

# HIV Infection in the US Military: Update and Policy Implications

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### Disclaimer



The views expressed in this lecture are my own and should not be construed to represent the positions of the US Army, US Navy, US Air Force, or the Department of Defense.



# Agenda

- HIV Epidemiology in DoD Overview
- DoD HIV policy
  - Service-specific policy updates
- Under Sec Def memo
  - Deployment implications/issues
  - Proposed COAs
- Update on PrEP uptake in US military





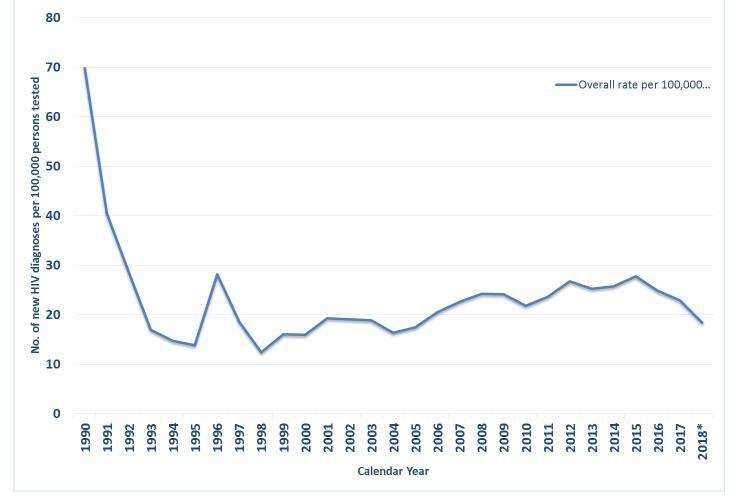
# **HIV Impact on the Military**

- Military mission and troop readiness
  - Incurable
  - Lifelong therapy required
  - High cost
  - Limitations to duty assignments
  - Legacy of "DADT"
- Need for screening measures
  - Accession screening
  - Standard testing: q2 years, w/in 6mo of deployment, STI screens<sup>\*</sup>





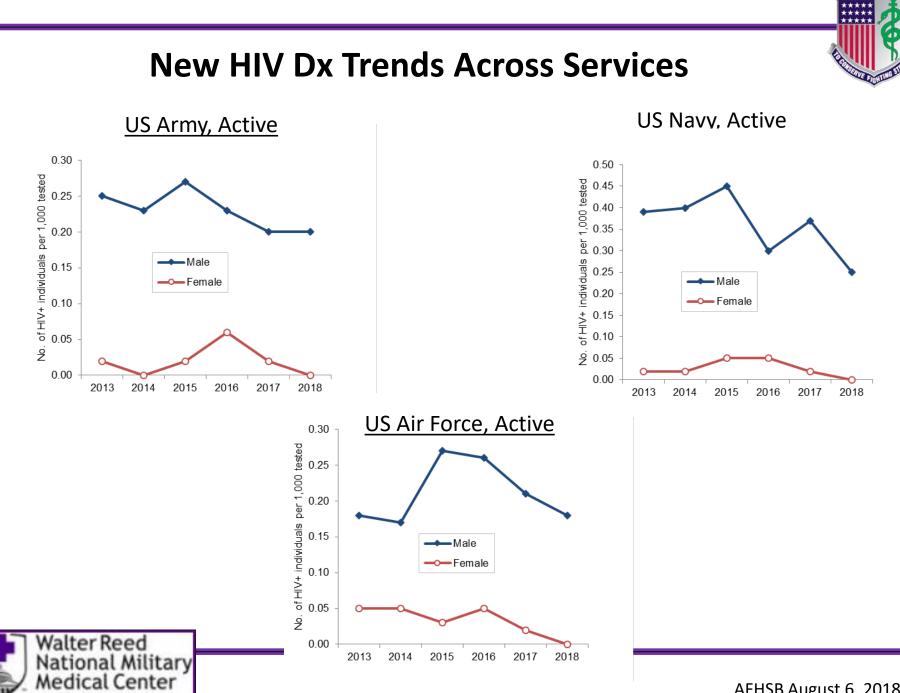
#### HIV Rates, US Armed Forces, 1990-2018\*



\*through August 6, 2018



AFHSB August 6, 2018



AFHSB August 6, 2018



### 2016-2017 HIV Infections by Service

<u>Air Force</u> (Source: SAMMC extract, Dr. Okulicz) 2016: AD - 41, NG - 2, R- 4, TOT=47 2017: AD - 32, NG - 0, R- 2, TOT=34

**<u>Army</u>** (Source: AFHSB extract from StephanieScoville) 2016: AD - 60, NG - 59,R - 39, TOT=158 2017: AD - 51, NG - 53,R - 37, TOT=141

#### Navy/Marines

2016: USN – AD (54), Res (8), USMC – AD (16), Res (6); TOT= 84 2017: USN – AD (66), Res (8), USMC – AD (21), Res (8); TOT =103



AFHSB August 6, 2018



### 2016-2017 HIV Infections by Service

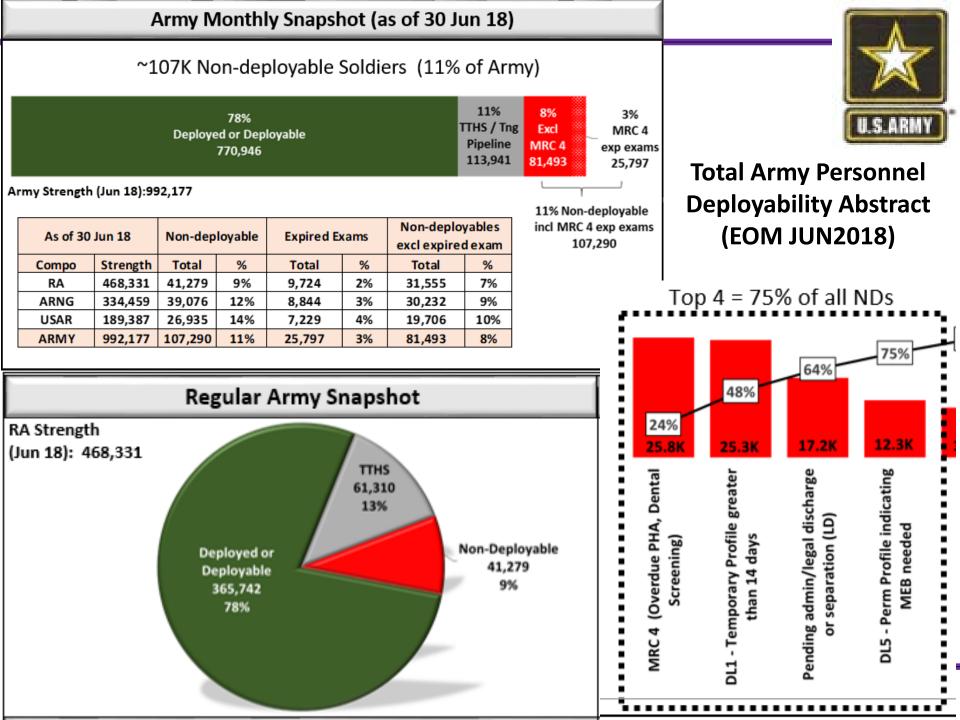
### HIV Infections, across all Services Army: ~925 Navy: ~479 Marine Corps: ~99 Air Force: ~274

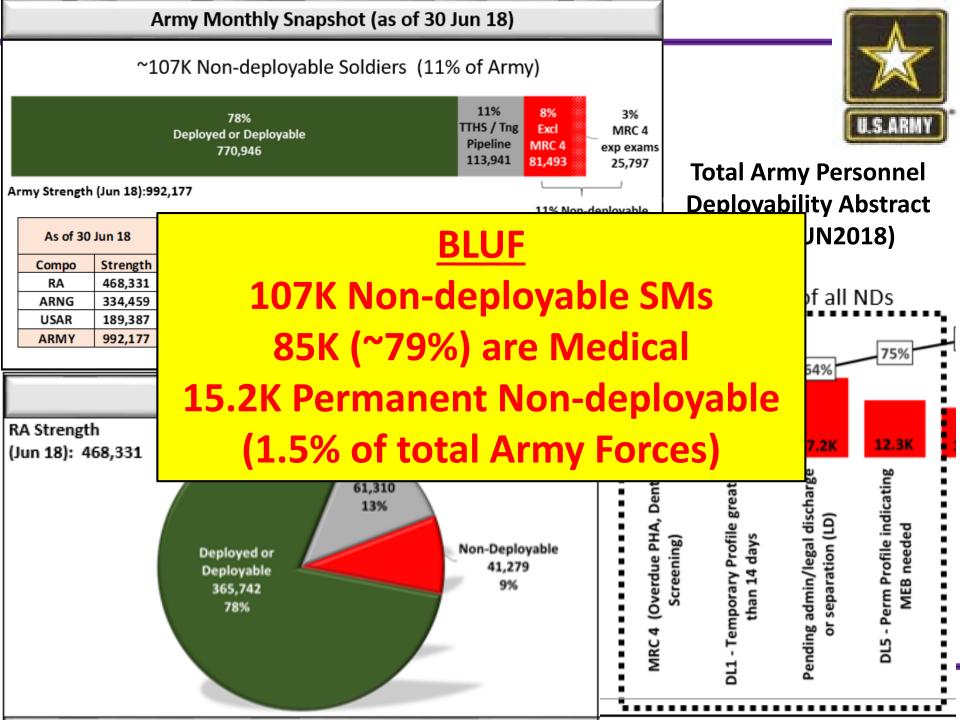
#### Navy/Warmes

2016: USN – AD (54), Res (8), USMC – AD (16), Res (6); TOT= 84 2017: USN – AD (66), Res (8), USMC – AD (21), Res (8); TOT =103



AFHSB August 6, 2018

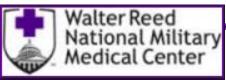






### HIV Infection in the Army (AUG2018)

- ~ 925 US Army SMs with HIV
  - Compo 1 (AC): 418; Compo 2 (NG): 263; Compo 3 (Res): 244
- Median age: 27 years old
- 74% non-Caucasian
- 64% assigned to a southern US command at dx
- 0.86% of non-deployable personnel
  - 6% of permanent non-deployable
- Median time in service after diagnosis: 3 ½ years





# **HIV Care: Estimated Cost to DoD**

- ~ \$25K per infected SM/year\*
  - \$17-18K/yr for ART<sup>\*\*</sup>
  - \$6-7K/yr for staging labs, clinical evaluations
  - \$1-2K/yr for travel/lodging/admin logistics

### ~ \$450K/person lifetime cost of HIV care\*\*\*



\*Current CDC estimates from: Gebo KA, et al. AIDS 2010

\*\*Courtesy of DHA Pharmacy Operations Division, unpublished data. \*\*\*Farnham PG, et al. J Acquir Immune Def Syndr 2013.



#### Department of Defense INSTRUCTION

NUMBER 6485.01 June 7, 2013

USD(P&R)

SUBJECT: Human Immunodeficiency Virus (HIV) in Military Service Members

b. In accordance with DoDI 6490.07 (Reference (j)), the cognizant Combatant Command surgeon will be consulted in all instances of HIV seropositivity before medical clearance for deployment.

3. <u>TRANSMISSION CONTROL</u>. Transmission of HIV will be controlled through aggressive disease surveillance and health education programs for Service members. A Service member with laboratory evidence of HIV infection will receive training on the prevention of further transmission of HIV infection to others and the legal consequences of exposing others to HIV infection.



Walter Reed National Military Medical Center

Executive Services Directorate. http://www.esd.whs.mil/Directives/issuances/dodi/



### Department of Defense INSTRUCTION

NUMBER 6490.07

February 5, 2010

USD(P&R)

SUBJECT: Deployment-Limiting Medical Conditions for Service Members and DoD Civilian Employees

(2) A diagnosis of human immunodeficiency (HIV) antibody positive with the presence of progressive clinical illness or immunological deficiency. The cognizant Combatant Command surgeon shall be consulted in all instances of HIV seropositivity before medical clearance for deployment.



Executive Services Directorate. http://www.esd.whs.mil/Directives/issuances/dodi/

#### Army Regulation 600–110 — Identification,

Headquarters Department of the Army Washington, DC 22 April 2014 Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus

HIV-infected Soldiers will **NOT**:

- be deployed or assigned overseas
- Perform official duties overseas for any duration of time

Will **NOT** be assigned to:

- any TO&E unit, and if newly infected, will be reassigned to a TDA unit
- military-sponsored education programs which would result in additional service obligation

**ARE** eligible for all military professional development schools and military training required to qualify for reclassification to new MOS or skill identifier





Report to the Committees on the Armed Services of the Senate and House of Representatives on Department of Defense Personnel Policies Regarding Members of the Armed Forces Infected with Human Immunodeficiency Virus



2018

**Response to Congressional Inquiry re: HIV infection in military** 





# **Revisions to AR 600-110\***

- Allow for OCONUS assignments
- Recommend <u>against</u> combat deployments
- Recommend <u>against</u> assignment to TO&E units, except by waiver
- Allow for participation in military-sponsored education programs and training

\*pre-Sec Def memo; based on 2015 Working Group assessment and 2015 white paper soliciting ID SME opinions





DEPARTMENT OF THE NAVY

OFFICE OF THE SECRETARY 1000 NAVY PENTAGON WASHINGTON DC 20350-1000

> SECNAVINST 5300.30E ASN(M&RA) 13 August 2012

#### SECNAV INSTRUCTION 5300.30E

- From: Secretary of the Navy
- Subj: MANAGEMENT OF HUMAN IMMUNODEFICIENCY VIRUS, HEPATITIS B VIRUS AND HEPATITIS C VIRUS INFECTION IN THE NAVY AND MARINE CORPS

a case-by-case basis in consultation with the treating HETU, NBIMC, and PERS-82 or USMC M&RA (if dealing with Marines), certain personnel who are considered to have controlled HIV disease as manifested by a reconstituted immune system, no viremia, an established history of medical compliance, and a history of professional attitude, may be considered for OCONUS or large ship platform tours. This placement will require the receiving command's acceptance. These personnel will not be considered for overseas individual augmentee (IA) tours given the austere environments where they potentially could be placed. This policy



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#### BY ORDER OF THE SECRETARY OF THE AIR FORCE



#### AIR FORCE INSTRUCTION 44-178

*4 MARCH 2014* Certified Current 28 June 2016 *Medical* 

#### HUMAN IMMUNODEFICIENCY VIRUS PROGRAM

be deployed outside of CONUS (except for Alaska, Hawaii, and Puerto Rico). HIV-infected members shall not be assigned to OCONUS mobility positions, and those on flying status must be placed on Duty Not Including Flying (DNIF) status pending medical evaluation/waiver determination. Waivers are considered using normal procedures established for chronic diseases. Aeromedical waivers are considered according to the Aerospace Medicine Waiver Guide. Members on the Personnel Reliability Program (PRP)





UNDER SECRETARY OF DEFENSE 4000 DEFENSE PENTAGON WASHINGTON, D.C. 20301-4000

FEB 1 4 2018

#### MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS CHAIRMAN OF THE JOINT CHIEFS OF STAFF UNDER SECRETARIES OF DEFENSE DEPUTY CHIEF MANAGEMENT OFFICER CHIEF, NATIONAL GUARD BUREAU DIRECTOR OF COST ASSESSMENT AND PROGRAM EVALUATION

#### SUBJECT: DoD Retention Policy for Non-Deployable Service Members

In July, the Secretary of Defense directed the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)) to lead the Department's effort to identify changes to military personnel policies necessary to provide more ready and lethal forces. In his initial memorandum to the Department, Secretary Mattis emphasized, "[e]very action will be designed to ensure our military is ready to fight today and in the future." Given the Secretary's guidance, OUSD(P&R) moved forward from the underlying premise that all Service members are expected to be world-wide deployable. Based on the recommendations of the Military Personnel Policy Working Group, the Deputy Secretary of Defense determined that DoD requires a Departmentwide policy establishing standardized criteria for retaining non-deployable Service members. The objective is to both reduce the number of non-deployable Service members and improve personnel readiness across the force.



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FEB 1 4 2018

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS CHAIRMAN OF THE JOINT CHIEFS OF STAFF UNDER SECRETARIES OF DEFENSE

#### <u>BLUF</u>

- Non-deployable for > 12 consecutive months process for administrative separation
- Secretaries of Military Departments authorized to grant waivers of retention
- DoDI in process to provide additional guidance

to ensure our military is ready to fight today and in the future." Given the Secretary's guidance, OUSD(P&R) moved forward from the underlying premise that all Service members are expected to be world-wide deployable. Based on the recommendations of the Military Personnel Policy Working Group, the Deputy Secretary of Defense determined that DoD requires a Departmentwide policy establishing standardized criteria for retaining non-deployable Service members. The objective is to both reduce the number of non-deployable Service members and improve personnel readiness across the force.



# Not all Deployments are Equal

Considerations for all medical conditions:

- Climate
- Altitude
- Rations
- Housing
- Duty assignment
- Medication re-supply
- Laboratory capabilities

Issues for HIV (and bloodborne pathogens):

- Medication re-supply
- Duty assignment
- Risk of MASCAL scenario
  - "walking blood bank"
- Lack of FDA-approved rapid point-of-care HIV test for blood donation





### HIV Transmission risk (CDC data)

Type of Exposure

Risk per 10,000 Exposures

#### Parenteral

Blood Transfusion	9,250
Needle-Sharing During Injection Drug Use	63
Percutaneous (Needle-Stick)	23



Patel P, et al. Estimating per-act HIV transmission risk. AIDS 2014.



# Alere Determine HIV-1/2 Ag/Ab

- First FDA-approved rapid point-of care test
- CLIA-waived for fingerstick whole blood
- Results in 20 minutes
- 99% sensitivity for all sample types



But...not for blood donation





### **Potential COAs**

- (1) Non-deployable, no exceptions
- (2) Deployable, with geographic limitations – USN (and likely USAF) approach
- (3) Deployable with waiver/approval— Modify AR 600-110 to align with DoDI
- (4) Exemption from policy







#### DOD INSTRUCTION 1332.45

#### RETENTION DETERMINATIONS FOR NON-DEPLOYABLE SERVICE MEMBERS

Originating Component:	Office of the Under Secretary of Defense for Personnel and Readiness
Effective:	July 30, 2018
Releasability:	Cleared for public release. Available on the Directives Division Website at http://www.esd.whs.mil/DD/.
Incorporates and Cancels:	Office of the Under Secretary of Defense for Personnel and Readiness Memorandum, "DoD Retention Policy for Non-Deployable Service Members," February 14, 2018
Approved by:	Robert L. Wilkie, Under Secretary of Defense for Personnel and Readiness





#### DOD INSTRUCTION 1332.45

#### RETENTION DETERMINATIONS FOR NON-DEPLOYABLE SERVICE MEMBERS

**3.3. DEPLOYABLE WITH LIMITATIONS.** Service members with a medical condition that requires additional medical screening, or Combatant Command approval prior to deployment outside the continental United States, will be categorized as Deployable with Limitations. This includes, but is not limited to, conditions referred to in DoDI 6490.07.

Memorandum, "DoD Retention Policy for Non-Deployable Service Members," February 14, 2018

Approved by:

Robert L. Wilkie, Under Secretary of Defense for Personnel and Readiness



### DoD Policy Updates: Opportunities for Change?

Align HIV policy across all Services

### **Increase HIV prevention services**



# DHA HIV Tri-Service Working Group

- Service leads: Army, Navy, USAF
- Consultants: pharmacy, laboratory, policy
- Report to TSSCAB

Main Goal:

 Align clinical care and admin processes for HIV treatment and prevention services





# **Service Policy Discrepancies**

- US Army:
  - OCONUS/unit assignment restrictions
  - Decentralized tracking
- US Navy:
  - Ship assignments with waivers
  - Centralized tracking –
     HETU/NBIMC



- US Air Force:
  - OCONUS assignments allowed
  - Required annual visits to SAMMC
  - MEB at diagnosis
  - Centralized tracking



### **HIV PrEP Update in Military**





### HIV Risk in the US Military

- US Army, 2012–2014 (n=181)<sup>1</sup>
  - 92% believed HIV exposure was through sexual contact
  - 64% indicated male-male sexual contact
    - 78% MSM only, and 22% with both men and women
- US Navy and Marine Corps, 2005-2010 (n=64)<sup>2</sup>
  - 55% reported MSM only; 30% with both men and women
- USAF, 2010-2014 (n=316)<sup>3</sup>
  - 79% reported same sex contact
    - 71% MSM and 8% bisexual men vs 18% heterosexual men and women



1-Hakre S, J Acquir Immune Defic Syndr 2015.

2-Hakre S, J Acquir Immune Defic Syndr 2012. 3-Patterson SB. MSMR 2014.



#### HIV PrEP: Military Provider Surveys, 2016-17

#### (1599 respondents out of 4217 providers)

- Providers support use of PrEP: Army 82%, Navy, 78%, Air Force 64%
- Patient demand is high: 29-48% of providers were asked about PrEP
- Knowledge among providers is generally low
  - Rated knowledge as "poor": Army 55%, Navy 41%, Air Force 59%
- 88% support development of DoD HIV PrEP CPG
- >50% are interested in HIV PrEP training opportunities





# Active Duty SMs on PrEP

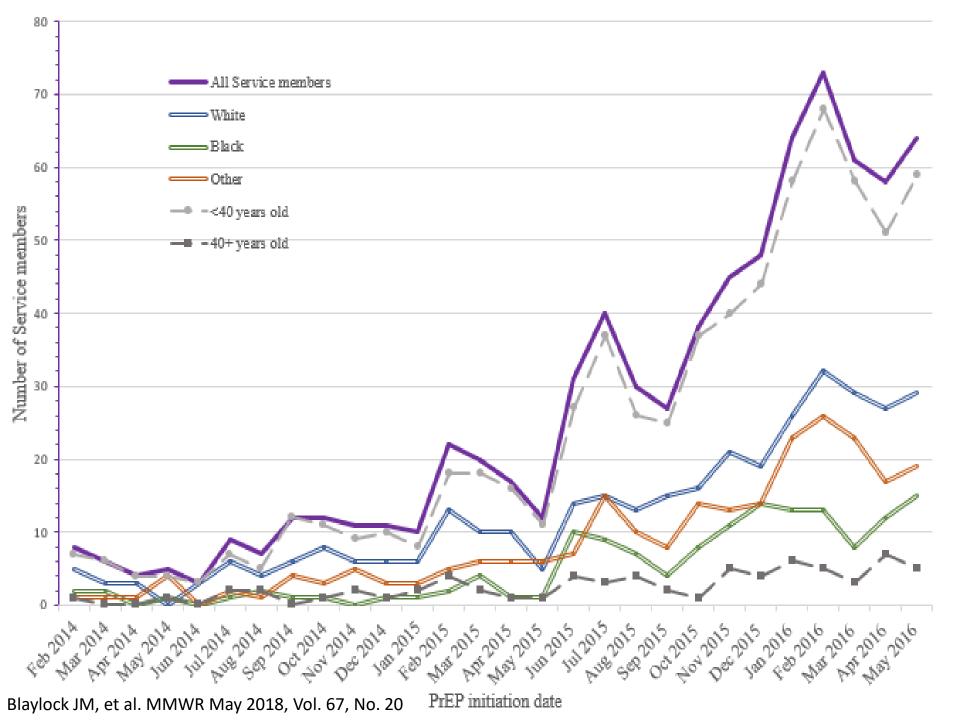
- N = 769 AD SMs on PrEP (FEB2014-JUN2016)
- MHS records/DoD pharmacy data review
  - Sole prescriptions for Truvada
    - Excluded HIV, HBV, and PEP
- Data collected:
  - Demographics, Service branch, risk behaviors,
     MSM risk index, required PrEP labs

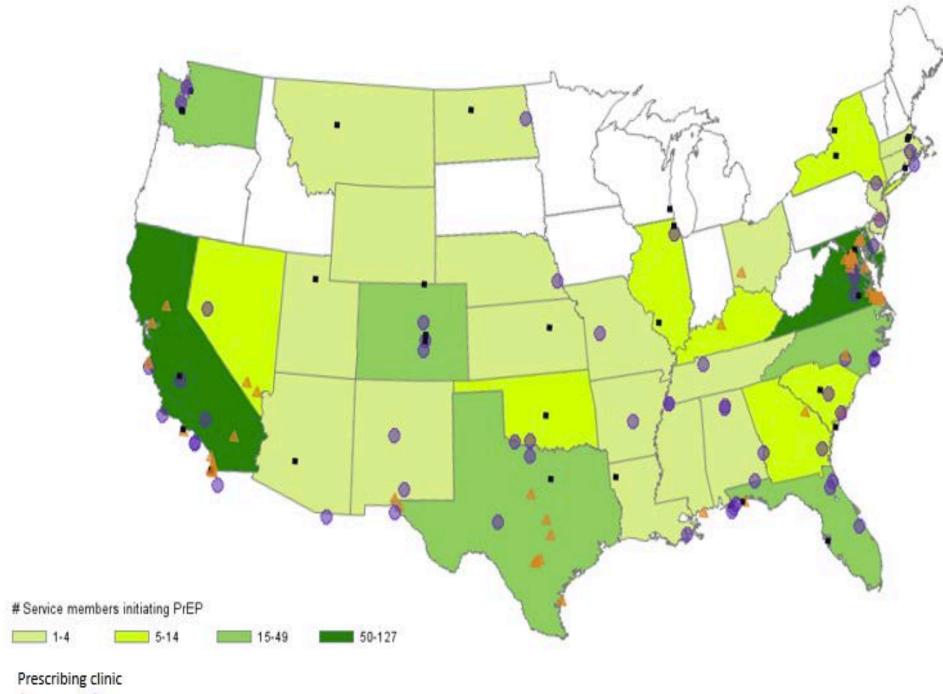


Characteristics	n (%)	
Total	769 (100)	
	109(100)	
Sex	750 (00)	420/ > 20, we ald
Male	759 (99)	42% > 28yrs old
Female	10 (1)	
Age (yrs)		
18–28	449 (58)	Only 19% blacks
29-40	263 (34)	
41-48	44 (6)	
≥49	13 (2)	87% identified as MSM
Race		
White	361 (47)	
Black	149 (19)	30% serodiscordant
Other*	259 (34)	
Service		
Army	207 (27)	20% with MSM risk scores
Navy	364 (47)	
Air Force	158 (21)	• 28% were < 10
Marine Corps	40 (5)	
Education, highest level		
High School or less	451 (59)	
Some College	84 (11)	
Bachelor's degree	120 (16)	
Higherthan Bachelor's degree	81 (11)	Blaylock JM, et al. MMWR May 2018, Vol. 67
Unknown	33 (4)	

TABLE. Characteristics of 769 U.S. military personnel on active service without HIV infection, who initiated human immunodeficiency virus preexposure prophylaxis, February 1, 2014–June 10, 2016

\*"Other" includes American Indian/Alaskan native, native Hawaiian/Pacific Islander, Asian, and unknown.





Non-ID Unknown

ID

Blaylock JM, et al. MMWR May 2018, Vol. 67, No. 20



## **PrEP: Potential Cost to DoD**

Assumptions:

- Males constitute 85% of 1.3 million AD SMs
- 4.23% are MSM
- 25% of MSM have increased risk for HIV infection
- Annual cost of Truvada to DoD is \$12K/person/yr





Hoover KW, et al. PLoS One 2017.

Smith DK, et al. MMWR Morb Mortal Wkly Rep 2015.

National Acquisitions Center, US Dept of VA. Pharmaceutical Catalog, 2017.



# **Next Steps for PrEP Research**

- Risk compensation on PrEP
  - STI rates pre- and post-PrEP
- Duration of PrEP use
  - Further inform financial cost to DoD
- Gaps in care
- Targeting nPEP transitions to PrEP
- Targeting high risk groups
  - Social Vaccine campaign (app-based)



\*\*\*\*\*

#### The Years Ahead in Biomedical HIV Prevention Research

AVAC

**Global Advocacy for HIV Prevention** 

Status of select biomedical HIV prevention clinical trials

																			THE FLOHTING	/
Efficacy Trial			2018			2019				2020				2021				2022		
	laginal Ring	HOPE (MTN 025)	Open-label t	rial of the	once-mon	thly slow-i	releas e da	pivirine va	ginal ring	ongoing	in 2,500 w	omen in N	lalawi, Sou	ith Africa,	Uganda, i	Zimbabwe				
	Dapivirine Ring	DREAM (IPM 032)	Open-label ti	ial of the (	once-mont	hly slow-r	elease daj	ivirine va	ginal ring;	ongoing i	in 1,400 w	omen in So	outh Africa	and Ugai	da					
	Antibody	AMP (HVTN 704/ HPTN 085)	Randomized	controlled	trial of the	VRCO1 a	ntibody in	lus ed ever	y two mon	ths; ongoi	ing in 2,70	0 MSM an	d transgen	der men a	women i	n Brazil, P	eru, Switze	rland and	US	
	VRC01	AMP (HVTN 703/ HPTN 081)	Randomized (	ontrolled	trial of the	VRCO1 a	ntibody ini	used ever,	y two mon	hs; ongoil	ng in 1,50	0 women i	h Bots wan	a, Kenya,	Malawi, M	bzambiqu	e, Tanzania	, South A	frica, Ziml	abwe
B	Oral PrEP F/TAF (Descovy)	DISCOVER	Randomized	controlled	trial of on	ce-daily F/	TAF as Pr	P; ongoin	g in 5,400	MSM and	transgend	der women	at approx	imately 90	sites in E	urope and	the Ameri	cas		
1	Long-Acting Iniectable	HPTN 083	Randomized (	ontrolled t	rial of injed	table cab	otegravir e	very two m	onths; ong	oing in 4,5	00 MSM a	nd transge	nder wome	n in Argen	tina, Brazi	, India, Pe	u, South A	frica, Thai	land, US, V	lietnam
M.	Cabotegravir	HPTN 084	Randomized	controlled	trial of inj	ectable ca	botegravi	every two	months;	lanned fo	or 3,200 w	omen in so	uthern an	d East Afr	ca					
<b>.</b>	Preventive H ALVAC/gp120 w/MF59	IV Vaccine HVTN 702	Randomized	controlled	trial of AL	VAC/gp120	0 prime-bo	ost with N	IF59 adjuv	ant, five o	loses over	12 month	s; ongoing	in 5,400 i	nen and v	omen in S	outh Afric	9		
	Ad26/gp140 boost	HPX2008/HVTN 705	Randomized	controlled	trial of Ad	26 prime I	with gp14	boost; pl	anned for	women in	southern	Africa enro	lling 2,600	9 women						
	Hormonal Cor , DMPA/ Levonorş implant/Copper		Randomized	open-labe	trial com	paring HIV	, incidence	and cont	aceptive l	enefits; o	ngoing in	7,800 won	ten in Kenj	a, South I	Africa, Sw	aziland an	d Zambia			



### **PrEP Rollout - DoD**

DHA Interim Procedures Memorandum –in development

Ensure pathways for PrEP:

- Larger MTFs typically utilize ID specialists
- Smaller MTFs
  - Need for providers as "early adopters" of PrEP
  - Alternative option: refer off base to PrEP-friendly civilian providers
- PrEP education resources:
  - PrEP "toolkit" for primary care clinics
  - CDC guidelines: provider supplement (2017); full guidelines under final review





#### HIV PRE-EXPOSURE PROPHYLAXIS (PrEP) PROVIDER REFERENCE KIT

May 2018

Dear Colleague,

This PrEP Provider Reference Kit includes information and resources needed to become a PrEP provider.

Its purpose is to set you and your clinic up for success in prescribing PrEP to patients who are at risk for acquiring HIV.

If you have questions or need further support, please contact our PrEP providers:

IDVIRTUALHEALTH@mail.mil

Sincerely,

The Tri-Service HIV Working Group



### Summary

- Policy updates regarding HIV in military

   Lots of uncertainty more to follow...
- Alignment of Service policies under DHA

   As much as possible...
- Increased incentive to protect SMs from HIV
- More research needed to target high risk groups





# **QUESTIONS?**

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