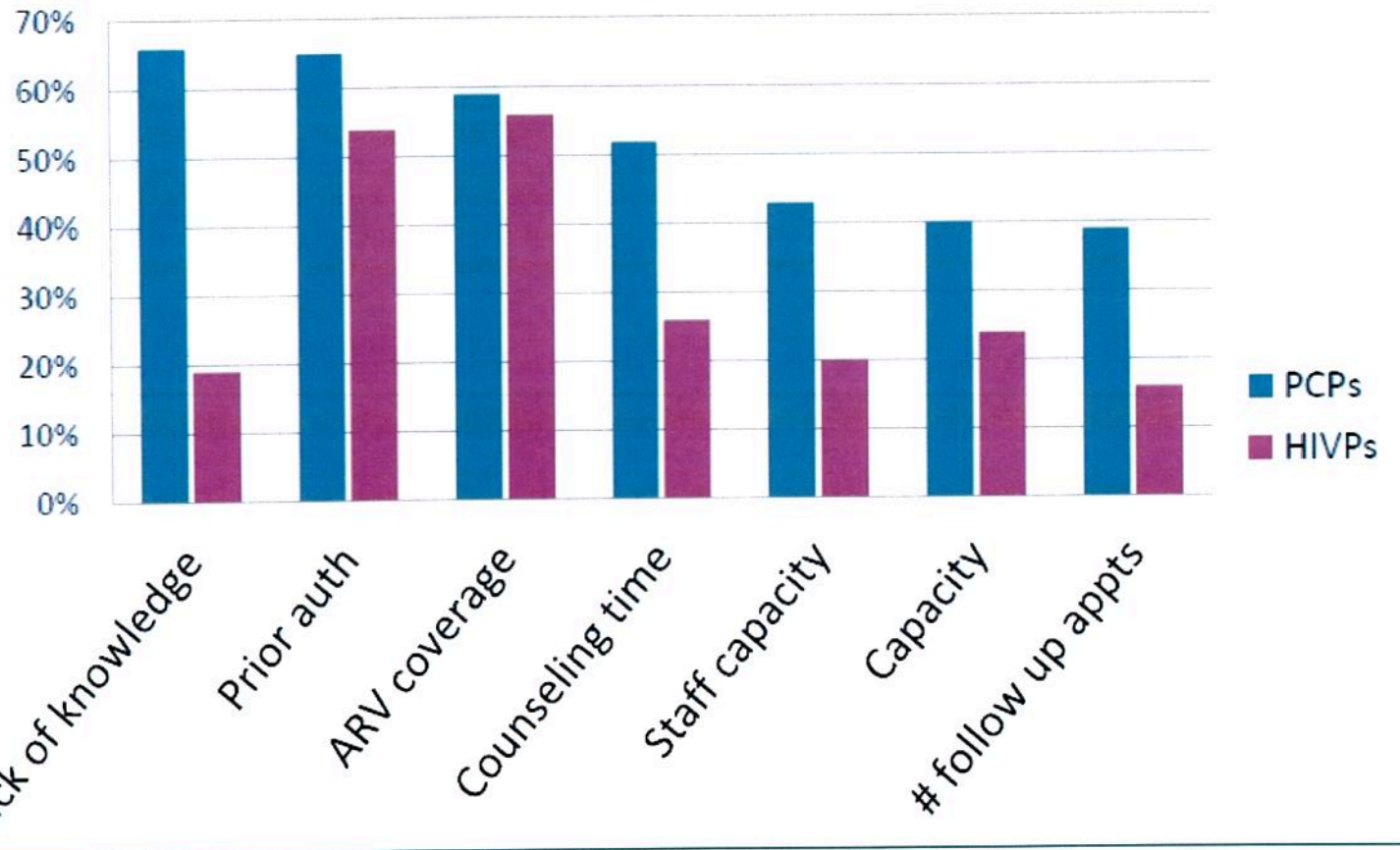
Racial Disparities in US PrEP Use Expansion From 2013 to 2016

- In 2015 and Q1 2016, likelihood of initiating PrEP 3.4 and 4.2 times higher for White vs Black or Latino women, respectively
  - Likelihood 8.1 and 6.6 times higher for white vs Black or Latino men, respectively

FTC/TDF PrEP Start by Race/ Ethnicity Within Sex Subgroups, %	Women	Men
White	65	76
Black	17	9
Latino	15	11
Asian	3	3

Bush S, et al. Glasgow 2016. Abstract O314.

Provider reported barriers to PrEP implementation



Primary care providers identify more barriers to implementing PrEP than HIV Providers

HIV Providers (HIVP) n = 245
Primary care providers (PCP) n = 280

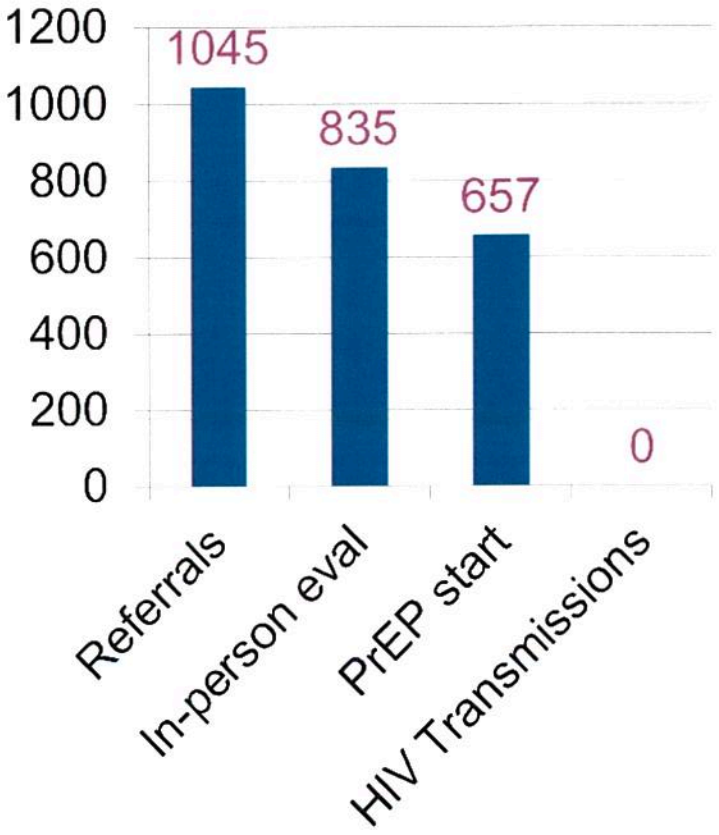
Petroll, A et al; GLMA2015

USAF PrEP Provider Survey - Results

- 404 (40%) ID and PCPs responded to an online survey
- The majority of providers rated their knowledge of PrEP as poor (overall 59%: PCP 62%, ID 5%)
- 26% prescribed ARVs to prevent HIV, commonly for PEP
- Only 9% of providers (5% PCP, 75% ID) reported ever prescribing PrEP
- 38% (PCP 34%, 95% ID) reported ever being questioned by a patient about PrEP
- Providers reported concerns about prescribing PrEP:
  - Medication adverse effects (overall 67%, PCP 68%, ID 85%)
  - Lack of clear evidence (overall 60%, PCP 65%, ID 62%)
  - Low adherence by patients (overall 54%; PCP 55%, ID 85%)

Hakre S, Scott PT, and Okulicz JF, Medicine 2016

PrEP Utilization in a Managed Care System (Kaiser Permanente)



- 388 person-years of PrEP use
- Mean duration of use 7.2 months
- Mean age 37
- 99% MSM (3 women, 1 trans man)
- Behavioral survey (n=143)
  - Sex partners unchanged in 74%
    - Decrease 15%; Increase 11%
  - Condom use unchanged in 56%
    - Decrease 41%; Increase 3%
- STD: 30% at 6 mo., 50% at 12 mo.
  - No baseline STD data available
- 0 HIV transmissions

"Given that STIs are independently associated with HIV acquisition, the frequent STI screening in [the] PrEP program may have facilitated earlier diagnosis and treatment of these infections and thus contributed to the protective benefit of PrEP against HIV infection. "

Volk, J et al. CID Sept . 2015

Extragenital STI Detection by Rectal/Pharyngeal Swabs - USAF

TABLE 2. Gonorrhea and chlamydia test results by anatomic site, HIV-infected service members, before and after implementation of extragenital screening

Screening period[a]	GC or CT infection			GC			CT		
Single-site[a]	Cases	Total tests	Prevalence (%)	Cases	Total tests	Prevalence (%)	Cases	Total tests	Prevalence (%)
Urethra	36	1,253	2.9	13	1,253	1.0	23	1,253	1.8
Multi-site[b]	Cases	Total tests	Prevalence (%)	Cases	Total tests	Prevalence (%)	Cases	Total tests	Prevalence (%)
Urethra[c]	9	486	1.9	4	486	0.8	5	486	1.0
Rectum	34	305	11.1	13	305	4.3	21	305	6.9
Pharynx	68	310	21.9	48	310	15.5	20	310	6.5

GC=*Neisseria gonorrhoeae*; CT=*Chlamydia trachomatis*

[a]1 January 2010 through 31 January 2013

[b]1 February 2013 through 31 May 2014

Patterson SB, Okulicz JF. MSMR 2014;21:7

A Vicious Cycle: STIs Predict Future HIV Risk

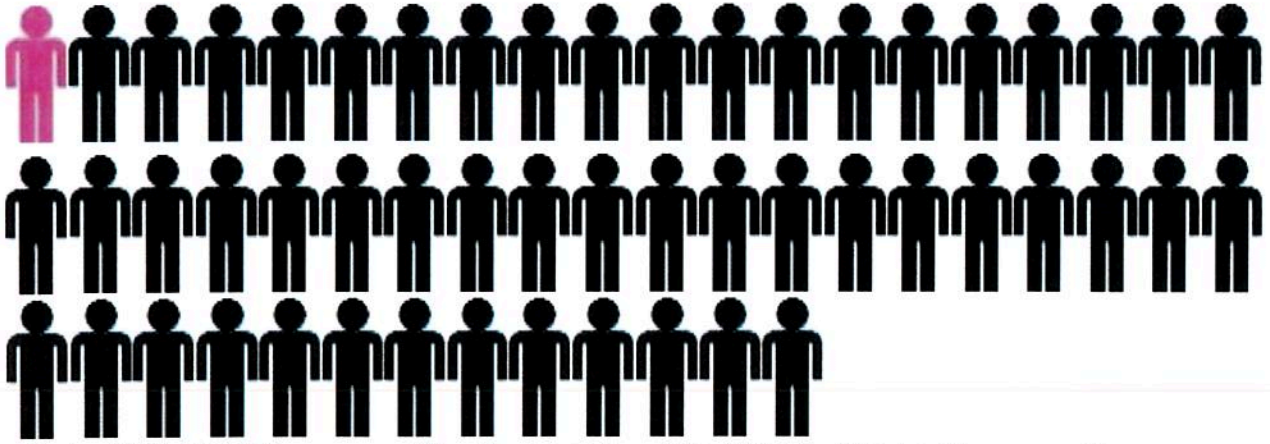
Rectal GC or CT

1 in 15 MSM were diagnosed with HIV within 1 year.*

Primary or Secondary Syphilis

1 in 18 MSM were diagnosed with HIV within 1 year.**

No rectal STD or syphilis infection



1 in 53 MSM were diagnosed with HIV within 1 year.*

**STD Clinic Patients, New York City. Pathela, CID 2013:57; **Matched STD/HIV Surveillance Data, New York City. Pathela, CID 2015:61*

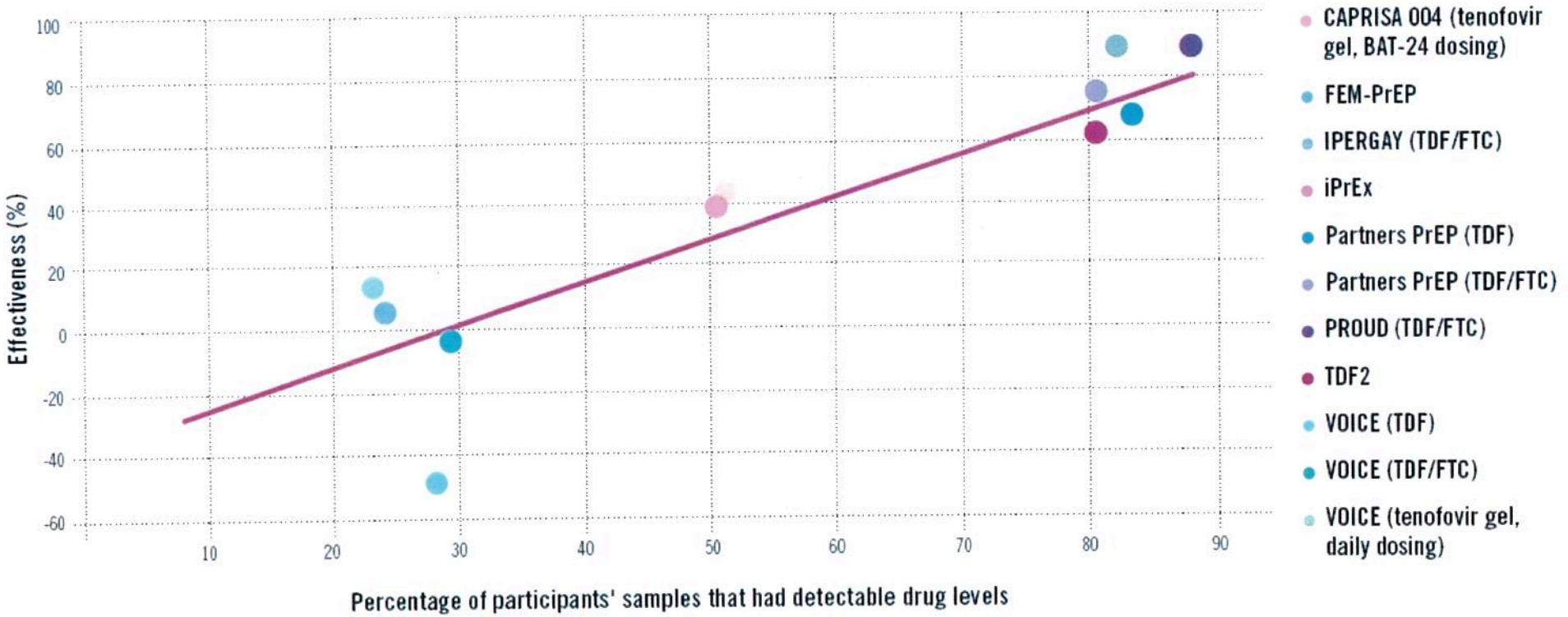
MSM STI Care – USAF Example

- Online survey was conducted to determine PCP knowledge and practices in the health care of MSM
  - 3 USAF MTFs in Northern CA
  - 65 respondents (46% response rate)
- Results
  - 15% correctly identified all CDC-recommended STI screens
  - 42% stated that they did not know the CDC screening guidelines
  - 51% did not screen male patients for MSM activity in the past year
  - 81% of respondents had not offered the full complement of MSM STI screening in the past year

Tong RL, Mil Med 2012;178:e248

PrEP Works if You Take It

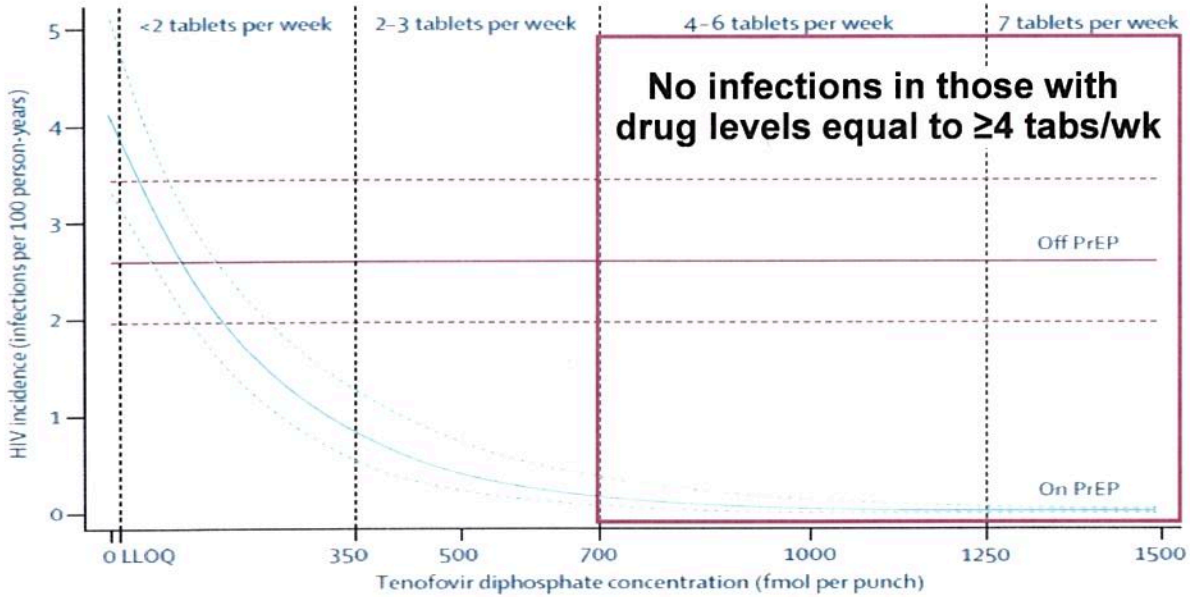
— Effectiveness and Adherence in Trials of Oral and Topical Tenofovir-Based Prevention



http://www.avac.org/sites/default/files/resource-files/PrEPbtn_FEB2016.pdf

HIV Incidence and Drug Concentrations in MSM

Modeling data from subjects in randomized placebo-controlled iPrEx, ATN 089, or US PrEP safety trials were enrolled in the 72-week open label extension (iPrEx OLE)



Drug Concentration	none	<2 pills/week	2-3 pills/week	≥ 4 pills/week	7 pills/week
HIV Incidence per 100 PY (95%CI)	*4.7 (2.99-7.76)*	*2.25 (1.19-4.79)*	*0.56 (0.00-2.50)*	*0*	*0*
Risk Reduction (95%CI)		*44% (-31-77)*	*84% (21-99)*	***100% (86-100)***	

Buchbinder S, et al. Lancet ID 2014;14(6):468-475
Truvada® (TVD). US Prescribing Information. Gilead Sciences Inc. 2013.

Recommended dose of TVD for PrEP in HIV-1 uninfected adults: One tablet once daily taken orally with or without food

Potential Candidates for PrEP

	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection	HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work	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	HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible	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		

CDC. Preexposure prophylaxis for the prevention of HIV infection in the United States – 2014. A clinical practice guideline. Available at http://www.cdc.gov/hiv/prevention/research/prep/.

CDC Risk Assessment Tool - HIV Incidence Risk Index for MSM (HIRI-MSM)

- Scored 7-item screening index predicted HIV seroconversion in two large prospective cohorts of MSM in the United States
- Useful to prioritize patients for PrEP and other intensive HIV prevention efforts

Score	Prevention Tactic
≥10	PrEP evaluation
≤9	Standard prevention

HIRI-MSM Risk Index*			
1.	How old are you today (yrs)?	<18 years	Score 0
		18-28 years	Score 8
		29-40 years	Score 5
		41-48 years	Score 2
		≥ 49 years	Score 0
2.	How many men have you had sex with in the last 6 months?	> 10 male partners	Score 7
		6-10 male partners	Score 4
		0-5 male partners	Score 0
3.	In the last 6 months, how many times did you have receptive anal sex without a condom (you were are the bottom) with a man?	1 or more times	Score 10
		0 times	Score 0
4.	How many of your male sex partners were HIV positive?	>1 positive partner	Score 8
		1 positive partner	Score 4
		<1 positive partner	Score 0
5.	In the last 6 months, how many times did you have insertive anal sex (you were the top) with a man who was HIV positive?	5 or more times	Score 6
		0 times	Score 0
6.	In the last 6 months, have you used methamphetamines such as crystal or speed?	Yes	Score 5
		No	Score 0
7.	In the last 6 months, have you used poppers (amyl nitrate)?	Yes	Score 3
		No	Score 0
	Add down entries in right column to calculate total score		Total Score†

*To identify sexually active MSM in their practice, we recommend clinicians ask all their male patients a routine question: "In the past (time) have you had sex? (if yes), with men, women, or both?"
† If Score is 10 or greater, evaluate for PrEP or other intensive HIV prevention services. If score is 9 or less, provide indicated standard HIV prevention services.

Adapted from Smith D. JAIDS 2012;60:421-427

TABLE 2. CONTRAINDICATIONS TO PrEP

Medical Contraindications:

- **Documented HIV infection**
  - Drug-resistant HIV has been identified in patients with undetected HIV who subsequently received TDV/FTC for PrEP
- **Creatinine clearance <60 mL/min**

Lack of readiness to adhere to a daily PrEP regimen is also a contraindication. Efficacy of PrEP is dependent on adherence to ensure that plasma drug levels reach a protective level.

Other considerations:

- Chronic active HBV infection?
- Pregnant or attempting to conceive?
- Adolescent?
- Taking other nephrotoxic drugs?
- Osteopenia/Osteoporosis?

Lack of use of barrier protection is NOT a contraindication to PrEP

New York State Department of Health AIDS Institute. 2014 PrEP guidance. Available at www.hivguidelines.org.

Obtain the following tests before prescribing PrEP:

- ☐ **Baseline HIV Test**
  - Obtain third-generation or fourth-generation HIV test (list of 3rd and 4th generation tests is available here)
  - Perform nucleic acid amplification test (NAAT, viral load) for HIV for:
    - Patients with symptoms of acute infection
    - Patients whose antibody test is negative but who have reported unprotected sex with an HIV-infected partner in the last month[1]

Drug-resistant HIV has been found in patients with undiagnosed HIV who were using TDF/FTC as PrEP.

- ☐ **Basic Metabolic Panel**
  - Do not initiate PrEP in patients with creatinine clearance <60 mL/min
- ☐ **Urinalysis**
  - Proteinuria is an early warning sign of tenofovir toxicity: baseline urinalysis is necessary to identify pre-existing proteinuria
- ☐ **Serology for Viral Hepatitis A, B, and C**
  - Immunize against hepatitis A and B in non-immune patients
- ☐ **Screening for Sexually Transmitted Infections**
  - Nucleic acid amplification test (NAAT) for gonococcal and chlamydial infection — three-site screening (genital, rectal, pharyngeal)
  - Rapid plasma reagin (RPR) for syphilis
- ☐ **Pregnancy Test**
  - If a woman is pregnant when starting PrEP or becomes pregnant while on PrEP, discuss the known risks and benefits

From NYSDOH AI guidance: www.hivguidelines.org

30-day visit:

Assess:

- Side effects
- Serum creatinine and calculated creatinine clearance for patients with borderline renal function or at increased risk for kidney disease (>65 years of age, black race, hypertension, or diabetes)
- Discuss risk reduction and provide condoms

Prescribe 60-day refill; patient must come in for 3-month visit for HIV test and follow-up assessments, then 90-day schedule can begin

3-month visit

- HIV test
- Ask about STI symptoms
- Discuss risk reduction and provide condoms
- Serum creatinine and calculated creatinine clearance
- Pregnancy test

6-month visit

- HIV test
- Obtain STI screening tests (see Table 8)
- Pregnancy test
- Discuss risk reduction and provide condoms

12-month visit

- HIV test
- Obtain STI screening tests (see Table 8)
- HCV serology for MSM, IDUs, and those with multiple sexual partners
- Discuss risk reduction and provide condoms
- Pregnancy test
- Urinalysis

PrEP in the USAF:

PROs

- Effective
- FDA-approved
- Well tolerated
- Improved public health prevention/STI capture
- Enhances provider-patient relationship

CONs

- Short-term data
- Daily adherence → cost
- Side effects
- Drug resistance?
- Increased STI risk?
- Logistics → restricted access?
- Variation in provider knowledge/ethics
- Lack of standardized care

Military-specific PrEP Issues

- Standardizing PrEP management practices
  - Criteria used to start PrEP (MSM risk index, etc.)
  - Follow ups, STI screening
- Appropriate access/monitoring outside of major MTFs
  - Prev Med, Public Health
  - Internal Med, Family Practice/PAs/NPs
- Use of PrEP on flight status
- Use of PrEP in OCONUS settings, on deployments
- Gaps in care: "intermittent" PrEP
- Is q3 month follow up necessary?

PrEP Rollout - USAF

- Establishing a pathway for PrEP is of major importance
  - Larger MTFs typically utilize uniformed ID specialists
  - Smaller MTFs
    - Need for uniformed providers who are "early adopters" of PrEP in their workspaces
    - Alternative option would be to refer off base to PrEP-friendly civilian providers
- PrEP education resources
  - CDC guidelines: https://www.cdc.gov/hiv/risk/prep/
  - NY Dept of Health:
    - https://www.health.ny.gov/diseases/aids/general/prep/index.htm#prep
- USAF/DoD guidelines – currently in development

Ongoing PrEP Initiatives

DHP-funded HIV/BBP Threat Reduction Program HIV PrEP Portfolio

- DoD-wide PrEP experience to date (Beckett, Okulicz, Blaylock/Garges, MHRP/WRAIR*)
  - Analysis of all DoD beneficiaries prescribed PrEP to-date
- Air Force Primary Care and Infectious Diseases provider PrEP assessment (Okulicz, MHRP/WRAIR)
  - Army and Navy PrEP provider assessments in progress
- DoD medical economic analysis of PrEP implementation (MHRP/WRAIR*)
  - Cost/benefit, cost effectiveness, and budget impact assessment
- Develop DoD PrEP policy, practice guidance, education/dissemination plan (Triservice, MHRP/WRAIR)

*Military HIV Research Program/Walter Reed Army Institute of Research

Thank You!