NATIONAL VIRAL HEPATITIS PROGRAM

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes policy for the VHA National Viral Hepatitis Program to ensure state-of-the-art, patient-centered therapy, and timely access to diagnosis and care for hepatitis C virus (HCV), hepatitis B virus (HBV), hepatitis A virus (HAV) and other less common viral hepatitides such as hepatitis D and E viruses.

2. SUMMARY OF MAJOR CHANGES: This directive updates VHA Directive 1300.01, National Viral Hepatitis Program, and incorporates VHA Directive 1299, Reflex Confirmatory Testing for Hepatitis C Virus Infection. Major changes include:

   a. Appendices on testing for hepatitis C virus (HCV), reflex confirmatory testing for HCV, and guidance on the prevention, testing, diagnosis, and treatment of hepatitis B virus (HBV).

   b. Reflecting the name change of the HIV, Hepatitis, and Public Health Pathogens Program (HHPHP) to HIV, Hepatitis and Related Conditions Programs (HHRC) within the Office of Specialty Care Services.

   c. Reflecting the realignment of HHRC under the Office of Specialty Care Services in the Office of the Deputy Under Secretary for Health for Policy and Services (10P).


4. RESPONSIBLE OFFICE: The Director, HIV, Hepatitis, and Related Conditions Program (HHRC) is responsible for the content of this directive. Questions may be addressed to Office of Specialty Care Services in the Office of the Deputy Under Secretary for Health for Policy and Services (10P), by phone at: 202-461-7120 or email: VHA 10P11 Actions or directly to HHRC at VAHHRC@va.gov.


6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of May 2023. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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Executive in Charge

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NATIONAL VIRAL HEPATITIS PROGRAM

1. PURPOSE

This Veterans Health Administration (VHA) directive outlines the requirements and responsibilities of VHA’s National Viral Hepatitis Program for (1) the prevention, testing, and treatment for hepatitis C virus (HCV), ensuring that all specimens tested for HCV reactive by initial serologic testing for HCV antibodies undergo reflex confirmatory Ribonucleic Acid (RNA) testing (Appendix A); (2) appropriate testing, prevention, and treatment for hepatitis B virus (HBV) (Appendix B); (3) appropriate prevention and care for hepatitis A virus (HAV) (Appendix C); and (4) addressing issues related to strains of viral hepatitis which are relatively uncommon in the United States (hepatitis D virus and hepatitis E) if they arise in the VA patient population. AUTHORITY: Title 38 United States Code (U.S.C.) 7301(b).

2. BACKGROUND

a. Chronic viral hepatitides are the most common blood-borne infections in both VHA and the United States (U.S.) and constitute a major public health problem because of the number of chronically infected individuals (paragraph 5.k.). VHA is the single largest HCV care provider in the U.S., and a national leader in the testing and treatment of HCV (paragraph 5.b. & 5.j.). Veterans in VA care have a higher prevalence than the general U.S. population (paragraph 5.a.). HBV and HCV infection may result in liver failure, cirrhosis, and liver cancer.

b. Following the 2010 U.S. Institute of Medicine (IOM) report on Hepatitis and Liver Cancer (paragraph 5.h.) the U.S. Department of Health and Human Services (HHS) released the first National Viral Hepatitis Action Plan in 2011. HHS subsequently issued Action Plan updates for 2014-2016 and 2017-2020 (paragraphs 5.l. and 5.m.). The current HHS Action Plan and the National Academies of Sciences Engineering and Medicine’s National Strategy for the Elimination of Hepatitis B and C: Phase Two Report (paragraph 5.k.) outline a national strategy to prevent new viral hepatitis infections; reduce deaths and improve the health of people living with viral hepatitis; reduce viral hepatitis health disparities; and coordinate, monitor, and report on implementation of viral hepatitis activities. VHA is a critical partner in this Federal collaborative effort.

c. Hepatitis A Virus (HAV) is a communicable liver disease, most frequently transmitted via contaminated food or water (i.e., fecal-oral transmission). HAV is vaccine-preventable, and has no current treatment. Most people with HAV recover without treatment within a few months. HAV can cause severe, acute liver disease (including death) but does not cause chronic infection (paragraph 5.c). There are intermittent HAV outbreaks in the US of varying severity.

d. Hepatitis D Virus (HDV) is relatively uncommon in the US and can only be contracted in people who are infected with HBV. HDV can either be an acute, short-term infection or lead to a long-term, chronic infection and is primarily transmitted through contact with infectious blood. Currently, no pharmacology treatment has been
approved for HDV (paragraph 5.d. and 5.i.). Hepatitis E Virus (HEV) is transmitted through contaminated food and water, and is relatively uncommon in the US. HEV is usually a short-term, acute infection, although can become a chronic infection among solid organ transplant recipients. There is currently no FDA approved vaccine or pharmacologic treatment for HEV (paragraph 5.e).

3. POLICY

It is VHA policy that Veterans with viral hepatitis are identified and provided with high quality, evidence-based care and treatment, through testing, management, care, and prevention of re-infection. And that Veterans uninfected with viral be provided with evidence-based prevention education and immunizations if available. NOTE: Specific guidance for HCV, HBV, and HAV is outlined in Appendices A-C.

4. RESPONSIBILITIES

a. Under Secretary for Health. The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. Deputy Under Secretary for Health for Operations and Management. The Deputy Under Secretary for Health for Operations and Management, or designee, is responsible for:

(1) Communicating the contents of this directive to each of the Directors of the Veterans Integrated Services Networks (VISN).

(2) Ensuring that each VISN Director has the resources required to support the fulfillment of the terms of this directive in all VA medical facilities within that VISN.

(3) Ensuring that information provided by the VA medical facilities is communicated to the HIV, Hepatitis and Related Conditions Programs (HHRC).

(4) Operational oversight to ensure the following:

(a) All facilities comply with VHA’s national recommendations for HCV testing, to include that all specimens tested for HCV reactive by initial serologic testing for HCV antibodies undergo reflex confirmatory testing for HCV RNA to determine whether an individual has chronic infection (Appendix A). In addition, patients must be offered clinically appropriate testing, prevention and treatment (Appendix B), and prevention and care for HAV (Appendix C).

(b) All facilities are in compliance with specific guidance on offering testing for HCV and HBV infections as outlined in the Clinical Preventive Services Guidance Statement on Screening for Hepatitis C and Clinical Preventive Services Guidance Statement on Screening for Hepatitis B from the VHA National Center for Health Promotion and Disease Prevention (available at: http://vaww.prevention.va.gov/Screening_for_Hepatitis_C.asp and http://vaww.prevention.va.gov/Screening_for_Hepatitis_B.asp, respectively. NOTE:
These are internal VA Web sites that are not available to the public.) and the Centers for Disease Control and Prevention (paragraph 5.f. & 5.g.; See Appendices A and B).

(c) All facilities are in compliance with specific guidance on immunization for HAV and HBV infections as outlined in the Clinical Preventive Services Guidance Statement on Hepatitis A Immunization and Clinical Preventive Services Guidance Statement on Hepatitis B Immunization from the VHA National Center for Health Promotion and Disease Prevention (available at: http://vaww.prevention.va.gov/CPS/Hepatitis_A_Immunization.asp and http://vaww.prevention.va.gov/CPS/Hepatitis_B_Immunization.asp (These are internal VA Web sites that are not available to the public.)

c. **Director, HIV, Hepatitis and Related Conditions Programs (HHRC).** The Director, HHRC, or designee, is responsible for:

(1) Advising the Under Secretary for Health on matters of VHA policy and services related to HCV, HBV, and HAV.

(2) Working with VA medical facility Viral Hepatitis Lead Clinicians (see paragraph 5.f.(1)) to support field-based initiatives and system redesign to improve care for HCV, HBV, HAV, and other viral hepatitides if they arise in the VA population.

(3) The continued functioning of the Viral Hepatitis Technical Advisory Group (TAG) made up of a multidisciplinary group of VA Subject Matter Experts (SMEs) who advise HHRC on issues related to national policy, clinical education, and patient care related to viral hepatitis.

(4) Obtaining input on national policy issues involving HBV, HCV, and other viral hepatitides from stakeholders, including Veterans Health Administration Central Office (VHACO) program offices, VISN leaders, the Viral Hepatitis TAG, Veteran stakeholders, Hepatitis and Liver Disease Innovation Teams (HITs), and VHA facility clinicians and administrative staff.

(5) Developing informational and other resources to support VHA facility clinicians providing care for patients with HCV, HBV, HAV and other viral hepatitides if they arise in the VA population.

(6) Assisting local or VISN teams in their efforts to understand, address, and monitor gaps in viral hepatitis care and implement strategies for increasing access.

(7) Providing scientific and technical guidance related to the diagnosis of chronic HCV infection to include that all specimens tested for HCV reactive by initial serologic testing for HCV antibodies undergo reflex confirmatory testing for HCV RNA to determine whether an individual has chronic infection (Appendix A).

(8) Ensuring the accuracy, completeness, and currency of information on the VHA Viral Hepatitis Web site at: www.hepatitis.va.gov.
(9) Collaborating with HHS, other government agencies, and non-governmental organizations to create cross-agency collaborations.

(10) Collaborating with internal VHACO program offices on issues relevant to the delivery of high quality viral hepatitis care in VHA, including prevention, testing and care for vulnerable populations, patient and provider education and outreach, and ensuring accurate data for monitoring quality of care.

d. Veterans Integrated Service Network Director. The VISN Director, or designee, is responsible for ensuring VA medical facility Directors adhere to this directive.

e. VA Medical Facility Director. The VA medical facility Director, or designee, is responsible for:

(1) Identifying a Viral Hepatitis Lead Clinician at the facility who has some level of expertise in viral hepatitis and/or infectious diseases to be the principal point of contact for all viral hepatitis program information (including HCV, HBV, HAV, and other viral hepatitides if they arise in the VA population) and notifying the facility, VISN, and the National Viral Hepatitis Program office in HHRC of that selection. Smaller facilities should also designate a Viral Hepatitis Lead Clinician who can communicate with Facility Medical Directors and Lead Clinicians at larger facilities in the VISN to coordinate communications about HCV, HBV, HAV, and other viral hepatitides if they arise in the VA population.

(2) Responding to HHRC’s an annual request through the Office of the Secretary for Health for Operations and Management (10N) for updating the contact information for the Viral Hepatitis Lead Clinician at their facility.

(3) Ensuring that reflex confirmatory HCV testing is implemented as a locally performed test, a community of care test, or as a test performed by another VA facility with established HCV RNA testing capability.

(4) Ensuring equal access to reflex confirmatory HCV testing at all points of care at the local health care facility where lab testing is provided.

f. Facility Viral Hepatitis Lead Clinician. The facility Viral Hepatitis Lead Clinician, or designee, is responsible for:

(1) Serving as the facility point of contact on patient-centered diagnosis and care of Veterans with chronic infection due to HCV, HBV, HAV and other viral hepatitides if they arise in the VA population.

(2) Serving as a point of contact for communications to and from the VHA’s National Viral Hepatitis Program in HHRC regarding training and quality improvement opportunities, policy and operational issues concerning viral hepatitis, and programs and initiatives related to viral hepatitis care in VHA.
(3) Providing consultation and support to the designated local Coordinator for the Hepatitis C Clinical Case Registry (CCR; paragraph 4.g.).

g. **The CCR HepC Coordinator.** Responsibilities of the facility CCR Coordinator for the Hepatitis C CCR are described in VHA Directive 2011-026, Clinical Case Registry (CCR) Software: Maintenance and Clinical Support Staff, dated June 23, 2011, or subsequent policy (paragraph 5.n.).

h. **Director, Pathology and Laboratory Medicine Service (P&LMS).** The Director, P&LMS at each facility is responsible for selecting appropriate methodologies for implementation of reflex confirmatory HCV RNA testing on all specimens reactive with HCV antibodies to determine whether an individual has chronic infection, and ensuring reflex confirmatory testing is being performed to current Centers for Disease Control and Prevention (CDC) guidelines (Appendix A) and available at: [https://www.cdc.gov/hepatitis/HCV/GuidelinesC.htm](https://www.cdc.gov/hepatitis/HCV/GuidelinesC.htm). The Director, P&LMS at each facility is also responsible for selecting appropriate methodologies for implementation of HBV serologic testing following current CDC guidelines (Appendix B) and available at: [https://www.cdc.gov/hepatitis/hbv/testingchronic.htm](https://www.cdc.gov/hepatitis/hbv/testingchronic.htm), and HAV serologic testing, following current CDC guidelines (Appendix C) and available at: [https://www.cdc.gov/std/tg2015/hepatitis.htm](https://www.cdc.gov/std/tg2015/hepatitis.htm).

5. REFERENCES


   c. Centers for Disease Control and Prevention. Hepatitis A Questions and Answers for Health Professionals, 2017. Available from: [https://www.cdc.gov/hepatitis/hav/havfaq.htm](https://www.cdc.gov/hepatitis/hav/havfaq.htm). **NOTE:** This linked document is outside of VA control and may or may not be concomitant with Section 508 of the Americans with Disabilities Act.

   d. Centers for Disease Control and Prevention. Hepatitis D, 2015. Available from: [https://www.cdc.gov/hepatitis/hdv/index.htm](https://www.cdc.gov/hepatitis/hdv/index.htm). **NOTE:** This linked document is outside of VA control and may or may not be concomitant with Section 508 of the Americans with Disabilities Act.


TESTING AND TREATMENT FOR HEPATITIS C VIRUS (HCV) INFECTION

This appendix provides additional information to VHA clinicians on current VHA recommendations and guidance on testing and treatment for hepatitis C virus (HCV) in Veterans.

1. HCV TESTING IN VHA

   a. Laboratory testing for HCV infection is recommended for those individuals who are at increased risk for HCV infection, particularly those born between 1945-1965 ("birth cohort testing"; paragraph 4.b. & 4.d.).

   b. Specific guidance on offering testing for HCV infection is outlined in the Clinical Preventive Services Guidance Statement on Screening for Hepatitis C from the VHA National Center for Health Promotion and Disease Prevention, available at http://vaww.prevention.va.gov/Screening_for_Hepatitis_C.asp. NOTE: This is an internal VA Web site not available to the public.

   c. Documentation of consent for HCV testing is no longer required, according to VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures. Care providers continue to have an ethical and professional obligation engage patients in an informed consent conversation about HCV testing, which should include specific information about the test, reasons for offering the test, and the risks and benefits of testing (3.f.).

   d. Given that 3 percent of all Veterans in VA care diagnosed with HCV also have co-morbid HIV, and 7 percent have comorbid HBV, it is strongly recommended that any patient testing positive for HCV is offered testing for HIV and HBV (paragraph 4.e.).

2. HCV REFLEX CONFIRMATORY TESTING:

   a. Laboratory testing for HCV includes serologic testing for the presence of anti-HCV antibodies to determine whether an individual has ever been infected with HCV, and subsequent confirmatory assays for HCV ribonucleic acid (RNA) in the blood (HCV viremia) to determine whether an individual has chronic infection. Confirmatory testing of individuals with a positive HCV serologic test result is necessary to identify those individuals who have chronic HCV. The CDC recommends such testing in patients with a positive serologic test result (paragraph 4a 4c), available at https://www.cdc.gov/hepatitis/HCV/GuidelinesC.htm. NOTE: This linked document is a non-VA document and may not be conformant with Section 508 of the Americans with Disabilities Act.

   b. Reflex confirmatory testing within VHA ensures that all patients with positive serologic reflex test results for HCV are evaluated for the presence of chronic HCV infection. This requires automatic performance of confirmatory testing for a patient with a positive HCV serologic test result without the need for an additional order by a clinician or collection of an additional specimen from a patient.
c. Among individuals who do not have a prior positive HCV RNA result, reflex confirmatory testing using RNA testing must be performed on all specimens that are reactive by initial serologic testing for HCV antibodies. This directive does not apply to individuals with a previous positive HCV RNA result.

3. HCV Treatment

When treating HCV infected Veterans enrolled in VA care, VHA will adhere to the most current VHA Chronic Hepatitis C Virus (HCV) Infection Treatment Considerations (paragraph A-3.d.). The recommendations contained in these guidelines are not intended to be a substitute for the judgment of a clinician who is an expert in HCV clinical care. Available at: https://www.hepatitis.va.gov/provider/guidelines/hcv-treatment-considerations.asp.

4. REFERENCES:

a. Centers for Disease Control and Prevention. Guidelines for Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus. Morbidity and Mortality Weekly Report (MMWR), February 7, 2003 / 52 (RR03); 1-16. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5203a1.htm. **NOTE:** This linked document is outside of VA control and may or may not be conformant with Section 508 of the Americans with Disabilities Act.

b. Centers for Disease Control and Prevention. Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945-1965. MMWR. 2012;61(RR04): 1-18, Available at: https://www.cdc.gov/mmwr/pdf/rr/rr6104.pdf. **NOTE:** This linked document is outside of VA control and may or may not be conformant with Section 508 of the Americans with Disabilities Act.


e. Veterans Health Administration Patient Care Services/Population Health. Veteran Data Reports, Selected Comorbid Conditions 2011-2014. Available from:
http://vaww.hepatitis.va.gov/data-reports/ccc-index.asp. **NOTE:** This is an internal Web site not available to the public.

f. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, revised in September 2017, or subsequent policy.
PREVENTION, TESTING, DIAGNOSIS AND TREATMENT OF HEPATITIS B VIRUS (HBV) INFECTION AND PREVENTION OF HEPATITIS D VIRUS (HDV) VIRUS INFECTION

This appendix provides information to VHA clinicians on the prevention, testing, and treatment of HBV in Veterans. It does not address evaluation of health care workers with occupational exposure to HBV or look-back investigations of potential health care-associated exposures to HBV.

1. HBV TESTING & DIAGNOSIS IN VHA

   a. Highly effective vaccines against HBV prevent HBV infection. Furthermore, for individuals who are chronically infected with HBV, treatment with antiviral agents helps prevent complications such as cirrhosis and liver cancer. Thus, identification of individuals who may benefit from either immunization or antiviral treatment is a key goal for clinicians caring for patients with, or at risk of HBV infection (4a-b).

   b. Appropriate methodologies for implementation of HBV serologic testing, include: hepatitis B surface antigen, surface antibody, core antibody, envelope antigen, antibody to hepatitis B envelope, and hepatitis B DNA. Serologies indicated in a particular clinical situation should be determined by the ordering provider according to current CDC guidelines (4.d.).

   c. Documentation of consent for HBV testing is no longer required, per VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures. Care providers continue to have an ethical and professional obligation engage patients in an informed consent conversation about HCV testing, which should include specific information about the test, reasons for offering the test, and the risks and benefits of testing (4.d.).

2. PREVENTION

   a. Specific guidance on immunization for HBV is outlined in the Hepatitis B Immunization Guidance Statement from the VHA National Center for Health Promotion and Disease Prevention, available at: http://vaww.prevention.va.gov/CPS/Screening_for_Hepatitis_B.asp. **NOTE:** This is an internal VA Web site not available to the public.

      (1) There is no vaccine for Hepatitis D, but it can be prevented in persons who are not already HBV-infected by Hepatitis B vaccination (CDC).

3. HBV TREATMENT

When treating hepatitis B Virus infection in Veterans enrolled in VA care, VHA will adhere to the most current guidelines from either the American Association for the Study of Liver Disease (AASLD) or the European Association for the Study of the Liver (EASL) on antiviral treatment of HBV-infected patients available at: AASLD: http://onlinelibrary.wiley.com/doi/10.1002/hep.28156/full and EASL: http://www.easl.eu/research/our-contributions/clinical-practice-guidelines/detail/easl-2017-clinical-practice-guidelines-on-the-management-of-hepatitis-b-virus-infection. The recommendations contained in these guidelines are not intended to be a substitute for the judgment of a clinician who is an expert in the care of HBV-infected individuals.

4. REFERENCES


   d. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, revised in September 2017, or subsequent policy.
TESTING AND PREVENTION OF HEPATITIS A VIRUS (HAV) INFECTION

This appendix provides information to VHA clinicians on the prevention of HAV in Veterans. It does not address evaluation of health care workers with occupational exposure to HAV or look-back investigations of potential health care-associated exposures to HAV.

1. HAV TESTING AND DIAGNOSIS

   a. Hepatitis A Virus (HAV) is a communicable liver disease, most frequently transmitted via contaminated food or water (i.e., fecal-oral transmission). HAV is vaccine-preventable, and has no current treatment. Most people with HAV recover without treatment within a few months. HAV can cause severe, acute liver disease (including death) but does not cause chronic infection.

   b. Specific guidance on identification of acute HAV is outlined by the Centers for Disease Control and Prevention (CDC’s), available at: [https://www.cdc.gov/hepatitis/hav/havfaq.htm](https://www.cdc.gov/hepatitis/hav/havfaq.htm).

   c. HAV serologic testing includes Total and IgM antibody testing. Serologies indicated in a particular clinical situation should be determined by the ordering provider according to current CDC guidelines (4.b.).

2. HAV PREVENTION

   Specific guidance on immunization for HAV is outlined in the Hepatitis A Immunization Guidance Statement from the VHA National Center for Health Promotion and Disease Prevention, available at: [http://vaww.prevention.va.gov/CPS/Hepatitis_A_Immunization.asp](http://vaww.prevention.va.gov/CPS/Hepatitis_A_Immunization.asp). NOTE: This is an internal VA Web site not available to the public.

3. REFERENCES
