Defense Health Agency
PROCEDURAL INSTRUCTION

NUMBER 6025.29
December 20, 2019

DAD, MA

SUBJECT: Provision of Human Immunodeficiency Virus (HIV) Pre-Exposure Prophylaxis (PrEP) for Persons at High Risk of Acquiring HIV Infection

References: See Enclosure 1.

1. PURPOSE. This Defense Health Agency-Procedural Instruction (DHA-PI), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (i):

a. Establishes the Military Health System (MHS) instructions for the provision of HIV PrEP for persons at high risk of HIV acquisition.

b. Describes the elements and resources required to implement an HIV PrEP program.

c. Establishes the indications for HIV PrEP, laboratory (lab) testing and monitoring, and prescribing of HIV PrEP.

d. Provides a link to an HIV PrEP toolkit for providers.

2. APPLICABILITY. This DHA-PI applies to the Office of the Secretary of Defense, the Military Departments (MILDEPs) (including the Coast Guard at all times, including when it is a Service in the Department of Homeland Security by agreement with that Department), the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands (CCMDs), the Office of the Inspector General of the DoD, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD.

3. POLICY IMPLEMENTATION. It is the Defense Health Agency's (DHA) instruction, in accordance with References (d) through (g), that the HIV PrEP will be available and delivered in a standardized fashion throughout the MHS in order to minimize the risk of HIV acquisition.

4. CANCELLED DOCUMENTS. This DHA-PI cancels the following document, Defense Health Agency-Interim Procedures Memorandum 18-020, "Guidance for the Provision of Human Immunodeficiency Virus (HIV) Pre-Exposure Prophylaxis (PrEP) for Persons at High Risk of Acquiring HIV Infection."

5. RESPONSIBILITIES. See Enclosure 2.

6. PROCEDURES. See Enclosure 3.

7. RELEASABILITY. **Cleared for public release**. This DHA-PI is available on the Internet from the Health.mil site at: www.health.mil/DHAPublications.

8. EFFECTIVE DATE. This DHA-PI:

a. Is effective upon signature.

b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date in accordance with Reference (c).

RONALD J. PLACE
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Director

Enclosures
1. References
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Glossary

ENCLOSURE 1

REFERENCES

(a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA))," September 30, 2013, as amended
(b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013
(c) DHA-Procedural Instruction 5025.01, "Publication System," August 24, 2018
(d) DoD Instruction 6485.01, "Human Immunodeficiency Virus (HIV) in Military Service Members," June 7, 2013
(e) "National HIV/AIDS Strategy for the United States: Updated to 2020," July 30, 2015
(f) Centers for Disease Control and Prevention: U.S. Public Health Service, "Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update, A Clinical Practice Guideline," March 2018
(g) Center for Disease Control and Prevention: U.S. Public Health Service, "Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update, Clinical Providers' Supplement," March 2018
(h) DoD Instruction 6490.07, "Deployment-Limiting Medical Conditions for Service Members and DoD Civilian Employees," February 5, 2010
(i) DoD Instruction 6480.04, "Armed Services Blood Program Operational Procedures," August 13, 2012, as amended.

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ENCLOSURE 2

RESPONSIBILITIES

1 DIRECTOR, DHA. Under the authority, direction, and control of the Assistant Secretary of Defense for Health Affairs, and in accordance with DoD policies and issuances. The Director, DHA, will direct compliance with this DHA-PI by the military medical treatment facilities (MTFs). This includes:

a. Ensuring MTFs have the capability to provide or coordinate health care for military and non-military beneficiaries who are at high risk for HIV acquisition.

b. Ensuring MTFs leverage HIV PrEP care capability and expertise across the MHS to include case consultation, provision of medical care, and telemedine.

c. Monitoring compliance with this DHA-PI, which may include assessing MILDEPs and DHA performance on all provisions contained in this DHA-PI.

2. DEPUTY ASSISTANT DIRECTOR (DAD), MEDICAL AFFAIRS (MA). The DAD-MA, will coordinate with the Secretaries of the MILDEPs and Commandant, U.S. Coast Guard to issue policies and establish procedures at MTFs under their control in accordance with the provisions in this DHA-PI.

3. DIRECTORS, MTF. The Directors, MTF will:

a. Provide a pathway for access to HIV PrEP for all military and non-military beneficiaries who are at high risk for HIV acquisition as detailed in current Centers for Disease Control and Prevention (CDC) guidelines (Reference (f)).

b. Ensure DoD healthcare providers and patient beneficiaries have access to a pathway, via MTF, Service/DoD clinical, reference, or contract lab, to lab services required for clinical evaluation and monitoring of HIV PrEP.

c. Ensure DoD providers use Reference (f), to provide beneficiaries HIV prevention services tailored to their needs based on risk screening information and HIV test results.

d. Provide U.S. Food and Drug Administration (FDA)-approved HIV PrEP treatment option(s) to those individuals determined to need them, either through the MTF pharmacy, or through other options.

e. Not recommend deployment disqualification for Active Duty and Reserve members on PrEP solely due to PrEP use, as PrEP can be stopped prior to deployment.

ENCLOSURE 3

PROCEDURES

1. HIV PrEP: EVALUATION AND MONITORING. The provider will follow current CDC guidelines (References (f) and (g)), for identification of appropriate candidates for HIV PrEP and evaluation and monitoring of HIV PrEP patients. Areas where this instruction deviates from current guidelines are detailed below.

a. HIV testing prior to initiating PrEP to ensure HIV-uninfected status. Prior to initiating PrEP, a patient must have the following to rule out HIV infection:

(1) A documented negative fourth generation HIV antigen (Ag)/antibody (Ab) test, ideally within 7 days if an Acute Human Immunodeficiency Virus infection (AHI) is **NOT** suspected;

(2) A documented negative fourth generation HIV Ag/Ab test **and** a documented negative Nucleic Acid Test (NAT), ideally within 7 days, if an AHI **is** suspected.

(a) Aptima HIV-1 Ribonucleic Acid Qualitative Assay is the preferred NAT and is FDA-approved for HIV diagnosis. If the Aptima NAT is not available, an HIV viral load (VL) is acceptable.

(b) HIV VL is not FDA approved for HIV diagnosis.

(c) Rapid diagnostic tests are not recommended due to suboptimal performance in the diagnosis of acute HIV infection.

(d) If the patient had exposure to antiretroviral medicines in the past 28 days (either as HIV, Nonoccupational Post-Exposure Prophylaxis (nPEP), or PrEP), the decision to initiate HIV PrEP should be deferred, and an Infectious Diseases (ID) physician should be consulted. Additional lab and diagnostic consultative services are available as needed from the Walter Reed Army Institute of Research (WRAIR) Human Immunodeficiency Virus Diagnostics and Reference Laboratory (HDRL).

b. HIV testing prior to continuation of PrEP and to rule out AHI. Follow up with the PrEP provider will occur at 3-month intervals (+/-30 days). Prior to continuation of PrEP, a patient must have the following to rule out HIV infection:

(1) Negative repeat fourth generation HIV Ag/Ab test; and

(2) Compliance with PrEP, side effects, and signs/symptoms of AHI. If the patient reports signs/symptoms of AHI, a documented negative fourth generation HIV Ag/Ab test **and** a documented negative NAT, ideally within 7 days, are required in order to continue PrEP.

c. HIV testing in nPEP to PrEP transition, PrEP non-adherence, and other exposure to antiretroviral therapy in the past 28 days.

(1) If a patient reports stopping PrEP for over 1 week prior to reevaluation, the provider should wait for a negative fourth generation HIV Ag/Ab test result prior to reinitiating PrEP; and

(2) If the patient had exposure to antiretroviral medicines in the past 28 days (either as HIV nPEP or PrEP), conduct the following:

(a) Assess for signs and symptoms of AHI;

(b) Repeat a fourth generation HIV Ag/Ab test and NAT;

(c) Defer the decision to initiate PrEP; and

(d) Consult an ID physician; additional lab and diagnostic consultative services are available from WRAIR HDRL as needed.

d. Annual hepatitis C virus screening. At each 12-month interval (+/-30 days), the hepatitis C Ab testing is to be assessed; this is not specifically stated in CDC HIV PrEP guidelines, but is a joint recommendation provided by the American Association for the Study of Liver Diseases and Infectious Diseases Society of America.

2. ELEMENTS OF AN OPTIMAL HIV PrEP PROGRAM. Elements of an optimal HIV PrEP program include:

a. Clinic staff and providers who are able to provide HIV PrEP adherence and risk reduction counseling and who are culturally competent to provide care to patients in the lesbian, bisexual, gay, and transgender community.

b. Administrative and front desk staff who are aware that HIV PrEP services are provided and who are able to triage patient inquiries and schedule visits appropriately.

c. One or more qualified HIV PrEP providers (as defined in this DHA-PI).

d. Lab capability or access to a DoD referral/reference lab or contract lab with the capability to perform required lab testing.

e. Access to PrEP via the TRICARE Pharmacy program, as prescribed according to existing CDC HIV PrEP guidelines.

f. Delivery of HIV PrEP via mail order pharmacy is highly discouraged. The current CDC PrEP guidelines recommend no more than 90 days of HIV PrEP without refills be provided at each visit in order to ensure HIV testing is obtained every 3 months while on HIV PrEP. The use of mail order pharmacy has the potential to result in significant delays in obtaining HIV

PrEP with resultant gaps in medication prophylaxis.

g. Due to the quantity limitation of a 30 day supply unique to the retail pharmacy network, providers who order PrEP from the retail pharmacy network should order the medication as a 30 day supply with 2 refills. Providers should emphasize to patients who obtain PrEP in this manner the importance of obtaining refills to ensure no gaps in medication prophylaxis.

3. MILITARY-SPECIFIC CONSIDERATIONS

a. Use of HIV PrEP should not be construed as having HIV infection when determining eligibility for re-enlistment or for accession into any Service branch.

b. In general, HIV PrEP medication will not be initiated during or within deployed environments. Possible exceptions exist where adequate resources could be made available (e.g., Outside Continental United States MTFs, hospital ships, etc.), although no guaranteed provisions can be demanded. Emtricitabine (FTC)/tenofovir disoproxil fumarate (TDF) for use as post-exposure prophylaxis for any occupational or non-occupational exposures will be initiated when warranted. Pharmaceutical supplies intended for emergency post-exposure prophylaxis will not be compromised for HIV PrEP. PrEP use during deployment may not be available. If available, PrEP use must be in accordance with relevant CCMD and Service-specific medical guidance.

c. Taking PrEP should not impact an individual's medical readiness status, as PrEP may be discontinued prior to deployment. Prior to deployment, the prescribing provider should provide education regarding alternative HIV prevention practices (e.g,. condom use) to initiate until the Active Duty or Reserve member returns from deployment, at which time the member can be reevaluated to restart PrEP. Refer to CCMD-specific guidance regarding medication restrictions in Outside Continental United States areas of operation, where applicable.

d. Special operational duty qualification standards for aviation, jump, undersea, and other special operational duties require consultation with appropriate waiver authorities to determine any potential impact of use of PrEP on the ability to accomplish the specified duties and missions (Reference (h)). Deployment-limiting medical condition waivers or special duty waivers may be required. Refer to available CCMD and Service-specific guidance for further disposition.

e. While current or past use of PrEP does not preclude participation and enrollment in a "walking blood bank" program during deployment, male Active Duty and Reserve members should be reminded that blood donation must be deferred for 12 months after last same-sex sexual contact, in accordance with FDA guidelines (Reference (i)).

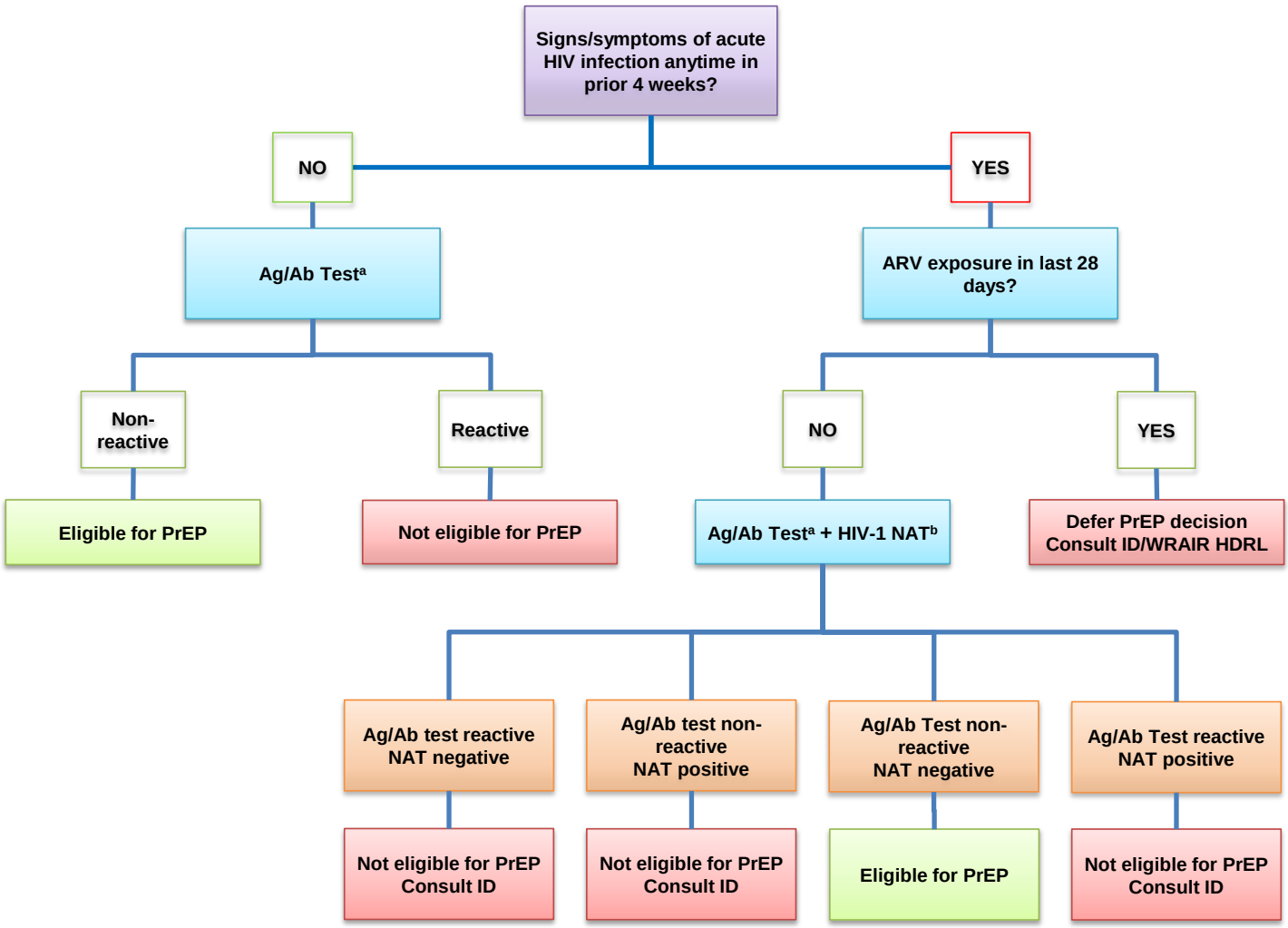

Figure: Human Immunodeficiency Virus Testing for Pre-Exposure Prophylaxis

[a]A Rapid test is not recommended; testing of oral fluids is not recommended.
[b]An Aptima HIV-1 RNA Qualitative Assay is recommended—this test is FDA-approved for HIV diagnosis. If unavailable, an HIV VL test is acceptable—this test is not FDA-approved for HIV diagnosis.

4. DIRECTOR, BLOOD BORNE PATHOGEN THREAT REDUCTION PROGRAM. Director, Blood Borne Pathogen Threat Reduction Program, will use existing surveillance, demographic, clinical, lab, and pharmacy data from DHA health directorates to monitor and evaluate quality of care and HIV PrEP outcomes and provide an annual report to the Director, DHA.

5. ID PHYSICIANS AND THE WRAIR HDRL. ID Physicians and WRAIR HDRL will provide consultation to PrEP providers to inform clinical decision making in challenging

diagnostic situations such as when considering initiation of PrEP in a patient who had exposure to antiretroviral medicines in the past 28 days and in the setting of suspected acute HIV infection.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

Ab	antibody
Ag	antigen
AHI	Acute Human Immunodeficiency Virus infection
CCMD	Combatant Command
CDC	Centers for Disease Control and Prevention
DAD	Deputy Assistant Director
DHA	Defense Health Agency
DHA-PI	Defense Health Agency-Procedural Instruction
FDA	U.S. Food and Drug Administration
FTC	emtricitabine
HDRL	Human Immunodeficiency Virus Diagnostics and Reference Laboratory
HIV	Human Immunodeficiency Virus
ID	Infectious Disease
lab	Laboratory
MA	Medical Affairs
MHS	Military Health System
MTF	military medical treatment facility
NAT	Nucleic Acid Test
nPEP	Nonoccupational Post-exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
RNA	Ribonucleic Acid
TDF	tenofovir disoproxil fumarate
VL	viral load
WRAIR	Walter Reed Army Institute of Research

PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purposes of this DHA-PI.

AHI. The phase of infection right after people are infected, but before they develop antibodies. AHI is a 'flu-like' syndrome with signs and symptoms which may include fevers, malaise, fatigue, skin rash, headache, pharyngitis, adenopathy, night sweats, arthralgia, and diarrhea. The onset of AHI is typically within 2-4 weeks after HIV infection; signs and symptoms may persist for a period ranging from a few days to several months.

HIV PrEP. A way for individuals who do not have HIV, but are at substantial risk of acquiring it, to prevent HIV infection by taking medication.

HIV PrEP Toolkit. Is available at: https://info.health.mil/coi/tshwg/SitePages/Home.aspx, and includes information and resources needed to develop a PrEP program.

HIV-uninfected. An individual who does not have HIV infection. Certain testing criteria must be met to meet the definition of HIV-uninfected:

> If an AHI is NOT suspected, a documented negative fourth generation HIV Ag/Ab test performed on serum, plasma, or whole blood ideally within 7 days prior to starting PrEP is required to meet the definition of HIV-uninfected.
>
> If an AHI is suspected, a negative fourth generation HIV Ag/Ab test and a documented negative HIV NAT, collected ideally within 7 days prior to starting PrEP, is required. The Aptima HIV-1 RNA Qualitative Assay is the preferred NAT because it is the only HIV NAT test FDA-approved for HIV diagnosis. If the Aptima NAT is unavailable, an HIV VL assay is acceptable. The HIV VL test is not approved for HIV diagnosis.

nPEP. Taking antiretroviral medicines after being potentially exposed to HIV to prevent becoming infected. nPEP should be used only in emergency situations and must be started within 72 hours after a possible exposure to HIV. nPEP regimens consist of at least three antiretrovirals such as FTC/TDF plus dolutegravir or FTC/TDF plus darunavir and ritonavir.

Qualified HIV PrEP provider. Any licensed provider with clinical evaluation and prescribing privileges in the MHS who:

> Has knowledge of: (1) how to take a detailed sexual history, and provide HIV risk reduction counseling, (2) indications for HIV PrEP, (3) eligibility, contraindications, and clinical considerations for HIV PrEP, and (4) current guidelines for lab and clinical evaluation and follow-up for HIV PrEP and sexually transmitted infections.
>
> Has access to MHS or contract network pharmacy services that include FDA-approved PrEP options on formulary.
>
> Has access to MHS, reference, or contract lab services.