Defense Health Agency

ADMINISTRATIVE INSTRUCTION

NUMBER 6025.32
March 26, 2024

DAD, MA

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

References: See Enclosure 1.

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

a. Increases awareness of Pre-Exposure Prophylaxis (PrEP) indications and medication availability to prevent acquisition of new Human Immunodeficiency Virus (HIV) infections in Service members and other beneficiaries and reduce unnecessary losses to force health and readiness due to new HIV infections.

b. Establishes the DHA instructions for the provision of HIV PrEP for persons at high risk of HIV acquisition.

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

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

e. Provides a link to an HIV PrEP toolkit for healthcare providers.

2. APPLICABILITY. This DHA-AI applies to the DHA Enterprise (components and activities under the authority, direction, and control of the DHA) to include assigned, attached, allotted, or detailed personnel.

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

4. CANCELLED DOCUMENTS. This DHA-AI cancels the following document, Defense Health Agency-Procedural Instruction 6025.29, "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. PROPONENT AND WAIVERS. The proponent of this publication is the Deputy Assistant Director, Medical Affairs (DAD-MA). When components and activities are unable to comply with this publication the activity may request a waiver that must include a justification, including an analysis of the risk associated with not granting the waiver. The activity director or senior leader will submit the waiver request through their supervisory chain to DAD-MA to determine if the waiver may be granted by the Director, DHA, or their designee.

8. RELEASABILITY. **Cleared for public release**. This DHA-AI is available on the Internet from the Health.mil site at: https://health.mil/Reference-Center/Policies and is also available to authorized users from the DHA SharePoint site at: https://info.health.mil/cos/admin/pubs/DHA%20Publications%20Signed/Forms/AllItems.aspx

9. EFFECTIVE DATE. This DHA-AI:

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).

10. SUMMARY OF CHANGES. There is change in the responsibility of data reports on HIV PrEP from the blood borne pathogen threat reduction program to the DHA Public Health Director reflecting the organizational change with the DHA transition. Specific reference to the vendor Aptima has been removed and replaced by reference to the U.S. Food and Drug Administration (FDA) approved HIV-1 Ribonucleic Acid (RNA) Qualitative Assay. The responsibility of the Defense Health Network Directors to provide oversight of the military medical treatment facility (MTF) Directors in development of an HIV PrEP program has been added.

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Director

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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," April 1, 2022
(d) White House Office of National AIDS Policy, "National HIV/AIDS Strategy for the United States (2022-2025)," December 14, 2021
(e) Centers for Disease Control and Prevention (CDC), U.S. Public Health Service, "Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update: A Clinical Practice Guideline," December 2021[1]
(f) CDC, U.S. Public Health Service, "Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update, Clinical Providers' Supplement," December 2021[2]
(g) Bhattacharya, Debika, Aronsohn, Andrew, Price, Jennifer, Lo Re, Vincent; American Association for the Study of Liver Diseases (AASLD)-Infectious Diseases Society of American (IDSA) Hepatitis C Virus (HCV) Guidance Panel. "Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection." *Clinical Infectious Disease*. May 25, 2023
(h) U.S. FDA, "Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products," May 2023[3].

[1] Available at https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.
[2] Available at https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf.
[3] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-evaluating-donor-eligibility-using-individual-risk-based-questions-reduce-risk-human.

ENCLOSURE 2

RESPONSIBILITIES

1. DIRECTOR, DHA. The Director, DHA, will ensure compliance with this DHA-AI by the MTFs. This includes overseeing implementation of the DHA-AI by 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.

2. DAD-MA. The DAD-MA will maintain overall responsibility for monitoring compliance to the guidance and establish procedures to implement requirements in this DHA-AI.

3. DIRECTOR, PUBLIC HEALTH. The Director, Public Health, will use or delegate to the Chief, Armed Forces Health Surveillance Division, the responsibility to use existing surveillance, demographic, clinical, lab, and pharmacy data from DHA health directorates to monitor and evaluate quality of care and HIV PrEP use and/or outcomes and provide a report to the DAD-MA, on an annual basis by February 15.

4. DIRECTORS, DEFENSE HEALTH NETWORKS. The Directors, Defense Health Networks, will:

a. Monitor compliance with and execution of procedures as outlined in Enclosure 3 for the MTFs in their areas of responsibility, and report compliance to DAD-MA on an annual basis by February 15.

b. Include establishment of an HIV PrEP program and percentage of providers who completed one time training in the annual report.

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

a. Establish an HIV PrEP program that incorporates a pathway for widely available access to HIV PrEP for all military and non-military beneficiaries who are at high risk for HIV acquisition as detailed in current CDC guidelines (References (e) and (f)).

b. Ensure DHA providers in the HIV PrEP program receive standardized training that incorporates the use of References (e) and (f) at a minimum, to provide beneficiaries HIV prevention services tailored to their needs based on risk screening information and HIV test results in accordance with the most current CDC guidelines. Standardized DHA training will be available before the end of Fiscal Year 2024 on the Joint Knowledge Online site. Training must incorporate the use of References (e and f) at a minimum using the most current CDC guidelines

with additional resources that are available at:
https://info.health.mil/sites/hro/CMT/PC/Pages/HIV-PrEP.aspx.
Joint Knowledge Online (JKO) training course has been developed – course number JKO DHA-US1318.

c. Provide FDA-approved HIV PrEP medication option(s) to those individuals determined to need them via the TRICARE pharmacy benefit or the TRICARE medical benefit as prescribed or administered according to existing CDC HIV PrEP guidelines.

d. Ensure DHA healthcare providers and all patient beneficiaries have access to a pathway to lab services required for clinical evaluation and monitoring of HIV PrEP.

e. Make recommendations to unit commanders about deployment for active duty and reserve component members on PrEP on a case-by-case basis. Use of PrEP is not a deployment disqualification as PrEP medication may be continued or discontinued prior to or during deployment without adverse effects to a service members health. PrEP can be evaluated for continuance during deployment depending on the individual's risk level, availability of medical resources, and nature of the deployment.

ENCLOSURE 3

PROCEDURES

1. HIV PrEP: EVALUATION AND MONITORING. Use of HIV PrEP must not be construed as having HIV infection. HIV PrEP may be discontinued at any time during situations where access to medication may not be guaranteed without adverse effects to their health. Generally, the provider will follow current CDC guidelines (References (e) and (f)), for identification of appropriate candidates for HIV PrEP and evaluation and monitoring of HIV PrEP patients. CDC guideline outlines indications for HIV PrEP which takes into consideration risk factors that include sexual history, injection drug use, and population risk for HIV acquisition. DHA specific guidance aligns mostly with CDC guideline with the exception of specific clinical procedures that are detailed below:

a. HIV testing prior to initiating PrEP to ensure HIV-uninfected status (algorithm in Figure 1). 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, drawn within 7 calendar days (longer turnaround time for HIV testing may result based on individual laboratory capabilities), when acute Human Immunodeficiency Virus infection (AHI) is **NOT** suspected (no signs/symptoms of AHI any time in the prior 4 weeks).

(2) A documented negative fourth generation HIV Ag/Ab test **AND** a negative HIV-1 RNA assay within 7 calendar days (longer turnaround time for HIV testing may result based on individual laboratory capabilities) if an AHI **is** suspected. The HIV-1 RNA assay is typically in the form of a qualitative or quantitative HIV nucleic acid test (NAT).

(a) The HIV-1 RNA assay must be an FDA-approved HIV-1 RNA Assay for HIV diagnosis. Using an HIV viral load (VL) assay is an acceptable HIV-1 RNA Assay if it is FDA approved for HIV diagnosis.

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

(3) Do not accept patient-reported results from home self-test kits.

(4) These guidelines are not intended for those with a diagnosis of HIV, or those who are on occupational post-exposure prophylaxis (PEP) for HIV. If the patient had exposure to antiretroviral medicines in the past 28 calendar days (e.g., PEP) or has been inconsistent in adhering with PrEP use), the decision to initiate HIV PrEP should be deferred, and an infectious disease (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 while continuing oral PrEP must be conducted every three months (+/-30 calendar days) to avoid continuation of a suboptimal antiretroviral regimen in a newly

established HIV infection. A patient must have the following to rule out HIV infection:

(1) Negative repeat fourth generation HIV Ag/Ab test (for both oral and injection PrEP); **AND**

(2) A documented negative HIV-1 RNA Assay (this is required for PrEP with cabotegravir injections and for oral PrEP use). At each 3-month visit, patients will receive a 90-calendar day supply of PrEP without refills. HIV testing ideally should be performed within 7 days of continuing PrEP (longer turnaround time for HIV testing may result based on individual laboratory capabilities). Up to and not to exceed one 30-calendar day refill may be prescribed, as needed, to accommodate clinic schedules, delays associated with testing, or temporary duty assignments.

c. Those on the long-acting injectable cabotegravir require more frequent monitoring with HIV testing every 2 months and should be prescribed in consultation with an ID specialist and per CDC guidelines.

d. Follow-up HIV testing for patients in PEP to PrEP transition, patients with PrEP non-adherence, and other patients exposed to antiretroviral therapy in the past 28 calendar days.

(1) If a patient reports stopping PrEP for over 1 week prior to reevaluation, then repeat baseline testing prior to reinitiating PrEP; and

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

(a) Assess for signs and symptoms of AHI;

(b) Repeat a fourth generation HIV Ag/Ab test **AND** HIV-1 RNA Assay;

(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.

e. Hepatitis C screening is to occur every 12 months (+/- 30 calendar days) by testing for hepatitis C antibodies. Annual hepatitis C virus screening, although not specifically stated within the CDC HIV PrEP guidelines, is recommended by Reference (g).

f. DHA providers must also adhere to the following three recommendations from the CDC and the Food and Drug Administration on HIV PrEP evaluation and counseling:

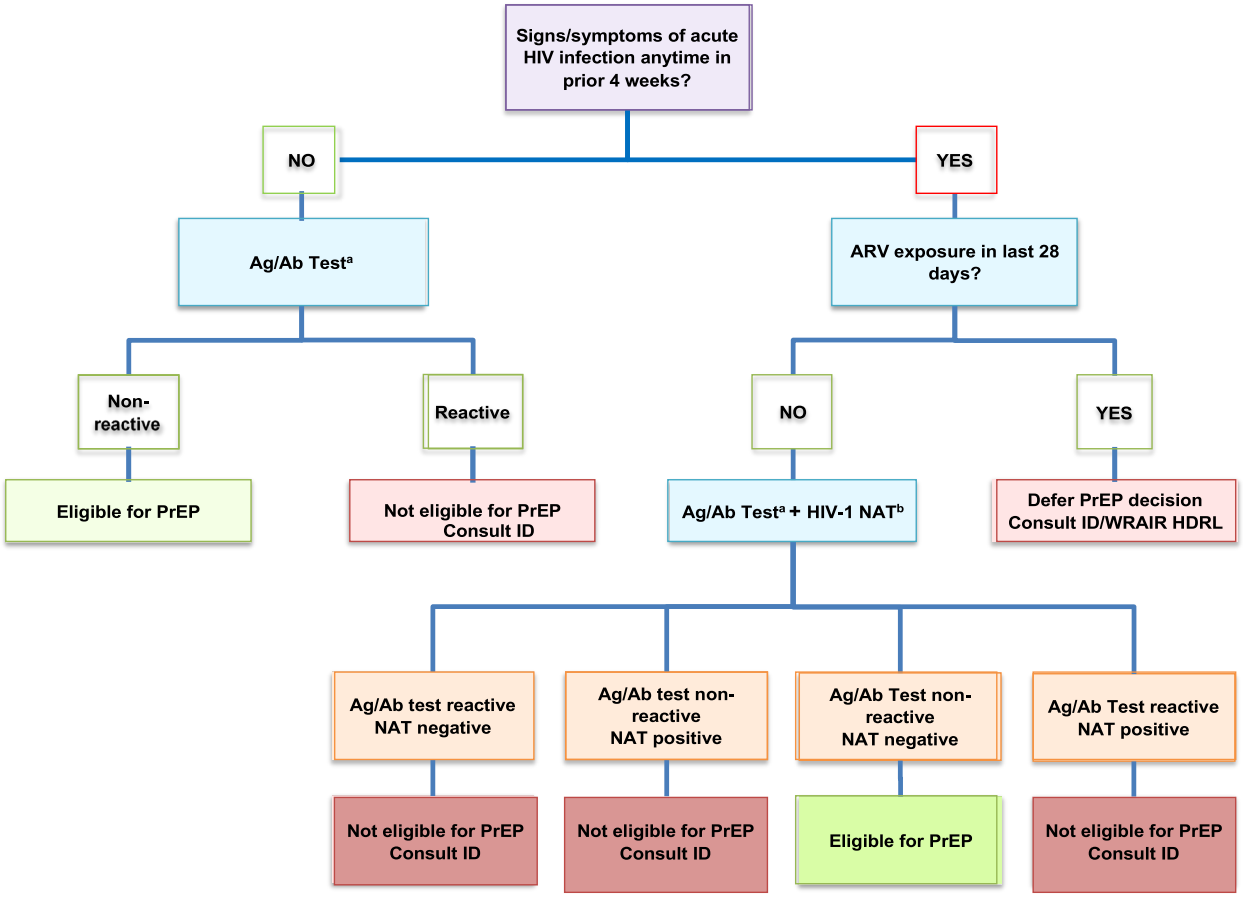
(1) As detailed in References (e) and (f), assessment of hepatitis B status is essential, as some PrEP medications have activity against hepatitis B. Discontinuation of these PrEP medications in individuals with hepatitis B may result in an acute hepatitis-flare. Due to the risk of hepatitis B infection through similar risk factors for HIV transmission, those found to be

uninfected without evidence of immunity should be vaccinated against hepatitis B.

(2) Baseline and follow-up laboratory screening for sexually transmitted infections (e.g., syphilis, gonorrhea, chlamydia), renal function, and lipid panel should be completed per CDC guidelines.

g. All patients must be deferred from blood donation for 3 months from the most recent dose of oral PrEP or PEP, or for 24 months from the most recent dose of injectable PrEP donation in accordance with Reference (h).

Figure 1: Human Immunodeficiency Virus Testing for Pre-Exposure Prophylaxis



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

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

a. Credentialed and non-credentialed providers and clinic personnel who are able to provide HIV PrEP adherence and risk reduction counseling and who are culturally sensitive and

competent to provide care to patients with different sexual orientations, practices, and/or sexual identity.

b. Administrative and front desk staff who work in areas where HIV PrEP services are provided who are culturally sensitive and who may refer patients to trained providers to triage patient inquiries and schedule visits appropriately.

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

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 ID subspecialist consultation for difficult or complicated cases. This can be accomplished by establishing contact information at a supporting large MTF with ID providers.

f. Access to PrEP via the TRICARE pharmacy benefit or the TRICARE medical benefit as prescribed or administered according to existing CDC HIV PrEP guidelines.

g. Oral medications for HIV PrEP available via three points of service: MTF pharmacy, home delivery, or retail. The provider and patient should discuss which pharmacy point of service is most beneficial. The patient will require a follow-up visit at 3 months, and then at 6-month intervals per CDC guidelines with labs to be conducted every 3 months, with a renewal prescription that will be provided as appropriate.

3. DEFENSE HEALTH NETWORK ANNUAL REPORTING REQUIREMENTS. The following compliance metrics must be reported on an annual basis to DAD-MA by 15 February:

a. Establishment of an optimal HIV PrEP program that incorporates all seven program elements described in Enclosure 3, Section 2, a-g.

b. Completion of training of providers, nurses, and clinical staff involved in the HIV PrEP program. Providers who are board certified in ID or public health are exempt from the training requirement. Training is intended for providers involved in the HIV PrEP program and in specialties providing primary care evaluations for patients at substantial risk for acquiring HIV infection (to include, at minimum, women's health, internal medicine, family medicine, and adolescent medicine).

4. ID PHYSICIANS AND THE WRAIR HDRL. ID Physicians at large MTFs and WRAIR HDRL may provide consultation to PrEP providers throughout the DHA to inform clinical decision making in challenging diagnostic situations; for example, when considering initiation of PrEP in a patient who had exposure to antiretroviral medicines in the past 28 calendar 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
AI	Administrative Instruction
CDC	Centers for Disease Control and Prevention
DAD	Deputy Assistant Director
DHA	Defense Health Agency
FDA	U.S. Food and Drug Administration
HDRL	Human Immunodeficiency Virus Diagnostics and Reference Laboratory
HIV	Human Immunodeficiency Virus
JKO	Joint Knowledge Online
ID	Infectious Disease
lab	Laboratory
MA	Medical Affairs
MTF	military medical treatment facility
NAT	Nucleic Acid Test
PEP	(Occupational) Post-exposure Prophylaxis
PrEP	Pre-Exposure Prophylaxis
RNA	Ribonucleic Acid
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-AI.

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. Development of antibodies while on antiretrovirals for PrEP may be delayed necessitating the need for RNA tests.

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. Patients at substantial risk for acquiring HIV infection include assessment of risk factors per CDC guideline that include following: HIV status of sexual partner, personal history of sexually transmitted infections in the past six months, use of intravenous drugs.

HIV PrEP Toolkit. Is available at: *https://info.health.mil/sites/hro/CMT/PC/Pages/HIV-PrEP.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:

a. 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 calendar days prior to starting PrEP is required to meet the definition of HIV-uninfected.

b. If an AHI is suspected, a negative fourth generation HIV Ag/Ab test and a documented negative HIV NAT, collected ideally within 7 calendar days prior to starting PrEP, is required. *The HIV NAT test must be FDA-approved for HIV diagnosis.* If the NAT is unavailable, an HIV VL assay is acceptable. The HIV VL test is not approved for HIV diagnosis.

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

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

a. 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.

b. Has access to DHA or contract network pharmacy services that include FDA-approved PrEP options on formulary.

c. Has access to DHA, reference, or contract lab services.