Frequently Asked Questions

New Amendments to VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures (originally published August 14, 2009):
Tests for Human Immunodeficiency Virus (HIV) and Other Sexually Transmitted Infections

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 joint aspiration. Oral informed consent for joint aspiration is sufficient. Signature informed consent for joint injections is still required.

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 joint aspiration 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 a specific 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.

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4. Are there educational materials 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.)
7. Who must obtain informed consent for an HIV test?

Policy specifies that informed consent must be obtained by the practitioner, defined in VHA Handbook 1004.01 (paragraph 3, page 2), as:

“j. Practitioner. A practitioner is defined as any physician, dentist, or health care professional granted specific clinical privileges to perform the treatment or procedure. For the purposes of this Handbook, the term practitioner also includes:
(1) Medical and dental residents, regardless of whether they have been granted specific clinical privileges; and
(2) Other health care professionals whose scope of practice agreement or other formal delineation of job responsibility specifically permits them to obtain informed consent, and who are appropriately trained and authorized to perform the procedure or to provide the treatment for which consent is being obtained.”

Based on this definition, the phrase “to perform the treatment or procedure” means to order an HIV test. Although other members of the treatment team may assist in the informed consent process, only health care professionals whose scope of practice agreement or other formal delineation of job responsibility specifically permits them to obtain informed consent, and who are appropriately trained and authorized to order the test may obtain the patient’s oral informed consent by ensuring that the patient has been appropriately informed, understands and consents to the test.

8. How long is a patient’s oral consent to an HIV test valid?

The relevant VA regulation (38 CFR 17.32) and policy (VHA Handbook1004.01) are silent on the length of time that an oral consent is valid. As a rule of thumb, it makes sense to use a 60-day timeframe for validity of oral informed consent since it is familiar (based on signature consent requirements for various treatments and procedures) and because it helps ensure that the patient has not forgotten details of the consent discussion prior to administration of the test. Because many workflows involve obtaining consent at the current appointment for tests conducted on labs drawn at the next appointment, it is permissible for the practitioner to document such an arrangement when the time elapsed between the consent and the test does not exceed 12 months. This requires clear documentation of the oral informed consent for the test, and for the test to be administered within a specified time period.

9. May a single informed consent be obtained for a series of HIV screening tests?

Yes, if repeat HIV screening is part of the treatment plan and the following conditions are met, as indicated in VHA Handbook 1004.01, paragraph 4c:

“VHA does not recognize “general” or “blanket” consent for medical treatment, but requires the patient’s separate consent for each treatment, procedure, therapeutic course of treatment for a particular problem or condition (e.g., inpatient or outpatient treatment for diabetes), or series of treatments (e.g., cycles of chemotherapy). When the proposed treatment plan involves multiple or recurrent treatments and procedures, it is generally not necessary to repeat the informed consent discussion for each new treatment or procedure, provided that the original consent encompassed the treatments or procedures to be performed. However, two circumstances exist where the informed consent discussion must be repeated and a new consent must be obtained, they are:

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(1) If there is a significant deviation from the treatment plan to which the patient originally consented; or
(2) If there is a change in the patient's condition or diagnosis that would reasonably be expected to alter the original informed consent.”

In the case of screening tests for HIV, examples of when consent may be obtained for a series of tests include:

a. A patient’s treatment plan includes pre-exposure prophylaxis and requires repeat screening; or
b. A patient has an indeterminate HIV test result and repeat HIV screening is needed to determine whether or not the patient has become HIV-positive; or
c. A patient’s treatment plan includes post-exposure prevention and screening on a serial basis is needed to determine whether or not the patient has become infected with HIV virus.

In these cases, when a series of HIV tests is part of the treatment plan, the practitioner must discuss the anticipated series with the patient in the initial informed consent and document this in the record. If the clinical circumstances or treatment plan change during the series, a new consent is required. Also, because it is likely that the patient’s clinical status will change, it is prudent to conduct the full oral informed consent process with the patient again in 12 months. The patient should be told each time an HIV test is being administered and given the opportunity to take or refuse the test.

10. If the health record suggests that an HIV test was administered after a patient refused the test, should I conduct a clinical disclosure to let the patient know?

If the health record shows that a patient refused an HIV test, but the test was administered anyway, it could be a case of incomplete documentation. In such a case, local staff should review the patient’s record to determine if there is any evidence that specific oral informed consent was obtained before the test. Then, if it appears that a patient was tested despite his or her refusal, a clinical disclosure should be conducted. See VHA Handbook 1004.08, Disclosure of Adverse Events to Patients and contact your local ethics consultation service for more information.

11. What should the practitioner do if the patient is unable or unwilling to give oral consent for a recommended HIV test?

If the patient is unable to consent because he or she lacks decision-making capacity, then the practitioner should conduct the informed consent process with the patient’s surrogate. If the patient is unwilling to consent to an HIV test that a practitioner believes is necessary, the practitioner should explain the importance of the HIV test and the reason for the recommendation. Patients have the right to accept or refuse any medical treatment or procedure, therefore, the practitioner may neither force the patient to have the test nor order the test without the patient’s consent.

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12. Even though signature consent for HIV testing is not required, may I obtain signature consent to administer an HIV test?

Although tests conducted to identify HIV disease are sensitive, this test does not meet the risk threshold for the signature consent requirement. In addition, the signature consent process requires a special workflow to obtain signatures and the risks associated with the HIV test are not sufficient to warrant the process that would be required to provide the practitioner and patient or surrogate with access to iMedConsent™ and the signature pad.

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