Frequently Asked Questions

New Amendments to VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures (originally published August 14, 2009)

1. What has changed with the April 4, 2019 publication of amended VHA Handbook 1004.01?

The April 4, 2019 amendment to VHA Handbook 1004.01, originally issued in 2009, removes the requirement for the specific documentation of oral informed consent for Human Immunodeficiency Virus (HIV) and other sexually transmitted infections (STIs). In addition, to align with VHA Directive 1113, Testing for Human Immunodeficiency Virus in Veterans Health Administration Facilities, dated May 5, 2015, the April 4, 2019 amendment to VHA Handbook 1004.01 removes the requirement to provide written educational materials to patients recommended for HIV testing. In 2017, an amendment to VHA Handbook 1004.01 removed the requirement for the specific documentation of consent for HBV and HCV.

The amendment also removes the requirement for signature informed consent for arthrocentesis. Oral informed consent for arthrocentesis is sufficient.

2. What has NOT changed with the April 4, 2019 publication of amended VHA Handbook 1004.01?

Patients have the right to accept or decline any recommended medical treatment, test or procedure. Therefore, practitioners who recommend arthrocentesis or HBV, HCV, HIV or STI testing continue to have an ethical and professional obligation to promote shared decision making through an informed consent communication process, and consent must be provided by the patient (or surrogate if the patient lacks decision-making capacity) prior to initiating this treatment or specific test(s).

3. What must a practitioner discuss as part of an oral informed consent discussion prior to HBV, HCV, HIV or STI testing?

A practitioner must provide information about the test: what it is, why it’s being recommended, the benefits and potential risks of testing, and the alternatives to testing. It is not sufficient to have a general discussion (e.g., about drawing blood for “tests”) without mentioning the information noted above.

4. Are there educational material available about STIs?

Yes. Although it is not required to provide written educational materials to patients recommended for testing for HIV, HCV, HBV, or STIs, clinicians may continue to provide educational materials and should assist patients in accessing those materials if requested.
A wide array of educational materials for patients are available from CDC at: https://www.cdc.gov/std/healthcomm/fact_sheets.htm, as well as training and materials for providers, available at: https://www.cdc.gov/std/training/onlinetraining.htm

In addition, a one-page document titled, “Infectious Disease Screening and Vaccination: What You Need to Know” summarizes key information that a Veteran who is considering a test for HIV, HBV, HCV or STI’s would want to know as part of decision making.

5. Why was the decision made to remove the requirement for specific documentation of the patient’s (or surrogate’s) oral informed consent to tests for HBV, HCV, HIV, and STIs?

Effective treatments for HIV and HCV have contributed to a lessening of stigma and an increased emphasis within VA on ensuring Veterans have early access to these treatments. In addition, provider concerns about the burden of documentation and unintended consequences resulting from facility efforts to adhere with the requirement were the basis for the decision to remove the requirement to specifically document the patient’s oral consent to the test in question.

6. Does the removal of the specific documentation requirement of oral informed consent to tests for HBV, HCV, HIV, and STIs also apply to documentation of informed consent for illicit drug use, alcohol intoxication, Methicillin-Resistant Staphylococcus Aureus (MRSA), and inheritable genetic abnormalities?

No. According to VHA Handbook 1004.01, tests for illicit drug use, alcohol intoxication, MRSA, and inheritable genetic abnormalities continue to require specific oral informed consent, including documentation of consent to the test in question (VHA Handbook 1004.01, paragraph 13a(1)(b), page 7).

“Specific oral informed consent,” also referred to as “specific consent,” is outlined in paragraph 13, of VHA Handbook 1004.01. It is the VA informed consent process for tests that provide information that is particularly sensitive or may have significant consequences that the patient might reasonably want to consider as part of their consent decision. Obtaining specific oral informed consent from the patient (or surrogate, if the patient lacks decision making capacity), requires a specific discussion about the test as well as specific documentation in the electronic health record of the patient’s (or surrogate’s) consent to the test. The documentation can be something as simple as “patient consented to X test” written in a progress note or lab order. (See VHA Handbook 1004.01, paragraph 13c(1)(b), page 10.)

For questions about VHA Handbook 1004.01, please contact vhaethics@va.gov.

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