



DEFENSE HEALTH AGENCY
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DHA-IPM 18-020
November 8, 2018

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (MANPOWER AND RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE NAVY (MANPOWER AND RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE AIR FORCE (MANPOWER AND RESERVE AFFAIRS)
DIRECTOR OF THE JOINT STAFF
DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH SERVICES POLICY AND OVERSIGHT)

SUBJECT: 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

References: See Attachment 1.

Purpose. This Defense Health Agency-Interim Procedures Memorandum (DHA-IPM), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (f):

- Establishes the Military Health System's (MHS) guidance for the provision of HIV PrEP for persons at high risk of HIV acquisition (ACQ).
- Describes the elements and resources required to implement an HIV PrEP program.
- Establishes the indications for HIV PrEP, laboratory (lab) testing and monitoring, and prescribing of HIV PrEP.
- Provides a link to an HIV PrEP toolkit for providers.
- This DHA-IPM is effective immediately; it will be converted to a DHA-Procedural Instruction. This DHA-IPM will expire effective 12 months from the date of issue.

Applicability. This DHA-IPM applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of DoD, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this DHA-IPM as the "DoD Components").

Policy Implementation. It is the Defense Health Agency's (DHA) instruction, pursuant to References (d) through (f), that this DHA-IPM optimizes the clinical use of HIV PrEP to prevent HIV ACQ and reduces variability in the provision of HIV PrEP in the MHS.

Responsibilities. See Attachment 2.

Procedures. See Attachment 3.

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



R. C. BONO
VADM, MC, USN
Director

Attachments:
As stated

cc:
Principal Deputy Assistant Secretary of Defense for Health Affairs
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Medical Officer of the Marine Corps
Joint Staff Surgeon
Director of Health, Safety, and Work-Life, U.S. Coast Guard
Surgeon General of the National Guard Bureau
Director, National Capital Region

ATTACHMENT 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 21, 2015, as amended
- (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) 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) Centers for Disease Control and Prevention: US Public Health Service: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update: Clinical Providers’ Supplement,” March 2018¹

¹ This reference can be found at: <https://www.cdc.gov/hiv/pdf/risk/prep-cdc-hiv-prep->

ATTACHMENT 2

RESPONSIBILITIES

1. MEDICAL TREATMENT FACILITIES (MTFs) COMMANDERS/DIRECTORS. The MTFs Commanders/Directors will:

a. Provide a pathway for access to HIV PrEP and equal access for military and non-military beneficiaries who are high risk for HIV ACQ as detailed in current Centers for Disease Control (CDC) guidelines.

b. Provide justification for denial of PrEP requests; these requests must be documented in the electronic medical record.

c. Ensure MTF pharmacies have U.S. Food and Drug Administration (FDA)-approved PrEP treatment option(s) available (emtricitabine (FTC)/tenofovir disoproxil fumarate (TDF)).

d. Ensure military members on HIV PrEP are deployable as HIV PrEP can be stopped prior to deployment.

2. DIRECTOR, ARMED SERVICES BLOOD PROGRAM OFFICE. The Director, Armed Services Blood Program Office through the Director, HIV/Blood Borne Pathogen Threat Reduction Program, will use existing surveillance, demographic, clinical, lab, and pharmacy data from DHA health directorates to periodically (e.g., quarterly), evaluate HIV PrEP uptake, adherence, compliance with initial evaluation and monitoring according to current published guidelines (References (f) and (g)), in order to evaluate HIV PrEP quality of care and utilization.

3. THE SERVICES. The Services will provide a pathway, via MTF, Service/DoD clinical, reference, or contract lab, for DoD Providers and patient beneficiaries to have access to the lab services required for clinical evaluation and monitoring of HIV PrEP.

4. TRI-SERVICE HIV WORKING GROUP. The Tri-Service HIV Working Group will be responsible for evaluating quality of care and HIV PrEP outcomes.

5. MHS PATIENTS. Patients agreeing to start and continue on HIV PrEP must be available to follow-up with the HIV PrEP provider at the appropriate intervals.

ATTACHMENT 3

PROCEDURES

1. PrEP: EVALUATION AND MONITORING. Follow current CDC guidelines for identification of appropriate candidates for PrEP and evaluation and monitoring of PrEP patients. Areas where this policy deviates from current guidelines are detailed below.

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

(1) A documented negative 4th 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 4th 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 (RNA) Qualitative Assay is the preferred NAT and is FDA-approved for HIV diagnosis. If not available, an HIV-1 viral load (VL) is acceptable.

(b) HIV-1 VL is not approved for HIV diagnosis.

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

(d) Infectious Disease (ID) Service and the Walter Reed Army Institute of Research HIV Diagnostics and Reference Laboratory (WRAIR HDRL) consultation. If the patient had exposure to antiretroviral medicines in the past 28 days (either as HIV, nPEP, or PrEP), the decision to initiate PrEP should be deferred, and an ID physician should be consulted. Additional lab and diagnostic consultative services are available as needed from WRAIR 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 FTC/TDF, a patient must have the following to rule out HIV infection:

(1) Repeat 4th generation HIV Ag/Ab test; and

(2) Compliance with FTC/TDF, side effects, and signs/symptoms of AHI. If the patient reports signs/symptoms of AHI, a documented negative 4th generation HIV Ag/Ab test **and** a documented negative NAT, ideally within 7 days, is required in order to continue FTC/TDF.

c. HIV testing in Nonoccupational Post-Exposure Prophylaxis (nPEP) to PrEP transition, PrEP non-adherence, and other exposure to antiretroviral therapy in past 28 days.

(1) If a patient reports stopping FTC/TDF for over 1 week prior to reevaluation, the provider should wait for a negative 4th generation HIV Ag/Ab test result prior to reinitiating FTC/TDF; 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) Defer the decision to initiate PrEP;

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

(c) Repeat a 4th generation HIV Ag/Ab test and NAT; and

(d) Assess for signs and symptoms of AHI.

d. Annual HCV screening. At each 12-month interval (+/- 30 days), the hepatitis C antibody testing is to be assessed, in addition to the above 3-month requirements; 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 A PrEP PROGRAM. Elements of an optimal HIV PrEP program include:

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

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

c. A qualified HIV PrEP provider.

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

e. Access to pharmacy services for FTC/TDF as prescribed according to existing CDC HIV PrEP guidelines without MTF/pharmacy-based restrictions.

3. MILITARY-SPECIFIC CONSIDERATIONS

a. Participation in an HIV PrEP program will not be used to deny re-enlistment to members on continuous active duty or deny eligibility for accession into any Service branch.

b. In general, HIV PrEP medication will not be initiated during or within deployed environments, particularly locations under hostile-fire or arduous duty. Possible exceptions exist where adequate resources could be made available (e.g., outside Continental United States, MTFs, hospital ships), although no guaranteed provisions can be demanded in various conditions. Pharmaceutical supplies intended for emergency nPEP will not be compromised for PrEP.

c. Participation in an HIV PrEP program can be discontinued prior to deployment; therefore, taking FTC/TDF medication will not impact an individual's medical readiness status.

(1) Exceptions (example). In cases where a Service member is stable on HIV PrEP for a period of at least 180 days and is assigned a short-term deployment (less than 90 days), FTC/TDF may be continued. If deployment is extended (beyond 90 days), and HIV ACQ risk is presumed low, then FTC/TDF will be discontinued and only restarted when adequate resources (qualified providers, HIV testing, sexually transmitted infection screening, pharmacy, etc.) once again become available.

(2) Service members should be counseled and advised accordingly of possible scenarios.

d. Responsible military deployment health providers (any provider reviewing a service member's readiness status) will determine potential individual restrictions based on duty type and/or area of operation (i.e., United States Central Command). Special duty waivers (aviation, undersea, etc.), may be required. Refer to available Service-specific guidance for further disposition.

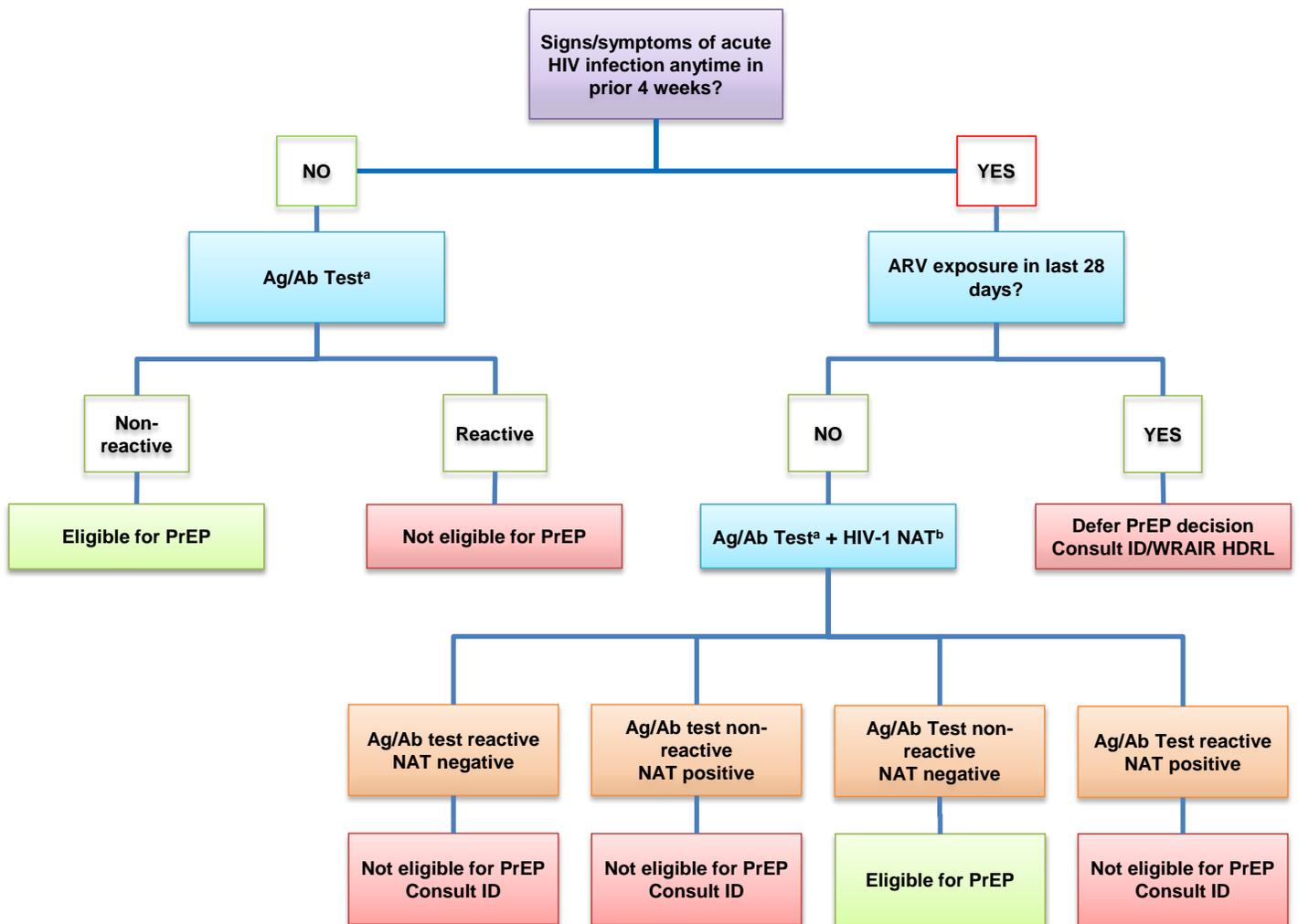


Figure: Human Immunodeficiency Virus Testing for Pre-Exposure Prophylaxis

^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-1 VLtest is acceptable—this test is not FDA-approved for HIV diagnosis.

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

ACQ	acquisition
Ag/Ab	Antigen/antibody
AHI	Acute Human Immunodeficiency Virus infection
CDC	Centers for Disease Control
DHA	Defense Health Agency
DHA-IPM	Defense Health Agency-Interim Procedures Memorandum
FDA	U.S. Food and Drug Administration
FTC	emtricitabine
HIV	Human Immunodeficiency Virus
ID	Infectious Disease
Lab	Laboratory
MHS	Military Health System
MTF	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 HDRL	Walter Reed Army Institute of Research HIV Diagnostics and Reference Laboratory

PART II. DEFINITIONS

AHI. The phase of infection right after people are infected, but before they develop antibodies. AHI is a ‘flu-like’ illness with signs and symptoms which may include fevers, malaise, fatigue, skin rash, headache, pharyngitis, cervical adenopathy, night sweats, arthralgia, and diarrhea. The

onset of AHI is typically 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 people who do not have HIV, but who are at substantial risk of acquiring it, to prevent HIV infection by taking medication. There is one combination medication FDA-approved for HIV PrEP (FTC/TDF) which contains two drugs (200 milligram FTC/300 milligram TDF).

HIV PrEP Toolkit. Includes information and resources needed to develop a PrEP program. The HIV PrEP Toolkit is available at: <https://info.health.mil/coi/tshwg/SitePages/Home.aspx>

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 4th 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 4th generation HIV Ag/Ab test AND a documented negative HIV-1 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-1 NAT test FDA-approved for HIV diagnosis. If unavailable, an HIV-1 VL is acceptable. HIV-1 VL 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 FTC/TDF on formulary.

Has access to MHS, reference, or contract lab services.