

HIV Screening for Adults Clinical Practice Guidelines

These guidelines are informational only. They are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by practitioners, considering each patient's needs on an individual basis.

Guideline recommendations apply to populations of patients. Clinical judgment is necessary to design treatment plans for individual patients.

Note: These guidelines are intended for adult patients ≥ 18 years old. The CDC and the US Preventive Services Task Force have called for greater routinization of HIV antibody testing and greater case identification. The HIV Initiative of Kaiser Permanente is committed to quality HIV care and HIV prevention education, including prevention of other sexually transmitted diseases and reduction of substance use. These guidelines are intended as a means to better serve our membership.

All guidelines have been approved by KP's Guideline Quality Committee.

**Approved by the
National Guideline Directors
August 2008**

**Endorsed by the
HIV Initiative Steering Committee**



Table of Contents

Introduction..... 1

Guidelines Summary 6

Supporting Documentation 8

 HIV Antibody Testing and Prevention 9

 Recommendation 10

 Evidence Tables 14

Appendix..... 15

References..... 19

Introduction

Purpose of HIV Screening Guidelines

The purpose of these guidelines is to reduce morbidity and mortality from the human immunodeficiency virus (HIV), specifically through HIV screening and (earlier) treatment of incident cases identified through the screening. Counseling of screened individuals is not addressed in these guidelines, but it will be addressed when the US Preventive Services Task Force update is published in the near future.

Overview

HIV testing data for Kaiser Permanente patients at risk for HIV indicate that 8% to 15% of the adult population at risk has been tested for HIV infection (even among patients with a diagnosed sexually transmitted disease, only approximately 40% in Kaiser Permanente Northern California (KPNC) were tested for HIV in 2005); this rate is not in keeping with the most recent Centers for Disease Control and Prevention (CDC) and National guidelines. The goal of these guidelines is to help Kaiser Permanente healthcare providers identify patients at higher risk for HIV infection, for whom HIV testing should be an essential element of care. Also, many regions have no written guidelines for HIV antibody testing.

The HIV Initiative of Kaiser Permanente is committed to a comprehensive HIV testing strategy both to identify greater numbers of undiagnosed infected individuals and to identify cases earlier in the course of the disease. Kaiser Permanente in its preventive health literature recommends HIV testing for persons at risk for HIV infection. The CDC recently called for universal HIV testing as part of routine medical care for all persons aged 13 to 64 years.

However, universal testing will be problematic in the many states that require signed informed consent for HIV antibody testing. In these situations, focused testing for certain patient populations at greater risk for HIV infection is more feasible. High-risk groups include individuals with another sexually transmitted infection or with newly acquired hepatitis B or C, persons who are having sex with multiple partners, substance abusers, and men who have sex with men. Patients in these groups have higher HIV infection rates and need to be targeted for increased HIV testing within our organization.

Further, to prevent mother-to-child transmission, every pregnant woman should be tested for HIV antibody early during each pregnancy and retested near the time of delivery if there is evidence that she may have acquired HIV infection during pregnancy. Although these guidelines are directed to members 18 years of age or older, they can apply to all members, regardless of age, who belong to any of the above high-risk groups.

Who Is This Manual Designed to Help?

This manual is designed to assist clinicians, nurse practitioners, health educators, and Kaiser Permanente HealthConnect implementation and design teams to improve HIV testing, case identification, and harm-reduction counseling in Kaiser Permanente.

Development and Scope of this Guideline

This guideline is in response to previous studies on the identification of HIV-infected patients and cases in Kaiser Permanente⁽¹⁾ and new CDC guidelines. Although no cost-effectiveness study specific to this topic has been conducted, previous work indicates that earlier identification of HIV disease is more cost-effective than later case identification because of the greater costs related to hospitalization, outpatient treatment, and medication for cases identified later.

The prevalence rates of HIV infection are not the same for persons in different risk categories (e.g., receptive anal intercourse vs. insertive vaginal intercourse) or with different coinfections (e.g., male with gonorrhea vs. female with chlamydia); however, there is value in HIV testing even when the absolute risk is less.*

KP's National Guideline Initiative

What Is the National Guideline Directors' Group?

The Kaiser Permanente (KP) National Guideline Directors' Group has been established to direct Programwide, interregional guideline development activities. This group is composed of representatives from the Care Management Institute (CMI), all eight regions, and National Prevention Partners.

What Is the National Guideline Initiative?

The KP National Guideline Directors have launched a national initiative to identify, create, and maintain a core set of high-quality, evidence-based clinical practice guidelines for use Programwide. This initiative will create economies of scale and allow regions to focus scarce resources on clinical guideline implementation. The National Guideline Initiative also will provide a consistent source of quality clinical content for KP HealthConnect.

The initiative's goals are to:

- Facilitate the endorsement and adoption of clinical practice guidelines by all regions
- Eliminate unnecessary duplication of effort and diminish “non-value-added” variability of clinical practice
- Leverage Programwide analytic and methodological resources
- Optimize the provision of evidence-based clinical content for KP HealthConnect and other venues
- Align guideline revision cycles to simplify the National Committee for Quality Assurance (NCQA) accreditation process

* There is some controversy about the absolute HIV risk associated with different coinfections and the cost-effectiveness of performing HIV antibody testing in all persons with any sexually transmitted infection. The authors feel that any sexually transmitted infection is associated with behaviors that lead to an increased risk of HIV transmission and infection, and, thus, all diagnoses of sexually transmitted infections should prompt HIV antibody testing.

What Is the Guideline Quality Committee?

The Guideline Quality Committee is a subcommittee of the National Guideline Directors consisting of a group of practitioners and analytic managers from the KP regions and CMI who facilitate the development, review, and exchange of evidence-based clinical practice guidelines.

How Are Guidelines Developed?

Evidence-based guidelines that have been reviewed by the Guideline Quality Committee are said to be National Guideline Directors Reviewed guidelines. Each individual recommendation of such a guideline is reviewed for its adherence to the policies of the National Guideline Directors Common Methodology on the development of evidence-based guidelines. Guidelines are developed with the use of an “evidence-based methodology” and involve a systematic literature search, critical appraisal of the research design and statistical results of relevant studies, and grading of the sufficiency (quantity, quality, consistency, and relevancy) of the evidence for drawing conclusions. For additional information on evidence grading, see Table 1 in Appendix on page 15.

What Does It Mean for a Guideline to Be Evidence-Based?

Each recommendation within a guideline is labeled as “evidence-based” or “consensus-based.” A recommendation is considered “evidence-based” if there are a sufficient number of high-quality studies from which to draw a conclusion and the recommended practice is consistent with the findings of the evidence. A recommendation can also be considered “evidence-based” if there is insufficient evidence and no practice is recommended. A recommendation is considered “consensus-based” if there is insufficient evidence and a practice is recommended on the basis of the consensus or expert opinion of the Guideline Development Team.

What Does It Mean for a Guideline to Be Approved and National?

A recommendation that is consistent with the above policies is labeled as National Guideline Directors Approved. A recommendation that fails to satisfy those criteria is not approved and will be noted as such. A National Guideline Directors Approved guideline for which at least 90% of the recommendations are approved by at least six of the eight KP regions is a “National Guideline.” National Guidelines are the preferred evidence source for KP HealthConnect.

Guideline Development

The medical community recognizes that clinical practice guidelines (CPGs) based on scientific evidence are an essential tool for improving and demonstrating the quality of care in the present environment of burgeoning technology and resource limitations. Increasingly, clinicians must consider not only issues of quality but also the resource implications of their decisions. This involves addressing health problems in a way that maximizes the health of the population, given the available resources.

The National Guideline Initiative supports physician development of explicit, scientifically based recommendations for clinical practice to assist physicians, administrators, and other health care professionals from KP in determining the most effective medical practices.



Development Process

The KP Care Management Institute (CMI) is a national entity that synthesizes knowledge on the best clinical approaches from both within and outside KP and develops integrated, evidence-based guidelines and care management programs that can be tailored to local settings and for individual members. CMI facilitates implementation of these guidelines and programs by working with health care professionals at the local level. CMI is involved in the creation of new care management programs for priority populations, as well as in the identification and synthesis of existing successful clinical practices. In the development of its programs, CMI utilizes an evidence-based approach and relies on population management principles and processes.

To develop a guideline, CMI consultants work with a multidisciplinary team of physicians and other health care professionals. This Guideline Development Team consists of a core multidisciplinary group of physicians representing the medical specialties most affected by the guideline topic, and other content experts from disciplines such as pharmacy, nursing, and social work, as appropriate. The members of the Guideline Development Team are endorsed by the National Guideline Directors from their region.

During the guideline development process, the Guideline Development Team reviews evidence published in peer-reviewed scientific journals, existing evidence-based guidelines, consensus-based statements from external professional societies and government health organizations, and clinical expert opinion of KP regional specialty groups. The members of the Guideline Development Team develop the guideline and facilitate the information exchange in both directions on behalf of the region that they represent. This process should include obtaining the buy-in of the local champions regarding the guideline so that it will be implemented once published.

Acknowledgments

The Kaiser Permanente (KP) HIV Clinical Practice Guidelines are the result of the extensive clinical expertise, collaborative efforts, and outstanding personal contributions of the following participants:

KP HIV Screening Guidelines Project Management Team

Michael Horberg, MD	Clinical Lead	Care Management Institute & HIV Initiative
Amanda Charbonneau	Project Manager	HIV Initiative
Paul Barrett, MD	EBM Methodologist	Care Management Institute

The KP HIV Screening Guidelines were adapted from ***HIV: DIAGNOSIS—Increasing HIV Antibody Testing Guideline***, which is the result of the extensive clinical expertise, collaborative efforts, and outstanding personal contributions of the following participants:

HIV: DIAGNOSIS—Increasing HIV Antibody Testing Project Management Team

Michael Horberg, MD	Clinical Lead	Care Management Institute & HIV Initiative
Amanda Charbonneau	Project Manager	HIV Initiative

HIV: DIAGNOSIS—Increasing HIV Antibody Testing Workgroup

Michael Horberg, MD	Clinical Lead	Care Management Institute & HIV Initiative
Amanda Charbonneau	Project Manager	HIV Initiative
Michael Allerton, MS	Coauthor	The Permanente Medical Group, Inc.
Michael Silverberg, PhD	Coauthor	HIV Initiative

HIV Initiative Steering Committee (includes all members of HIV: DIAGNOSIS—Increasing HIV Antibody Testing Workgroup)

Diana Antoniskis, MD	Northwest Permanente Medical Group
Susan Bersoff-Matcha, MD	Mid-Atlantic Permanente Medical Group
William Blake, MD	The Southern Permanente Medical Group
Steven Carzasty, MSW	Group Health Cooperative
Robert Dobrinich, MD	Ohio Permanente Medical Group
Enid Eck, RN	Southern California Permanente Medical Group
Daniel Klein, MD	The Permanente Medical Group, Inc.
Drew Kovach, MD	Hawai'i Permanente Medical Group
Miguel Mogyoros, MD	Colorado Permanente Medical Group
William Towner, MD	Southern California Permanente Medical Group
Winkler Weinberg, MD	The Southern Permanente Medical Group



Guidelines Summary

These guidelines are informational only. They are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by practitioners, considering each patient's needs on an individual basis.

Guideline recommendations apply to populations of patients. Clinical judgment is necessary to design treatment plans for individual patients.

Note: These guidelines are intended for adult patients ≥ 18 years old. The CDC and the US Preventive Services Task Force have called for greater routinization of HIV antibody testing and greater case identification. The HIV Initiative of Kaiser Permanente is committed to quality HIV care and HIV prevention education, including prevention of other sexually transmitted diseases and reduction of substance use. These guidelines are intended as a means to better serve our membership.

All guidelines have been approved by KP's Guideline Quality Committee.

HIV Antibody Testing and Prevention

1. The Guideline Development (GDT) strongly recommends HIV antibody testing for all patients diagnosed with sexually transmitted infections, including syphilis, gonorrhea, chlamydia, and herpes simplex virus 2, and for all those with incident human papilloma virus infection.
Evidence-based: A
2. The GDT strongly recommends HIV antibody testing for all patients with newly acquired hepatitis B or C.
Evidence-based: A
3. The GDT strongly recommends HIV antibody testing for all pregnant women early during each pregnancy, with retesting at 36 weeks if a woman has the possibility of HIV exposure during the course of the pregnancy (e.g., if she acquires a new sexually transmitted infection during pregnancy or if her partner is known to be HIV-infected).
Evidence-based: A
4. The GDT strongly recommends HIV antibody testing for patients using injection drugs and other at-risk patients enrolled in chemical dependency rehabilitation programs.
Evidence-based: A
5. The GDT strongly recommends that all injection-drug users not in chemical dependency rehabilitation programs be offered HIV testing regularly (except for patients who have already been tested in the previous six months or who have already been documented as HIV-positive). Repeat testing on a periodic basis should be based on risk assessment obtained periodically.
Evidence-based: A
6. The GDT strongly recommends that that all sexually active adults who are not in a monogamous relationship with an HIV-negative partner and all men who are having sex with men be offered HIV antibody testing (except for patients who have already been tested in the previous six months or who have already been documented as HIV-positive). Repeat testing on a periodic basis should be based on risk assessment obtained periodically.
Evidence-based: A

Although these guidelines are directed to members 18 years of age or older, they can apply to all members, regardless of age, who belong to any of the above high-risk groups.

For the most recent Clinical Considerations, see the USPSTF Screening for Human Immunodeficiency Virus Guideline (July 2005) at:
<http://www.ahrq.gov/clinic/uspstf05/hiv/hivrs.htm#clinical>

Supporting Documentation

For each of the topic areas, the following supporting documentation is presented:

- Problem Formulation** This explains the questions we seek to answer with these particular recommendations.
- Evidence Search** This documents the approach taken to review the literature on this topic.
- Recommendations and Rationale Statement** This documents the recommendations and the rationale (or basis) for the recommendation, including a summary of supporting evidence and a description of how decisions were made in the face of conflicting or insufficient evidence.
- Evidence Tables** These outline the methods and major findings of relevant resources reviewed for each topic.

Methods for Presenting Findings:

The criteria for grading the evidence as either “good,” “fair,” or “insufficient” adheres to the KP National Guideline Directors policy document entitled “A Common Methodology Process for Interregional National Guidelines” which is located in Appendix on page 15.

HIV Antibody Testing and Prevention

Problem Formulation

Clinical Question(s)	<p>What is the effectiveness of HIV testing in reducing morbidity and mortality from HIV infection?</p> <p>What groups, if any, should be selectively targeted for HIV testing (because of their higher prevalence or risk of HIV and the resulting enhanced effectiveness of HIV testing)?</p>
Intended Use of the Guideline	Kaiser Permanente providers, health educators, nurses
Population	Kaiser Permanente adult population (>17 years old)
Health Problem	HIV Infection
Health Intervention	<ul style="list-style-type: none"> ◆ Increased HIV antibody testing ◆ Increased harm-reduction education ◆ Compared with no change in HIV testing or harm-reduction education
Practitioners	KP physicians, physician assistants, nurse practitioners, nurses, and pharmacists
Setting	Outpatient office visit
Most Important Health Outcomes Associated with the Intervention	<ul style="list-style-type: none"> ◆ Increased HIV antibody testing ◆ Greater HIV case identification ◆ Earlier HIV case identification ◆ Decreased HIV morbidity and mortality
Side Effects of the Intervention	<ul style="list-style-type: none"> ◆ Greater harm-reduction patient education (positive side effect) ◆ Anxiety, labeling, effects on close relationships
Intermediate (Biological) Outcomes:	<ul style="list-style-type: none"> ◆ None



Recommendation

Guideline:	HIV Antibody Testing and Prevention
Recommendation:	<ol style="list-style-type: none"> 1. The Guideline Development (GDT) strongly recommends HIV antibody testing for all patients diagnosed with sexually transmitted infections, including syphilis, gonorrhea, chlamydia, and herpes simplex virus 2, and for all those with <i>incident</i> human papilloma virus infection. 2. The GDT strongly recommends HIV antibody testing for all patients with newly acquired hepatitis B or C. 3. The GDT strongly recommends HIV antibody testing for all pregnant women early during each pregnancy, with retesting at 36 weeks if a woman has the possibility of HIV exposure during the course of the pregnancy (e.g., if she acquires a new sexually transmitted infection during pregnancy or if her partner is known to be HIV-infected). 4. The GDT strongly recommends HIV antibody testing for patients using injection drugs and other at-risk patients enrolled in chemical dependency rehabilitation programs. 5. The GDT strongly recommends that all injection-drug users not in chemical dependency rehabilitation programs be offered HIV testing regularly (except for patients who have already been tested in the previous six months or who have already been documented as HIV-positive). Repeat testing on a periodic basis should be based on risk assessment obtained periodically. 6. The GDT strongly recommends that that all sexually active adults who are not in a monogamous relationship with an HIV-negative partner and all men who are having sex with men be offered HIV antibody testing (except for patients who have already been tested in the previous six months or who have already been documented as HIV-positive). Repeat testing on a periodic basis should be based on risk assessment obtained periodically. <p style="text-align: center;">Although these guidelines are directed to members 18 years of age or older, they can apply to all members, regardless of age, who belong to any of the above high-risk groups.</p>
Methodology:	Evidence-based: A

For the most recent Clinical Considerations, see the US Preventive Services Task Force (USPSTF) Screening for Human Immunodeficiency Virus Guideline (July 2005) at: <http://www.ahrq.gov/clinic/uspstf05/hiv/hivrs.htm#clinical>

Rationale:

Evidence: Good

The USPSTF recommendations for nonpregnant adults and adolescents call for routine testing for HIV in all patients at increased risk⁽³⁾ for HIV infection. This recommendation is based on the accuracy of HIV testing and the fact that the benefits of highly active antiretroviral therapy (HAART) substantially outweigh the harms.⁽²⁾ The search⁽³⁾ and evidence summary⁽²⁾ are published separately. Specific high-risk groups are addressed in below.

1. HIV antibody testing is strongly recommended for all patients diagnosed with sexually transmitted infections, including syphilis, gonorrhea, chlamydia, and herpes simplex virus 2, and for all those with incident human papilloma virus infection.

Persons being treated for sexually transmitted diseases (no exceptions are given for specific sexually transmitted diseases should be tested regularly. The USPSTF notes also in its clinical considerations that patients at increased risk have increased yield of positive HIV antibody testing with “routine HIV screening.” This is a grade A recommendation from the USPSTF.

Source: <http://www.ahrq.gov/clinic/uspstf/uspshivi.htm>

2. HIV antibody testing is strongly recommended for all patients with newly acquired hepatitis B or C.

The USPSTF has made a grade A recommendation that patients with a diagnosed sexually transmitted disease or a history of past or present injection-drug use be tested for HIV. Because these are the modes of transmission of hepatitis B and C, these newly diagnosed patients should be tested also for HIV infection.

Source: <http://www.ahrq.gov/clinic/uspstf/uspshivi.htm>

3. HIV antibody testing is strongly recommended for all pregnant women early during each pregnancy, with retesting at 36 weeks if a woman has the possibility of HIV exposure during the course of the pregnancy (e.g., if she acquires a new sexually transmitted infection during pregnancy or if her partner is known to be HIV-infected).

The USPSTF recommendation depends on the accuracy of testing for HIV and the effectiveness of prophylactic retroviral therapy and elective cesarean section for pregnant women who are HIV-positive.⁽²⁾ The search⁽⁵⁾ and evidence summary are published separately.⁽⁶⁾

Source: <http://www.ahrq.gov/clinic/uspstf/uspshivi.htm>



Other considerations: The CDC recommendations⁽⁷⁾ specifically note that early identification of HIV seropositivity and effective HIV therapy effectively prevent mother-to-child transmission of HIV during pregnancy and labor. Further, the CDC guidelines note that women who decline testing early in pregnancy should be reoffered testing again later in pregnancy.⁽⁷⁾ The CDC also recommends testing at 36 weeks if there is evidence of HIV risk behavior during the pregnancy (new sexually transmitted disease, injection-drug use, or more than one sexual partner during pregnancy).⁽⁷⁾ The new CDC guidelines for HIV antibody testing recommend opt-out HIV testing for all pregnant women early during each pregnancy to ensure that all potential HIV risk exposures are identified. Opt-out testing is not realistically possible in states that still require written, informed consent for HIV antibody testing.

4. HIV antibody testing is strongly recommended for patients using injection drugs and other at-risk patients enrolled in chemical dependency rehabilitation programs. (For detailed material regarding this recommendation, see page 14.)

The USPSTF has made a grade A recommendation that patients with history of past or present injection-drug use or who engage in higher-risk sexual behavior (including paying or receiving money for sex or having partners who do so) be routinely tested for HIV. KPNC data⁽⁸⁾ from younger adults in chemical dependency rehabilitation programs indicate that increased multiple HIV risk behaviors occur with heavy alcohol use and narcotic use (both seen among patients in chemical dependency rehabilitation programs).

A systematic review done by Care Management Institute staff for these guidelines found three cross-sectional studies of the prevalence of HIV infection in outpatient or mixed inpatient and outpatient chemical dependency rehabilitation programs.^(10,11,12) HIV seroprevalence was approximately 6.0% (range, 4.5% to 8.5%) among patients who were not injection-drug users in these chemical dependency rehabilitation programs. In addition, up to 54% of patients who were not injection-drug users have had multiple (three to five) sexual partners.^(10,11) Two of these studies were conducted in community chemical dependency rehabilitation programs and the other at a Veterans Affairs facility, and therefore it is likely that the subjects in these studies were of lower socioeconomic status than Kaiser Permanente members. In addition the racial and ethnic composition of these study populations was different from that of the Kaiser Permanente populations.⁽¹³⁾ Because of the differences between these study populations and the clients of Kaiser Permanente substance abuse programs, the study results are believed to justify a heightened sense of awareness of risky behaviors, but not universal screening, in the Kaiser Permanente clients.

Source: <http://www.ahrq.gov/clinic/uspstf/uspshivi.htm>
See Evidence Tables on page 14.

Other Considerations: The CDC reports that even among heterosexual men, users of noninjected crystal methamphetamine have a higher prevalence of HIV risk behaviors.⁽⁹⁾

- 5. It is strongly recommended that all injection-drug users not in chemical dependency rehabilitation programs be offered HIV testing regularly (except for patients who have already been tested in the previous six months or who have already been documented as HIV-positive). Repeat testing on a periodic basis should be based on risk assessment obtained periodically.**

The USPSTF has made this a grade A recommendation. Many of our members who are substance users (including users of crystal methamphetamine, injection drugs, cocaine, and alcohol on a regular basis), do not utilize chemical dependency rehabilitation programs in Kaiser Permanente but are a higher-risk population for HIV acquisition and transmission. Although the USPSTF makes no recommendation about the optimal frequency of HIV screening, it does state that clinicians should consider the prevalence of HIV infection and the risk characteristics of the population they serve in determining an appropriate screening strategy

Source: <http://www.ahrq.gov/clinic/uspstf/uspshivi.htm>

Other Considerations: The CDC concurs with this recommendation and specifically recommends annual testing of all persons likely to be at high risk for HIV, including active injection-drug users.

- 6. It is strongly recommended that all sexually active adults who are not in a monogamous relationship with an HIV-negative partner and all men who are having sex with men be offered HIV antibody testing (except for patients who have already been tested in the previous six months or who have already been documented as HIV-positive). Repeat testing on a periodic basis should be based on risk assessment obtained periodically.**

The USPSTF has made screening of this population a grade A recommendation. Although the USPSTF makes no recommendation about the optimal frequency of HIV screening, it does state that clinicians should consider the prevalence of HIV infection and the risk characteristics of the population they serve in determining an appropriate screening strategy.

Source: <http://www.ahrq.gov/clinic/uspstf/uspshivi.htm>

Other Considerations: The CDC concurs with this recommendation and specifically recommends annual testing of all persons likely to be at high risk for HIV, including active injection-drug users.



Evidence Tables

HIV Prevalence Among Users of Nonintravenous Drugs in Chemical and Drug Rehabilitation Programs

Name	N	Age Distribution	% Female	Ethnicity	Education	No. of Partners	HIV Seroprevalence	Biases*
Avins AL, Woods WJ, Lindan CP, Hudes ES, Clark W, Hulley SB. HIV infection and risk behaviors among heterosexuals in alcohol treatment programs. <i>Journal of the American Medical Association</i> 1994;271:515-518.	860	≤ 30 years = 33% 31 - 40 years = 45% > 40 years = 22%	26%	White = 34% Black = 52% Hispanic = 10.4% Other = 4%	<12 years = 30% ≥12 years = 70%	≥ 2 = 54% 95% CI: 51% - 57%	5.0% 95% CI: 3.0% - 6.0%	2

Comments: This study was designed to identify predictors of HIV status in non-injection-drug-using clients of chemical dependency rehabilitation programs. To address the clinical question appropriately, baseline-only information about the study subjects and HIV status is presented in the table above.

Name	N	Age Distribution	% Female	Ethnicity	Education	No. of Partners	HIV Seroprevalence	Biases*
Jacobson JM, Worner TM, Sacks HS, Lieber CS. Human immunodeficiency virus and hepatitis B virus infections in a New York City alcoholic population. <i>Journal of Studies on Alcohol</i> 1992;53:76-79.	143	Average age = 40.8 years	1%	White = 28% Black = 58% Hispanic = 16%	NR	≥ 4 = 15.4% 95% CI: 9.1% - 21.7%	8.5% 95% CI: 3.5% - 13.5%	2

Comments: This study was designed to identify predictors of HIV status in non-injection-drug-using clients of chemical dependency rehabilitation programs. To address the clinical question appropriately, baseline-only information about the study subjects and HIV status is presented in the table above.

Name	N	Age Distribution	% Female	Ethnicity [§]	Education	No. of Partners	HIV Seroprevalence	Biases*
Schleifer SJ, Keller SE, Franklin JE, LaFarge S, Miller SI. HIV seropositivity in inner-city alcoholics. <i>Hospital and Community Psychiatry</i> 1990;41:248-249, 254.	99 total patients; 68% reported alcohol use exclusively; 5% reported abuse of other drugs in addition to alcohol, but no intravenous drug use	Average age range = 30 - 50 years	24%	White = 4% Black = 92% Hispanic = 4%	NR	NR	4.5% of the 67 patients reporting alcohol use exclusively were HIV seropositive 95% CI: 0.0% - 10.2%	2

Comments: This study was designed to identify predictors of HIV status in non-intravenous-drug-using clients of chemical dependency rehabilitation programs. To address the clinical question appropriately, baseline-only information about the study subjects and HIV status is presented in the tables above.

NR = Not reported

* = Biases: N: None; 1: Sample attrition >15%; 2: Sample selection bias; 3: Detection bias (e.g., measurement error, ITT analysis, power); 4: Omitted variable bias

§ = The statistics presented in this column apply to the total number of participants recruited into the study. It may not be reflective of the 130 non-intravenous-drug-using participants in whom we are interested for our clinical purposes.

Appendix

Evidence Grading Scheme Summary

RECOMMENDATION LABEL	RECOMMENDATION STATEMENT*	EVIDENCE BASE
Evidence-Based Recommendations		
Evidence-Based, A	The GDT strongly recommends the intervention.	The intervention improves important health outcomes, based on good evidence, and the Guideline Development Team (GDT) concludes that benefits substantially outweigh harms and costs.
Evidence-Based, B	The GDT recommends the intervention.	The intervention improves important health outcomes, based on 1) good evidence that benefits outweigh harms and costs; or 2) fair evidence that benefits substantially outweigh harms and costs.
Evidence-Based, C	The GDT makes no recommendation for or against the intervention. †	Evidence is sufficient to determine the benefits, harms, and costs of an intervention, and there is at least fair evidence that the intervention improves important health outcomes. But the GDT concludes that the balance of the benefits, harms, and costs is too close to justify a general recommendation.
Evidence-Based, D	The GDT recommends against the intervention.	The GDT found at least fair evidence that the intervention is ineffective, or that harms or costs outweigh benefits.
Evidence-Based, I	The GDT makes no recommendation for or against the intervention. †	Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined.
Consensus-Based Recommendations		
Consensus-Based	The GDT recommends the intervention.	The recommendation is based on the consensus of the GDT, typically in the setting of insufficient evidence.
Consensus-Based	The GDT has determined that the intervention is an option.	The recommendation is based on the consensus of the GDT, typically in the setting of insufficient evidence.
Consensus-Based	The GDT recommends against the intervention.	The recommendation is based on the consensus of the GDT, typically in the setting of insufficient evidence.
Note that most consensus-based recommendations will have evidence grade "Insufficient." For the rare consensus-based recommendations which have "Good" or "Fair" evidence, the evidence must support a different recommendation, because if the evidence were good or fair, the recommendation would usually be evidence-based.. In this kind of consensus-based recommendation the evidence label should point this out, e.g., "Good, supporting a different recommendation."		

* All statements specify the population for which the recommendation is intended.

† At the discretion of the GDT, the recommendation may use the language, "option," but must list all the equivalent options.



Table 2: System for Grading the Strength of a Body of Evidence *

Grade	Therapy/Prevention/Screening	Diagnosis	Prognosis
GOOD	<p>Type and number of studies</p> <ul style="list-style-type: none"> At least one well-designed and -conducted systematic review (SR) or meta-analysis (MA) (consider heterogeneity) of RCTs Two or more well-designed and -conducted RCTs with narrow confidence intervals One well-designed and -conducted multicenter RCT with narrow confidence intervals <p>Quality</p> <ul style="list-style-type: none"> Low risk of bias Adequate sample size and power No major methodological concerns <p>Consistency</p> <ul style="list-style-type: none"> For SR or MA, no major conflict in results (consider heterogeneity). If significant heterogeneity exists, drops to "Poor" For individual RCTs, no major conflict in results If major conflicts do exist, drops to "Insufficient" <p>Relevancy</p> <ul style="list-style-type: none"> No compelling reason not to generalize the published work to the target Kaiser Permanente (KP) population 	<p>Type and number of studies</p> <ul style="list-style-type: none"> At least one well-designed and -conducted SR or MA (consider heterogeneity) of cross-sectional studies using independent gold standard Two or more well-designed and -conducted cross-sectional studies using an independent gold standard <p>Quality</p> <ul style="list-style-type: none"> Low risk of (verification) bias Independent gold standard No major methodological concerns <p>Consistency</p> <ul style="list-style-type: none"> For SR or MA, no major conflict in results (consider heterogeneity) For individual studies, consistent diagnostic accuracy <p>Relevancy</p> <ul style="list-style-type: none"> No compelling reason not to generalize the published work to the target KP population 	<p>Type and number of studies</p> <ul style="list-style-type: none"> At least one well-designed and -conducted SR or MA (consider heterogeneity) of prospective cohort studies Two or more well-designed and -conducted prospective cohort studies <p>Quality</p> <ul style="list-style-type: none"> Low risk of bias Acceptable loss to follow-up (< 20%) No major methodological concerns <p>Consistency</p> <ul style="list-style-type: none"> For SR or MA, no major conflict in results (consider heterogeneity) For individual studies, consistent prognosis in similar populations <p>Relevancy</p> <ul style="list-style-type: none"> No compelling reason not to generalize the published work to the target KP population

* Evidence is graded with respect to the degree it supports the specific clinical recommendation. For example, there may be good evidence that Drugs 1 and 2 are effective for Condition A, but no evidence that Drug 1 is more effective than Drug 2. If the recommendation is to use either Drug 1 or 2, the evidence is good. If the recommendation is to use Drug 1 in preference to Drug 2, the evidence is insufficient.

Table 2: System for Grading the Strength of a Body of Evidence* Continued

Grade	Therapy/Prevention/Screening	Diagnosis	Prognosis
FAIR	<p>Type and number of studies</p> <ul style="list-style-type: none"> – Single well-designed and -conducted RCT with narrow confidence intervals – Two or more RCTs of lower quality – Well-designed and -conducted SR or MA of cohort studies (consider heterogeneity) – For screening interventions only, the following are also acceptable as Fair evidence: – Two or more well-designed and -conducted cohort studies – Two or more well-designed and -conducted case-control studies – Two or more well-designed and -conducted time series studies <p>Quality</p> <ul style="list-style-type: none"> – Minor methodological concerns <p>Consistency</p> <ul style="list-style-type: none"> – For SR or MA, no major conflict in results (consider heterogeneity) – For individual studies, no major conflict in results – If major conflicts do exist, drops to “Insufficient” <p>Relevancy</p> <ul style="list-style-type: none"> – No compelling reason not to generalize the published work to the target KP population 	<p>Type and number of studies</p> <ul style="list-style-type: none"> – Single well-designed and -conducted cross-sectional study – Two or more cross-sectional studies of lower quality – Well-designed and -conducted SR or MA of lower quality studies <p>Quality</p> <ul style="list-style-type: none"> – Minor methodological concerns – Independent gold standard <p>Consistency</p> <ul style="list-style-type: none"> – For SR or MA, no major conflict in results (consider heterogeneity) – For individual studies, no major conflict in results <p>Relevancy</p> <ul style="list-style-type: none"> – No compelling reason not to generalize the published work to the target KP population 	<p>Type and number of studies</p> <ul style="list-style-type: none"> – Single well-designed and -conducted prospective cohort study – Two or more prospective cohort studies of lower quality – Well-designed and -conducted SR or MA (consider heterogeneity) of either retrospective cohort studies or untreated control arms in RCTs <p>Quality</p> <ul style="list-style-type: none"> – Minor methodological concerns <p>Consistency</p> <ul style="list-style-type: none"> – For SR or MA, no major conflict in results (consider heterogeneity) – For individual studies, no major conflict in results <p>Relevancy</p> <ul style="list-style-type: none"> – No compelling reason not to generalize the published work to the target KP population

* Evidence is graded with respect to the degree it supports the specific clinical recommendation. For example, there may be good evidence that Drugs 1 and 2 are effective for Condition A, but no evidence that Drug 1 is more effective than Drug 2. If the recommendation is to use either Drug 1 or 2, the evidence is good. If the recommendation is to use Drug 1 in preference to Drug 2, the evidence is insufficient.



Table 2: System for Grading the Strength of a Body of Evidence* Continued

Grade	Therapy/Prevention/Screening	Diagnosis	Prognosis
<p>INSUFFICIENT</p> <p>NOTE: Any evidence that fails to meet criteria for GOOD or FAIR evidence is considered to be INSUFFICIENT. Examples of insufficient evidence are provided for the different criteria.</p>	<p>Type and number of studies</p> <ul style="list-style-type: none"> – Single RCT of lower quality or insufficient size – Cohort study <p>Quality</p> <ul style="list-style-type: none"> – Major methodological concerns (e.g., lack of concealed allocation, inadequate blinding, no intention-to-treat analysis) <p>Consistency</p> <ul style="list-style-type: none"> – Studies that are well-designed and -conducted (Good or Fair) but with major conflict in results – SR or MA with major conflict in results (consider heterogeneity) <p>Relevancy</p> <ul style="list-style-type: none"> – Compelling reasons why the results do not apply to the target KP population 	<p>Type and number of studies</p> <ul style="list-style-type: none"> – Single cross-sectional study of lower quality – Case-control study <p>Quality</p> <ul style="list-style-type: none"> – Major methodological concerns (nonconsecutive, poor or no independent gold standard) <p>Consistency</p> <ul style="list-style-type: none"> – Studies that are well-designed and -conducted (Good or Fair) but with major conflict in results <p>Relevancy</p> <ul style="list-style-type: none"> – Compelling reasons why the results do not apply to the target KP population 	<p>Type and number of studies</p> <ul style="list-style-type: none"> – Single prospective cohort study of lower quality – Retrospective cohort study – Untreated control arm of RCT – Case series <p>Quality</p> <ul style="list-style-type: none"> – Major design or methodological concerns (sampling bias, high dropout, nonblinded outcome assessment, lack of adjustment for confounders) <p>Consistency</p> <ul style="list-style-type: none"> – Studies that are well-designed and -conducted (Good or Fair) but with major conflict in results <p>Relevancy</p> <ul style="list-style-type: none"> – Compelling reasons why the results do not apply to the target KP population

* Evidence is graded with respect to the degree it supports the specific clinical recommendation. For example, there may be good evidence that Drugs 1 and 2 are effective for Condition A, but no evidence that Drug 1 is more effective than Drug 2. If the recommendation is to use either Drug 1 or 2, the evidence is good. If the recommendation is to use Drug 1 in preference to Drug 2, the evidence is insufficient.

References

1. Klein, Hurley, Merrill, Quesenberry, Consortium for HIV/AIDS Interregional Research, *JAIDS*, 2003;32(2):143-52
2. US Preventive Services Task Force. Screening for HIV: recommendation statement. *Annals of Internal Medicine* 2005;143:32-37.
3. Chou R, Korthuis PT, Huffman LH, Smits AK. Screening for human immunodeficiency virus in adolescents and adults. Evidence Synthesis No. 38. (Prepared by the Oregon Evidence-Based Practice Center under Contract No. 290-02-0024). Rockville, MD: Agency for Healthcare Research and Quality. July 2005. (Available on the AHRQ Web site at: www.ahrq.gov/clinic/serfiles.htm)
4. Chou R, Huffman LH, Fu R, et al. Screening for HIV: a review of the evidence for the U.S. Preventive Services Task Force. *Annals of Internal Medicine* 2005;143:55-73.
5. Chou R, Smits AK, Huffman LH, Korthuis PT. Prenatal screening for human immunodeficiency virus in pregnant women. Evidence Synthesis No. 39. (Prepared by the Oregon Evidence-Based Practice Center under Contract No. 290-02-0024). Rockville, MD: Agency for Healthcare Research and Quality. July 2005. (Available on the AHRQ Web site at: www.ahrq.gov/clinic/serfiles.htm)
6. Chou R, Smits A, Huffman LH, et al. Prenatal screening for HIV: a review of the evidence for the U.S. Preventive Services Task Force. *Annals of Internal Medicine* 2005;143:38-54.
7. Centers for Disease Control and Prevention. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *Morbidity and Mortality Weekly Report (MMWR)* September 22, 2006;55(RR-14):1-16.
8. Ammon L, Sterling S, Mertens J, Weisner C. Adolescents in private chemical dependency programs: who are most at risk for HIV? *Journal of Substance Abuse Treatment* 2005;29:39-45.
9. Centers for Disease Control and Prevention. Methamphetamine use and HIV risk behaviors among heterosexual men—preliminary results from five Northern California counties, December 2001-November 2003. *Morbidity and Mortality Weekly Report (MMWR)* March 17, 2006;55(10):273-277.
10. Avins AL, Woods WJ, Lindan CP, Hudes ES, Clark W, Hulley SB. HIV infection and risk behaviors among heterosexuals in alcohol treatment programs. *Journal of the American Medical Association* 1994;271:515-518.
11. Jacobson JM, Worner TM, Sacks HS, Lieber CS. Human immunodeficiency virus and hepatitis B virus infections in a New York City alcoholic population. *Journal of Studies on Alcohol* 1992;53:76-79.



12. Schleifer SJ, Keller SE, Franklin JE, LaFarge S, Miller SI. HIV seropositivity in inner-city alcoholics. *Hospital and Community Psychiatry* 1990;41:248-249, 254.
13. Kaiser Permanente. National Market Research Satisfaction Tracking and Reporting Program (STAR). Demographic Report on KP members: 1990 to present. Oakland, CA: Kaiser Permanente, 2000.