

U.S. Department of Veterans Affairs

# VA HIV Prevention Handbook

A Guide for Clinicians (2nd Edition)

**Office of Public Health** 

**Veterans Health Administration** 

### **VA HIV Prevention Handbook** A Guide for Clinicians (2nd Edition)

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# The VA HIV Prevention Handbook

A Guide for Clinicians (2<sup>nd</sup> Edition)

Office of Clinical Public Health Programs Veterans Health Administration

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# Foreword

by

Richard A. Kaslow, MD, MPH

In the three decades since HIV/AIDS was first recognized, the epidemic has taken more than 25 million lives worldwide. There is nevertheless good reason to be encouraged. Treatment regimens have become both simpler and increasingly effective, and the pace of vaccine development has been accelerating. Decisive implementation of strategies to diagnose, treat and prevent HIV infection has saved thousands of lives. With these kinds of advances it becomes just that much more realistic to envision an end to the epidemic.

In the Department of Veterans Affairs, through our more than 1,000 VHA health care facilities nationwide, we have the opportunity to provide state-of-the art care of HIV-infected individuals along with an array of evidence-based prevention measures. The VA has lately introduced routine HIV serologic screening, of which the primary goal is to test every Veteran at least once in his or her lifetime. With the second edition of the *VA HIV Prevention Handbook: A Guide for Clinicians*, the VA Office of Public Health is providing VHA clinicians in primary care and specialty care settings with guidance on approaches to prevention such as routine HIV testing and riskreduction counseling. The publication is a thoughtful distillation that documents more than 30 years of research and experience, focusing on individuals at risk for HIV infection as well as those living with the disease. VHA is the single largest provider of HIV/AIDS services in the United States. As such, we embrace the core public health commitment to HIV prevention through care and treatment. We know that thoughtful and honest exchanges between clinicians and patients can lead to healthier lives. Nowhere more than in the acts of HIV counseling, testing, treatment and prevention could those exchanges be more important. Hopefully, the *Handbook* will assist our many clinicians in incorporating HIV prevention into their patient encounters. Veterans and their families are counting on all of us to use this and every other resource available to make their lives healthier.

> Richard A. Kaslow Deputy Chief Officer, Office of Public Health VA Central Office Department of Veterans Affairs Washington, DC

## Introduction

Ι.

"The science is clear: HIV prevention can and does save lives.... But the HIV crisis in America is far from over....The future course of the U.S. HIV epidemic will be determined by the scale of our response, and by how effectively we utilize proven and emerging approaches to preventing HIV."<sup>1</sup>

---HIV Prevention in the United States: At a critical crossroads Centers for Disease Control and Prevention Thirty years after the start of the U.S. HIV/AIDS epidemic, the country is thought to be at an HIV prevention "crossroads."<sup>2,3</sup> While the United States has learned much over the last three decades, resulting in significant prevention and treatment progress, a staggering 50,000 new HIV infections in this country are estimated each year and one of five individuals living with HIV is unaware of their infection.<sup>4</sup>

How do we now use three decades of collective knowledge to reduce HIV incidence rates and provide top quality care to individuals living with HIV/AIDS? In 2010, the White House released its roadmap for this effort, the National HIV/AIDS Strategy for the United States (NHAS). The NHAS signaled the federal government's renewed commitment to HIV prevention and contains a number of targets for achievement by 2015 including:

- Lowering the annual number of new infections by 25% (from 56,300 to 42,225).
- Reducing the HIV transmission rate by 30% (from five persons infected per 100 people with HIV to three and a half persons infected per 100 people with HIV). The HIV transmission rate is a measure of annual transmissions in relation to the number of people living with HIV.
- Increasing the percentage of people living with HIV who know their serostatus from 79% to 90% (from 948,000 to 1.08 million people).<sup>5</sup>

### National HIV/AIDS Strategy for the United States' Vision Statement

The United States will become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity, or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination. In order to succeed, NHAS' targets cannot rely on any one entity for implementation. The effort requires an active, effective partnership involving multiple federal, state and local government agencies; community- and faith-based organizations; and entire communities. A key member of this partnership is the United States Department of Veterans Affairs (VA)—**the largest single provider of HIV/AIDS care in the country**. In 2010 alone, VA provided state-of-the-art HIV care and treatment to more than 24,000 HIV-infected Veterans through its Veterans Health Administration (VHA) facilities.

In 2002, VHA released The VA HIV Prevention Handbook: A Guide for Clinicians so VHA providers could better understand how to support HIV prevention among Veterans and link HIV-infected Veterans to care. This second edition of the VA HIV Prevention Handbook: A Guide for Clinicians reflects the dramatic prevention advances of the past 10 years. It provides guidance on implementing long-standing and more recently developed evidence-based interventions including routine HIV testing, patient counseling on high-risk transmission behaviors and prevention strategies (e.g., condom use), expeditious referrals of HIV-infected individuals to care and treatment, and support of patients' adherence to antiretroviral therapy (ART). These interventions are for use in VHA settings such as primary care facilities, mental health programs, substance use disorder (SUD) treatment programs, community-based outpatient clinics (CBOCs) and Vet Centers. The handbook also examines the anticipated next generation of HIV prevention interventions including pre-exposure prophylaxis (PrEP), non-occupational post-exposure prophylaxis (nPEP) and adult male circumcision.

One of the greatest changes reflected in this handbook is VA's 2009 adoption of HIV testing as a part of routine medical care requiring verbal, rather than written, consent. Until 2009, Federal law and regulations barred VHA from offering widespread HIV testing to Veterans in VHA care. In addition, VHA providers were required to obtain, in writing, informed consent for HIV testing and provide extensive scripted pre- and post-test counseling. Following Congressional repeal of these restrictions in late 2008, VA aligned its HIV testing policies with the 2006 HIV testing recommendations of the Centers for Disease Control and Prevention (CDC).

"It is VHA policy that HIV testing be a part of routine medical care; that providers routinely provide HIV testing to all Veterans (if they consent): and that those Veterans who test positive for HIV infection are referred to state-of-the-art HIV treatment, prevention of complications, and care of related conditions, including mental health needs, as soon as possible after diagnosis."

> — Testing for Human Immunodeficiency Virus in Veterans Health Administration Facilities [VHA Directive 2009-036, August 2009]

### HIV Prevention Works<sup>7,8</sup>

Thirty years of prevention efforts in the United States have contributed to a dramatic reduction in HIV transmission. It is estimated that these efforts, from the beginning of the epidemic in 1981 to 2006, have averted more than 360,000 HIV infections in this country.<sup>9</sup> Evidence-based prevention interventions crucial to this success are:

- **HIV testing:** Among people who test HIV positive, the majority modify their behavior to avoid transmitting the virus to others.<sup>10</sup> An HIV positive test also often triggers entry into HIV care and treatment.
- **HIV treatment:** Research has demonstrated that people living with HIV/AIDS who are on ART and experience a drop in viral load are less likely to transmit the virus to others.<sup>11,12,13</sup>
- **Condoms:** Use of this barrier method greatly reduces HIV transmission risk.<sup>14</sup>

- Targeted prevention programming for at-risk individuals: A multitude of HIV prevention programs aimed to meet the needs of specific individuals and communities have shown that at-risk behaviors can be reduced.<sup>15</sup>
- Prevention with positives: Evidence-based behavioral interventions can increase quality of life, increase treatment adherence, and reduce substance use and sexual risk behaviors among people living with HIV.<sup>16</sup>
- Screening and treating for sexually transmitted infections: People diagnosed with sexually transmitted infections (STIs) are at higher risk for contracting HIV through sexual contact. Concurrent STIs in an HIV-infected individual may increase shedding of HIV in the genital tract.<sup>17</sup> Testing for and treating STIs can reduce an individual's risk of HIV transmission.<sup>18</sup>
- Substance use disorder (SUD) treatment and needle exchange programs: Access to SUD treatment and needle exchange programs can result in changes in risky sexual behaviors and decrease the number of HIV infections among individuals who inject drugs.<sup>19,20</sup>
- **Partner notification services:** Assisting people who may not know they were exposed to HIV helps connect them to HIV testing and if necessary, treatment and care.<sup>21,22</sup>
- **Referrals for support services:** Referrals to vital support services such as HIV case management, mental health counseling and housing assistance can positively affect health care utilization and medication adherence.<sup>23,24,25</sup>

ΙΙ.

# The U.S. HIV/AIDS Epidemic

The HIV Epidemic Among the U.S. General Population and Veterans in the VHA System

## The U.S. HIV/AIDS Epidemic

### Statistics

- Approximately 1.2 million people are living with HIV infection<sup>26</sup>
- More than 50,000 people become infected with HIV each year<sup>27</sup>
- In 2009, more than 13,400 people with AIDS died<sup>28</sup>
- Men who have sex with men<sup>\*</sup> (MSM) represent the majority of people living with HIV (48%) and accounted for more than 61% of new infections in 2009<sup>29</sup>
- In 2007, new HIV diagnoses among MSM were 44-86 times that of other men and 40-77 times that of women<sup>30</sup>
- Approximately one in 16 African American men and one in 32 African American women will be diagnosed with HIV<sup>31</sup>
- Nearly 60% of women living at year-end 2009 with HIV were African American<sup>32</sup>
- In 2009, new HIV infections among Hispanic men were
   2.5 times that of Caucasian men and nearly 4.5 times higher in Hispanic women compared to Caucasian women<sup>33</sup>
- In 2009, an estimated 9% of new HIV infections were attributed to injection drug use<sup>34</sup>
- By year-end 2009, the largest percentage of people living with HIV were between the ages of 45-49 (20%)<sup>35</sup>
- It is estimated that by 2015, 50% of individuals living with HIV will be 50 years of age or older<sup>36</sup>

<sup>\*</sup> In this publication, the term "men who have sex with men" encompasses gay men, bisexual men, and men who do not place themselves in either of these categories, but engage in sex with other men.

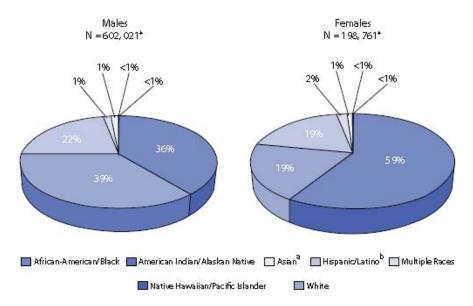
#### THE U.S. HIV/AIDS EPIDEMIC

In 1981, a report was published that marked the start of the HIV epidemic in this country.<sup>37</sup> The report described five cases of Pneumocystis carinii pneumonia<sup>†</sup>, an infectious disease unfamiliar to most clinicians at that time, among homosexual men in Los Angeles. Worldwide nearly 30 million people have died in the HIV/AIDS pandemic<sup>38</sup>; and in the United States alone, nearly 594,500 individuals.<sup>39</sup> Alarmingly, one in five people living with HIV in the United States is unaware of their infection.<sup>40</sup>

The U.S. HIV epidemic continues to have a disproportionate effect on MSM and communities of color.<sup>41</sup> MSM are the only group of individuals in this country who are experiencing a rise in the number infected.<sup>42</sup> In 2009, 68% of males living with HIV in the United States were infected through male-to-male sexual contact.<sup>43</sup> African Americans represented 42% of all people living with HIV and 44% of new HIV infections in 2009, yet constitute just 14% of the U.S. population.<sup>44</sup>

<sup>†</sup> Now referred to as Pneumocystic jiroveci pneumonia.

### Adults and Adolescents Living with a Diagnosis of HIV Infection, by Sex and Race/Ethnicity, Year – end 2009 — 46 States and 5 U.S. Dependent Areas



*Note.* Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

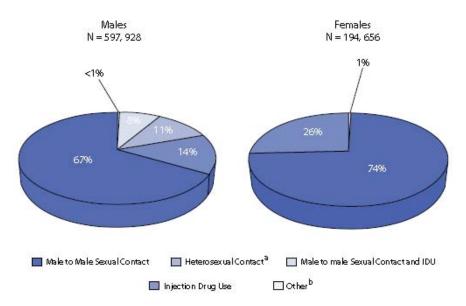
<sup>a</sup> Includes Asian/Pacific islander legacy cases.

<sup>b</sup> Hispanics/Latinos can be of any race.

\* Total males include 584 persons and total females include 184 persons with unknown race/ethnicity

*Note.* From the Centers for Disease Control and Prevention. HIV surveillance - Epidemiology of HIV infection. Retrieved from <u>http://www.</u> <u>cdc.gov/hiv/topics/surveillance/resources/slides/general/slides/general\_18.pdf</u>

### Adults and Adolescents Living with a Diagnosis of HIV Infection, by Sex and Transmission Category, Year – end 2009 — 46 States and 5 U.S. Dependent Areas



*Note.* Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

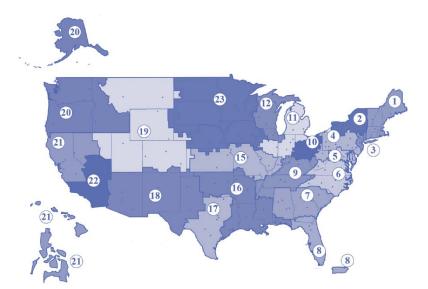
<sup>a</sup> Heterosexual contact with a person known to have, or to be at high risk, for HIV infection. <sup>b</sup> Includes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.

*Note*. From the Centers for Disease Control and Prevention. HIV surveillance - Epidemiology of HIV infection. Retrieved from <u>http://www.cdc.gov/hiv/topics/</u> <u>surveillance/resources/slides/general/slides/general\_19.pdf</u>

### The VHA System and HIV-Infected Veterans in Care

VHA is divided into 21 geographic regions called VISNs (Veterans Integrated Service Networks), each of which encompasses a number of local VA health care systems. These systems include more than 1,100 facilities consisting of medical centers; CBOCs; domiciliaries; extended care facilities; hospices; and specialty centers for mental health, blind rehabilitation, spinal cord injury, polytrauma, and traumatic brain injury.<sup>45</sup>

In federal FY2010, 5.8 million (70%) of the 8.3. million VHA enrollees received care at VHA facilities. VHA nursing homes had an average daily census of 34,001 and more than 75 million outpatient visits were provided; 16.5 million of which were in CBOCs.<sup>46</sup>



### Figure 1. VHA VISN Map

### THE U.S. HIV/AIDS EPIDEMIC

The VHA is the largest, single provider of HIV/AIDS care in the United States. To date, nearly 65,000 Veterans with HIV have received care through VHA. In 2010 VHA clinicians saw more than 24,000 HIV-infected Veterans—their health care delivered in every one of the 21 VISNs. Approximately one in every 240 Veterans in VHA care is living with HIV/AIDS. The number of HIV-infected Veterans in care has been relatively stable over the past five years with approximately 9% entering VHA care and approximately 9% leaving (including deaths) in a given year.<sup>47</sup> VISN HIV caseloads range from 338 to 3,225 Veterans.

Using the HIV Clinical Case Registry (CCR), which draws data from VHA's Computerized Patient Record System (CPRS), VHA captures both clinical and demographic data on HIV-infected Veterans and uses these data to examine the health status of HIV-infected Veterans and quality of care these Veterans receive through VHA. During 2008, HIV-infected Veterans accounted for more than 8,800 inpatient discharges, 708,000 outpatient visits, and 1.6 million filled prescriptions. These Veterans were overwhelmingly male (97%) and 64% were between the ages of 50 and 69. The majority was African American (47%) while 39% were White and 7% were ethnically Hispanic.<sup>‡</sup> Approximately 20% of HIV-infected Veterans who received VHA care in 2008 had co-morbid conditions: the majority of these Veterans received a diagnosis of either alcohol use or illicit drug use or depression, 64% and 51% respectively.

Unique to HIV-infected Veterans receiving VHA care was the percentage 50+ years of age—68%<sup>48</sup>compared to approximately 30% living with HIV in the U.S. general population.<sup>49</sup> This demographic is significant because older individuals are less likely to be HIV tested and when infected, often experience a different disease progression. In a study of older individuals (50+) with HIV, more than half were simultaneously diagnosed with AIDS or received an AIDS diagnosis

**<sup>‡</sup>** Because the provision of racial and ethnic identifiers by Veterans is voluntary, race and ethnicity data is not available for all patients in the CCR.

within one year of their HIV diagnosis.<sup>50</sup> So at the time of their diagnosis, many older adults are at a more advanced stage of the disease. Older adults with HIV are also likely to have non-HIV related health conditions that can complicate their treatment.

This disproportionate percentage of older Veterans living with HIV has been consistent for some time, but may begin to shift as Veterans from Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) enter the VHA system. Since 2002, 42% (approximately 400,000) of OEF/OIF/OND Veterans eligible for VHA care have been engaged in such care<sup>51</sup> making the VA the largest single provider of their health care.<sup>52</sup>

Currently, all FDA-approved HIV antiretroviral medications are included on the VA National Formulary, meaning these medications are available and must be provided by VA Medical Centers. During 2008, 92% of HIV-infected Veterans were prescribed antiretroviral medication, reflecting a treatment rate of 89-95% across all VISNs. Of Veterans living with HIV/AIDS who received VHA care in 2010, 77% had undetectable HIV viral loads and of the Veterans with CD4 counts under 350, 94% were on antiretroviral medication.

## VHA Standard of Care for Veterans Living with HIV/AIDS

Any Veteran eligible for VHA care<sup>§</sup> who discovers they are HIV infected (whether through VHA or non-VHA testing) will receive a standard of care based on the guidelines and recommendations put forth by the country's premiere public health agencies and organizations. VHA stands at the forefront of HIV care and treatment through its meticulous monitoring and implementation of treatment protocols

<sup>§</sup> Individuals who receive a dishonorable discharge are ineligible for VHA services.

for HIV-infected individuals. Under VA policy, VHA HIV providers follow the U.S. Department of Health and Human Services (DHHS) treatment guidelines, thereby ensuring the delivery of high-quality comprehensive HIV care to all Veterans who seek it.

## The VHA HIV Clinical Case Registry: Data Collection and Uses

Established in 2001 and re-engineered in 2006, the CCR is populated with data drawn from the VHA CPRS, with manual confirmation of individual patients in the CCR by local registry coordinators at all VHA facilities. These coordinators review the medical records of Veterans with laboratory results and/or diagnosis codes reflecting potential infection with HIV and confirm their addition to the local CCR if the condition is actually present.<sup>53</sup>

CCR data and resulting reports serve as a rich source of information on Veterans seeking VHA HIV care. This information includes their immune-suppression conditions; their health trajectory as it relates to the use of ART; and commonly experienced co-morbid conditions. The CCR does not contain data on the HIV transmission categories (e.g., heterosexual sexual contact, male-to-male sexual contact, injection drug use) of individuals in the registry.

Local CCR coordinators, as well as other designated facility staff, can access local CCR reports containing data specific to their facility or at the VISN level. These data illuminate HIV care and treatment within a facility or VISN and offer valuable information that can be used in practice, such as:

 Measuring patient volume and health care utilization to inform decisions about how care is delivered, allocation of staff and other resources

- Using patient demographic characteristics and co-morbidities to assess types of services likely to be required, such as treatment for age-related issues, chronic conditions, and mental health or SUD treatment needs
- Assessing quality measures such as adherence to national guideline recommendations, including receipt of appropriate prophylactic medications, and monitoring CD4+ lymphocyte count and HIV viral load levels
- Identifying trends over time, such as trends in uptake or monitoring of a specific medication or other treatment
- Measuring treatment outcomes and effectiveness of current practices, protocols or guidelines
- Performing ongoing comparisons across VISNs or health care systems of like size to identify rates of variation that may indicate quality issues or opportunities for improvement<sup>54</sup>

Each VISN's or facility's CCR coordinator can answer questions regarding available data. Access <u>http://vaww.publichealth.va.gov/docs/</u> <u>quality/CCR HIV Coordinators.pdf</u> for CCR coordinator information and <u>http://vaww.hiv.va.gov</u><sup>1</sup> for data on current HIV demographics and selected quality measures.

<sup>¶</sup> Both of these resources are accessible only through a computer connected to the VA network.

## |||.

# Primary and Secondary HIV Prevention Interventions

HIV epidemiology and surveillance data have clearly demonstrated that an effective response to the U.S. epidemic must target not only HIV-negative individuals (known as primary prevention), but also the more than one million individuals in this country living with the disease (an approach known as secondary prevention or prevention with positives). Each new infection begins with a single HIV-infected person thereby making a combination of secondary and primary prevention our best strategy for reducing the number of new infections.

While the first 25 years of the U.S. epidemic heavily focused on keeping people who were not HIV infected from becoming so,<sup>55</sup> there are now a number of both primary and secondary HIV prevention interventions available. Health care providers and specialists can use these interventions in venues that include primary care clinics, HIV clinics, community-based health centers, hospitals, SUD treatment programs, mental health programs, correctional facilities, homeless shelters, and needle exchange programs. Understanding how to integrate these interventions into your work will result in more Veterans learning their HIV status and for those who test positive, accessing care and treatment and reducing high-risk behaviors.

High-risk HIV transmission behaviors include sexual activities and substance use, topics sometimes difficult to broach with patients. The trust you have developed with your patients will serve as the foundation for these discussions and foster an environment where personal, health-related issues can be explored.

Some providers find it difficult to discuss these topics with patients unless the patient brings them up. These providers may feel such questions are too personal, that they do not know how to ask the questions, and that they do not know how to handle "awkward silences" that may occur during discussions. If you find that, as a provider, you are uncomfortable discussing these topics with your patients and are not sure how to respond to patient reactions, talk to your colleagues about their techniques and seek professional development opportunities addressing provider-patient communications.

This chapter details the following primary and secondary HIV prevention interventions for use in VHA settings:

Interventions Targeted Individuals		iduals
	HIV negative	HIV infected
Routine HIV testing	$\checkmark$	
Facilitation and support	$\checkmark$	$\checkmark$
of changes in high-risk		
transmission behaviors		
Condom use	$\checkmark$	$\checkmark$
Antiretroviral therapy and		$\checkmark$
adherence support		
Sexually transmitted infection		$\checkmark$
testing and treatment		
HIV partner notification services	$\checkmark$	$\checkmark$
Referrals for support services	$\checkmark$	$\checkmark$
including SUD treatment and		
mental health treatment		
Reproductive health care	$\checkmark$	$\checkmark$
for women		

## **Routine HIV Testing**

Interventions Targeted Individuals		iduals
	HIV negative	HIV infected
Routine HIV testing	$\checkmark$	

HIV testing is central to the goal of reducing the number of new infections in the United States.<sup>56,57</sup> Following recommendations issued by CDC, VA demonstrated strong support of non-risk based HIV testing when in 2009 it changed its policy to one of testing as a routine part of medical care with voluntary verbal consent. An individual who knows they are HIV infected will often make changes to their sexual and/or substance use behaviors<sup>58,59,60</sup> and connect with HIV care and treatment, which has been shown to increase their longevity and quality of life. For full details on this critical intervention and guidance on its implementation, please see Chapter IV.

## Facilitation and Support of Changes in High-Risk Transmission Behaviors

Interventions	Targeted Individuals	
	HIV negative	HIV infected
Facilitation and support	$\checkmark$	$\checkmark$
of changes in high-risk		
transmission behaviors		

# Why are activities that facilitate and support changes in high-risk transmission behaviors an effective HIV prevention intervention?

Risk-reduction interventions encourage individuals to make healthful behavioral changes that will reduce their risk for HIV transmission.

### PRIMARY AND SECONDARY HIV PREVENTION INTERVENTIONS

Such interventions, especially when used with HIV-infected individuals<sup>61</sup>, have been found to reduce sexual- and drug-use risk behaviors.<sup>62,63,64</sup> In its Compendium of Evidence-Based HIV Behavioral Interventions, CDC recognized more than 70 behavior-based HIV risk-reduction interventions targeting both HIV negative and infected individuals.<sup>65</sup> These interventions, representing the best available, engage individuals in activities where vital prevention knowledge and skills are gained, such as:

- The benefits of knowing one's HIV serostatus
- How to reduce one's number of sex partners
- Correct use of condoms
- Condom use negotiation
- How to access clean needles
- How to identify sources of support for behavioral change
- · How to develop coping strategies
- HIV facts vs. misconceptions

Behavioral interventions are most effective when they are highly interactive; involve providers with adequate skills, knowledge, and empathy; theory based; and tailored to fit the individual's situation.<sup>66</sup>

### How do I implement this type of intervention?

During patient appointments:

- Recommend HIV testing to all patients whose serostatus is undocumented in CPRS
- Take a patient's sexual health and substance-use histories as a part of routine practice
- Engage patients in discussions on their desire and ability to change high-risk behaviors and support these changes

### **Recommend HIV Testing**

Guidance on recommending HIV testing to all patients and test administration is found in Chapter IV.

# Take Sexual Health and Substance-use Histories as Part of Routine Practice

A patient's sexual health and substance-use histories are part of their comprehensive medical profile and also provide valuable information for guiding discussions on high-risk behaviors. Because patients may be inexperienced and uncomfortable providing this information, it is vital to explain that you ask for this health information from all your patients and that knowing about all areas of their health allows you to provide them with the best possible care.

To elicit information on your patient's sexual health, including their risk for HIV and STIs, you can use the following questions.

- "I want to ask you some questions about your sexual health so I can provide you with the best care available. Is that okay with you?"
- 2. "Are you currently having or have you ever had sexual intercourse?"
- 3. "Have you recently had any new partners or sexual contacts?"
- 4. "If having sexual intercourse, is it with men or women or both?"
- 5. "Do you protect yourself from STIs every time you have sex?"
- "How do you protect yourself from pregnancy and STIs, including HIV?"
- 7. "Have you ever been diagnosed with a STI?"
- 8. "Would you like to be screened for STIs?"
- "Do you need contraception or are you planning on becoming pregnant?"

- 10. "Are you currently experiencing or have you experienced sexual abuse?"
- 11. "What questions can I answer for you regarding HIV transmission through sexual contact?"

An additional sexual health questionnaire is found in *Appendix A*. Below is a brief set of questions on substance use you can use with your patients. Should you need to probe for further information on their substance use, *Appendix B* contains assessment instruments.

During the past 6 months...

- "Have you used alcohol or other drugs? (Such as wine, beer, hard liquor, pot, coke, heroin or other opiates, uppers, downers, hallucinogens, or inhalants.) (yes/no)"
- "Have you felt that you use too much alcohol or other drugs? (yes/no)"
- "Have you tried to cut down or quit drinking or using drugs? (yes/no)"

Now I have a question that is not limited to the past 6 months...

 "Do you feel that you have a drinking or drug problem now? (yes/no)"

"Thanks for answering these questions. Do you have any questions for me? Is there something I can do to help you?"<sup>67</sup>

# Engage Patients in Discussions on Making Behavioral Changes and Support Such Changes

Help the patient identify risky behaviors and target these behaviors for discussions.<sup>68</sup> Many people may not want, or may not be willing, to adopt behaviors that entirely eliminate their risk of HIV transmission. For most individuals, the goal is to move from riskier activities to less-risky activities. Patients may do this in increments, with support, as they are ready and able. Keep in mind some patients have a low level of HIV knowledge, so providing them with basic HIV information (found in *Appendix C*) can help them identify personal behaviors they can change.

Provider-patient discussions should be non-judgmental, tailored to the patient, and move them along a continuum toward behavioral changes such as:

- Consistent and constant condom use
- Reducing one's number of sex partners
- Finding out one's HIV status
- Seeking STI testing
- Entering a SUD treatment program
- Consistent use of new needles

When asking your patients the questions on the pages 21-22, they may want to know why you are bringing up these topics and what you, as their provider, will do with the information they provide. It is important to let them know that your goal is to provide them with comprehensive health care based on the most current medical recommendations. In order to do this, you need to know about behaviors related to their health so that you can assist them in making healthy decisions. You can address their concerns about confidentially by telling them about VA confidentiality regulations that protect patient health information and how certain information would appear in their medical record (e.g., a notation that they are sexually active, but not the gender of their partner(s)).

# Examples of scripted dialogue for risk-reduction counseling related to sexual transmission

The following are examples of questions that a clinician might use when assessing risk in different situations. Many of the follow-up questions will lead smoothly into individualized risk-reduction counseling. Some questions are closed-ended, allowing for yes/no or brief answers. Open-ended questions allow for more information to be reported. Motivational interviewing, among other principles, relies on asking open-ended questions to achieve a more complete understanding of the patient's situation. Motivational interviewing then assesses importance and confidence to achieve safer behaviors.

Examples of closed-ended	<ul> <li>Are you having sex?</li> </ul>
questions that can be used as "openers"	• Do you presently have a sex partner?
	<ul> <li>How often do you have sex?</li> </ul>
Motivational interviewing	• Tell me a little about your sex life
approach	and how safer sex fits into it.
	• What sex and drug use behaviors are you currently involved in? How might you be able to reduce the riskiness of these behaviors? On a scale of 1 to 10, how important is reducing risk behavior to you? On a scale of 1 to 10, how confident are you that you can do it? (After the patient gives their initial rating, follow up with questions such as "Why is it a three and not a one?" and "What would it take to bump it up to a four or five?" The conversation taking place after the rating is key to the provider-patient exchange, not the rating number per se.

Examples of scripted dialogue for risk-reduction counseling related to sexual transmission		
If the clinician knows that the patient is involved in a committed relationship, he/she might open the discussion with:	<ul> <li>Tell me a little about your relationship. (However, the clinician needs to be careful to not just ask about the relationship, because then the patient may not reveal information about casual sexual encounters that may have occurred outside of the relationship.)</li> </ul>	
For patients who say that they are not currently sexually active:	<ul> <li>Closed-ended questions: <ul> <li>In the next few months, do you expect that you will have sex?</li> <li>If you change your mind, will condoms be a part of your sex life? How do you plan to protect yourself and your partner(s)?</li> </ul> </li> <li>Open-ended question: <ul> <li>It is common for people who are not currently sexually active to become sexually active to become sexually active again. How do you plan to protect yourself and your partner(s)?</li> </ul> </li> </ul>	

# Examples of scripted dialogue for risk-reduction counseling related to sexual transmission

For patients who report using condoms, the clinician might follow up with these open-ended questions:	<ul> <li>Many people are using protection for intercourse but not so much for oral sex. How do you handle that? (If the patient then reports not using condoms for oral sex, the clinician may ask whether he/she avoids exposure to ejaculate during oral sex. A discussion of relative risks should occur.)</li> <li>Some people will use protection most of the time but occasionally slip. Are there ever times when you don't use protection? (If a patient confides that his/ her partner does not want to use protection, the clinician should follow with a discussion about why that might be and try to empower the infected partner to insist on protecting the other one. An offer to refer the couple for counseling should occur.)</li> </ul>
For patients who are engaging in anal intercourse, the clinician might follow up with the following closed-ended question:	<ul> <li>Do you engage in insertive anal, receptive anal, or both (top, bottom, or both)?</li> <li>(A discussion of the differential risks should occur.)</li> </ul>

Examples of scripted dialogue for risk-reduction counseling related to sexual transmission			
	your safer sex practices may change if or when you are in a relationship that has the prospect of		
	<ul> <li>becoming serious.</li> <li>What kind of situations and partner (characteristics and type) might tempt you to have risky sex? On a scale of 1 to 10, how important is reducing risk behavior to you? On a scale of 1 to 10, how confident are you that you can do it?</li> </ul>		

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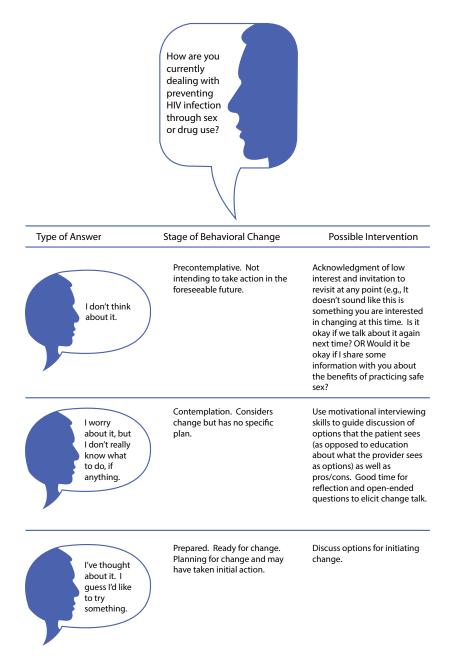
Examples of scripted dialogue for risk-reduction counseling related to sexual transmission			
To ascertain the role of drugs/alcohol in sexual risk-taking, some closed-ended questions can be asked:	<ul> <li>Closed-ended questions: <ul> <li>Have you ever had risky sex while drunk or high? If patient answers yes to question, ask:</li> <li>Why do you think you took the risk?</li> <li>Do you mix alcohol or drugs with sex occasionally?</li> </ul> </li> <li>Open-ended questions: <ul> <li>Tell \me about your ability to practice safer sex when you drink or use drugs. What are your thoughts about trying to reduce your use of drugs and alcohol before and during sex?</li> <li>Tell me about the drugs you tend to use before or during sex.</li> <li>How does alcohol or drugs change sex?</li> <li>What problems might be created by using alcohol or drugs before or during sex?</li> </ul> </li> </ul>		
After assessment and risk-reduction counseling has occurred, the clinician might choose to conclude with something along the lines of:	I've given you quite a bit of information here, and, at this point, I wonder what you make of all this and what you're thinking. On a scale of 1 to 10, how important is reducing risk behavior to you? On a scale of 1 to 10, how confident are you that you can do it?		

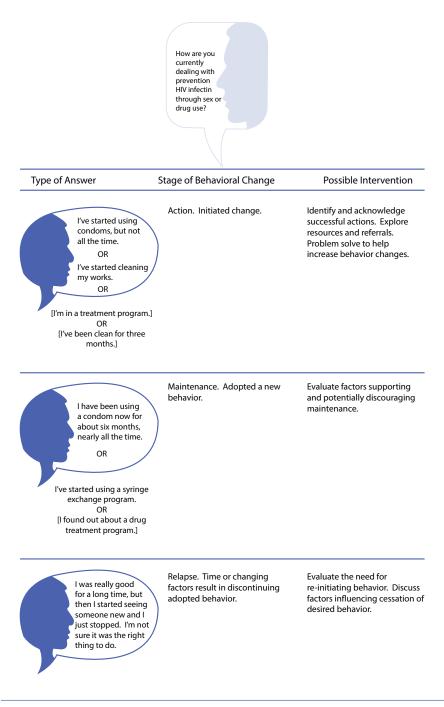
*Note*. Copyright<sup>©</sup> New York State Department of Health AIDS Institute, 2000-2011.<sup>69</sup>

Understanding a person's readiness (their stage of change) in their desire and ability to change a behavior will help you develop discussions and support strategies.

Using the question "How are you currently dealing with preventing HIV infection through sex or drug use?" as an example, the chart on the page 30 illustrates statements patients may make and strategies that may prove useful. This chart is based on the Transtheoretical Model of the Stages of Change (described in detail in *Appendix D*), a frequently used model in HIV prevention interventions.

# Figure 2. Based on the Transtheoretical Model of the Stage of Change





### **Understand Behavioral Change Theories and Models**

Understanding the theoretical basis of behavioral interventions will help you identify effective elements and ways these theories can guide provider-patient discussions and behavioral changes in the patient. Two frequently-used theoretical models used in HIV prevention interventions are motivational interviewing and the Transtheoretical Model of the Stages of Change Theory. For detailed information on these models and their use as well as examples of HIV prevention behavioral interventions see *Appendices D and E*.

## Condom Use

Intervention	Targeted Individuals	
	HIV negative	HIV infected
Condom use	$\checkmark$	$\checkmark$

#### Why is condom use an effective HIV prevention intervention?

In 2010, 88% of individuals diagnosed with HIV became infected through sexual contact.<sup>70</sup> Condoms, particularly male condoms, when used consistently and correctly are highly effective in preventing HIV transmission through sexual contact.<sup>71,72</sup> In a review on the use of condoms to prevent HIV transmission in serodiscordant couples, it was concluded that consistent condom use resulted in an 80% reduction in HIV incidence.<sup>73</sup> Condoms also play an important role in preventing transmission of STIs such as Chlamydia urethritis, gonorrhea, and trichomoniasis.<sup>74</sup>

#### How can I implement this intervention?

During patient appointments:

 Recommend HIV testing to all patients whose serostatus is undocumented in CPRS

- Take a patient's sexual history, including questions about condom use, and help them understand their risk for HIV transmission
- Provide patients with a prescription for condoms or access to free condoms
- Provide patients with guidance on condom use and negotiation skills

#### **Recommend HIV Testing**

Guidance on recommending HIV testing to all patients and test administration is found in Chapter IV.

#### Take a Sexual History

Taking a patient's sexual history (see pages 21-23 and *Appendix A* for sample sexual history questions), gives you an opportunity to learn about their risk for HIV, understand contextual factors that may contribute to sexual risk-taking behaviors, discuss HIV transmission risk, and stress the effectiveness of condoms. Condom-related questions that can be woven into the sexual history include:

- During what types of sexual contact do you use a condom?
- How do you determine which partners you will use a condom with?
- Are you more likely to use a condom with one partner than with another?
- What types of condoms do you use (e.g., latex, natural membrane, lubricated) and when do you use lubricant?
- If you are under the influence of alcohol and/or drugs, do you find yourself less likely to use a condom?

#### **Provide Patients with Access to Condoms**

Condoms should be made available to all Veterans and are listed on the VHA National Formulary. Patients can obtain condoms by prescription<sup>\*\*</sup> and there is no co-pay for VHA-prescribed condoms. Ideally, free condoms, sometimes made available to VHA clinics by local and state health departments, should be available to all patients and easily accessible (e.g., in a container in an examination room and clearly marked "free for patients").

VHA recommends that all patients with HIV routinely be asked if they wish to receive a prescription for condoms (VHA IL 10-2001-012: Access to Condoms as HIV Prevention). In addition, condom use and the need for such a prescription should be routinely discussed with patients who:

- have been diagnosed with an STI,
- have a history of injection drug use or substance use,
- have tested positive for hepatitis C or B, and/or
- have requested pharmacologic or other treatments for impotency or erectile dysfunction.

Patients receiving a condom prescription should be asked their preference for male or female condoms, or lubricated or non-lubricated condoms. If choosing non-lubricated condoms, remind them that water-based lubricant is recommended with condom use as it reduces the chance of condom breakage and tears occurring within the vagina and anus, which can lead to HIV and STI transmission.

At this time, CDC recommends condoms lubricated with the spermicide nonoxynol-9 not be used as a part of HIV and STI prevention.<sup>75</sup> Research has concluded that nonoxynol-9 is ineffective

<sup>\*\*</sup> VHA categorizes condoms as a medical supply and they should be ordered as such.

against HIV transmission and it may in fact cause vaginal irritation and damage to the lining of the rectum, which may facilitate HIV transmission.<sup>76</sup> See Table 1. for further condom information.

#### **Table 1. Condom Types and Properties**

Condom Types	Properties	
Latex	<ul> <li>Barrier protection against HIV</li> </ul>	
Polyurethane	<ul> <li>Efficacy in preventing HIV transmission likely to be similar to latex condoms (limited number of efficacy studies to date)</li> <li>More expensive</li> <li>Alternative for latex allergy</li> <li>Conducts heat</li> </ul>	
Female	<ul> <li>Efficacy in preventing HIV transmission estimated to be equivalent to, or slightly less than, the male condom (limited number of efficacy studies to date)</li> <li>Allows for direct control by the woman, especially in situations where a partner is not willing to use a condom</li> <li>Covers both internal and external genitalia</li> </ul>	
Lubricated with nonoxynol-9	<ul> <li>Avoid using condoms lubricated with nonoxynol-9; nonoxynol-9 may cause vaginal irritation, which may enhance transmission</li> </ul>	
Lambskin	Does not protect against HIV transmission (microscopic pores allow transfer of HIV virions, but not bacterial STI pathogens)	

*Note.* Copyright<sup>®</sup> New York State Department of Health AIDS Institute, 2000-2011.<sup>77</sup>

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#### Guidance on Condom Use and Negotiation Skills

Consistent condom use is supported by condom availability, condom-use skills, and a partner (male or female) who agrees to its use. Condom usage and negotiation guidance (found in *Appendices F and G*) should be given to anyone who receives a condom prescription and placed near free condoms.

## Antiretroviral Therapy (ART) and Adherence Support

Intervention	Targeted Individuals	
	HIV negative	HIV infected
Antiretroviral therapy (ART) and		$\checkmark$
adherence support		

# Why are ART and adherence support effective HIV prevention interventions?

The use of ART has created an unequivocally positive health shift for millions of people living with HIV/AIDS. It has drastically changed the progression of the disease and the quality of life for many individuals. HIV's shift from an acute illness to a chronic disease,<sup>78</sup> largely due to ART, has meant that many HIV-infected individuals are living healthier and longer lives.

ART can reduce an individual's HIV viral load, making them less susceptible to opportunistic infections and significantly reducing the risk of transmitting the virus to others. Findings from the NIH-sponsored clinical trial HPTN 052 involving mainly serodiscordant heterosexual couples, found that initiating ART in individuals with "relatively healthy immune systems" resulted in a 96% reduction in HIV transmission to the uninfected partner.<sup>79,80</sup> In this study ART was given immediately to the HIV-infected partner or delayed until their peripheral blood CD4 cell count was <250/µl. Among the 39 new infections observed, 28 were associated with virus from the infected partner and 27 of these transmissions occurred in those not receiving ART.<sup>81</sup> It does remain important to explain to patients that although a person may have an undetectable HIV load, they can still transmit the virus. Therefore, condom use should be promoted for serodiscordant couples.

ART's role in reducing perinatal (mother-to-child) HIV transmission has proven to be one of the most successful HIV prevention interventions of the last 15 years. ART used in conjunction with universal testing of pregnant women, scheduled cesareans when indicated, and avoidance of breastfeeding, can result in an HIV transmission rate of less than 2%.<sup>82</sup>

Adherence to ART gives the medication its best chance at suppressing an individual's HIV viral load.

Adherence can prove challenging due to psychological issues faced by patients, the complexity of ART regimens, one's ability to take medication, medication side effects, and patient literacy.<sup>83</sup> As with other medications, patient adherence to ART may not be 100%, yet an ART adherence rate of 95% or better is considered the standard for optimizing virologic outcomes.<sup>84</sup> The most commonly reported reason for nonadherence to HIV medication (defined as missing doses) is patient forgetfulness.<sup>85</sup>

#### How can I implement these interventions?

During patient appointments:

- Recommend HIV testing to all patients whose serostatus is undocumented in CPRS
- Expeditiously refer HIV-infected patients to care and treatment
- Support ART adherence by suggesting methods to improve adherence

#### **Recommend HIV Testing**

For individuals unaware of their HIV status, a positive test result can hasten their entry into care and treatment, which may involve ART. Guidance on recommending HIV testing to all patients and test administration is found in Chapter IV.

#### **Refer Patients to HIV Care and Treatment**

Veterans who test positive for HIV infection "must be expeditiously referred for ongoing HIV-related care..."<sup>86</sup> Early access to care can result in the initiation of ART at the optimal time and thus improve their survival.<sup>87</sup> Every VA Medical Center is required to have an HIV lead clinician who can provide practical guidance on linkage to care. Contact your facility's leadership for information on its HIV lead clinician. See Chapter IV for further details on Veterans who test positive for HIV.

#### Support ART Adherence

To help your patients correctly take their medication, let them know about tools aiding adherence. You can provide them with pillboxes and direct them to resources such as medication reminder tools (<u>www.epill.com</u>) and programs offering emailed or texted medication reminders (<u>https://secure.medactionplan.com/mymedschedule/</u>). A variety of pill organizers are available through VA pharmacies without co-pay. Veterans with visual impairments are eligible for ScripTalk<sup>®</sup> Talking Prescription labels.

Another way to support adherence is through the implementation of an intervention such as The Partnership for Health - Medication Adherence intervention.<sup>++</sup> One activity of this intervention has the provider and patient together develop a visual chart of the

<sup>++</sup> For further information on this intervention, contact Joel Milam, PhD., Department of Preventive Medicine, University of Southern California, 1441 Eastlake Avenue MS-9175, Los Angeles, CA, 90033 milam@usc.edu and visit <u>www.cdc.gov/hiv/topics/</u> <u>research/prs/resources/factsheets/pfh-ma.htm</u>.

patient's daily medication schedule. The actual schedule consists of a laminated chart where hours of the day are plotted and stickers with pictures of specific pills and related activities are applied along with special instructions (e.g., take medication with no food, light snack, water).

The Partnership for Health – Medication Adherence intervention takes into consideration that adherence is affected by an individual's belief in their ability to follow the medication regimen, their environment, and the availability of social supports. The intervention consists of 3-5 minute provider-patient sessions taking place over a 10-11 month period that focus on:

- The patient having a clear understanding of their ART regimen
- ART side effects
- The importance of ART adherence
- Developing problem-solving skills
- Identifying people who can provide support and encouragement to the patient
- Increasing patients' confidence in their ability to adhere to their ART regimen<sup>88</sup>

## Sexually-Transmitted Infection Testing and Treatment

Intervention	Targeted Individuals	
	HIV negative	HIV infected
Sexually-transmitted infection		$\checkmark$
testing and treatment		

# Why is testing for and treating STIs an effective HIV prevention intervention?

The same behaviors associated with STI transmission cause the majority of HIV infections in the United States. Research has demonstrated the "epidemiological synergy"<sup>89</sup> between HIV and STIs—individuals with an STI are 3-5 times more likely to become HIV infected, through sexual contact, than someone without such an infection.<sup>90</sup> This increased risk for individuals with an STI is due to physiological factors as specific STIs leave a person with genital ulcers that create tears of the skin, including the genital tract lining, which can serve as an entry point for HIV.<sup>91</sup> In addition, inflammation accompanying some STIs may result in the presence of a greater number of target cells susceptible to HIV infection at the inflamed site.<sup>92</sup>

Further, an individual who is HIV positive and has an STI is more likely to transmit HIV (through sexual contact) than a person with HIV but no other STI.<sup>93</sup> For these individuals, their genital secretions are more likely to contain HIV than a person with HIV alone.<sup>94</sup> They may also have more HIV in specific secretions—the amount of HIV in the semen of a male with both HIV and gonorrhea has been found to be as much as 10 times higher than in a person living with HIV only. The higher the amount of HIV in semen, the more likely HIV will be transmitted through sexual contact with a partner.<sup>95</sup> When someone with an STI and HIV receives STI treatment, it can reduce the frequency in which HIV is found in their genital secretions and the amount of HIV in those secretions, making it less likely for them to transmit HIV through sexual contact.<sup>96</sup>

#### How can I implement this intervention?

During patient appointments:

- Take a patient's sexual history
- Test the patient for HIV (if testing undocumented in CPRS) and

STIs and if infected, treat (or refer for treatment and care)

Engage patients in risk-reduction discussions

#### Take a Sexual History

Determining your patient's risk for and history of STIs can occur when you take their sexual history (see pages 21-23 and *Appendix A* for sample sexual history questions) or when they express concerns about their sexual health (e.g., lesion, pain). You can use this information to assess their need for STI testing.

### Test for HIV and STIs and Treat (or Refer)

Recommend HIV testing to all patients whose serostatus is undocumented in CPRS. Let patients know that routine HIV testing is part of VHA's comprehensive approach to their health care. Routinely ask all patients if they have any symptoms of STIs and for any patient presenting with such, diagnostic testing is indicated, regardless of their HIV status. All HIV-infected Veterans should be screened for STIs at baseline and regularly thereafter, depending on their risk factors (e.g., every 3-6 months in a patient with a new sex partner, multiple sex partners, or a partner who is an injection drug user). They should undergo specific tests according to sites of possible exposure (as outlined below). Veterans who test HIV negative and present with no risk factors or immune suppression conditions do not need to be tested again unless their circumstances change. Veterans who test HIV negative and engage in high-risk behaviors should be tested at least annually.

STI	Screening Test
Syphilis	Nontreponemal tests: Rapid plasma reagin (RPR);
	Venereal Disease Research Laboratory test (VDRL)

#### Table 2. Screening for STIs in HIV-infected Patients<sup>97</sup>

#### PRIMARY AND SECONDARY HIV PREVENTION INTERVENTIONS

STI	Screening Test	
Chlamydia	Urogenital infection: Nucleic acid amplification test* (NAAT) on first-void urine (men and women), or cervical (women), or vaginal women*, or urethral (men) swab specimen Rectal infection: NAAT of rectal swab** (for all who report engaging in anal receptive sex)	
Gonorrhea	Urogenital infection: NAAT on first-void urine (men and women), or cervical (women), or vaginal women*, or urethral (men) swab specimen; culture of male urethral or female endocervical swab specimen (for men with symptoms of urethritis, Gram stain of urethral specimen may be done.) Pharyngeal infection: NAAT or culture of oral swab* (for all who report engaging in oral receptive sex) Rectal infection: NAAT or culture of rectal swab* (for all who report engaging in anal receptive sex)	
Trichomoniasis	Wet-mount examination or culture of vaginal secretions or NAAT test*** for all women	
HSV	Serologic testing for HSV-2; recommended by some experts (for patients not previously diagnosed with HSV).	
*Specimen of choice – may be either clinician-collected or patient-collected. **NAAT is not currently approved for this indication by the FDA. There is evidence that NAAT can accurately diagnose pharyngeal and rectal gonorrhea and rectal chlamydia, however, and many local public health departments and commercial laboratories have obtained Clinical Laboratory Improvement Amendment (CLIA) waivers to perform NAAT on pharyngeal and rectal swabs. ***APTIMA TV Analyte Specific Reagents (ASR; manufactured by Gen-Probe, Inc.) was		

FDA-approved April 2011 for cervical swabs, vaginal swabs, urine, and specimens collected in PreservCyt solution.

*Note:* Adapted from VHA. (2009). *Primary Health Care for Veterans with HIV.* Retrieved from <u>http://www.hiv.va.gov/pdf/pcm-manual.pdf</u>. Adapted from the Centers for Disease Control and Prevention. (2006). Sexually transmitted diseases treatment guidelines. *Morbidity and Mortality Weekly Report, 55*(RR-11), 1-94. The guidance below is applicable to patients in a primary care setting who test positive for a STI and have CPRS documentation of a negative HIV test in the past year:

- Provide STI care and treatment and necessary follow up
- Repeat HIV test (based on timeframe of previous test)
- Provide a prescription for condoms (male or female)
- Provide support and guidance on changing high-risk behaviors (guidance found on pages 19-32)
- Refer, if appropriate, to services such as SUD treatment and mental health counseling that can support behavioral changes (additional information found on pages 46-51)
- Determine the need for pregnancy testing

For patients testing positive for a STI and HIV, the following guidance is for services that may occur in a primary care or HIV clinic setting:

- Expeditiously refer the HIV-infected patient to HIV-related care and treatment (care most likely provided by an infectious disease provider)
- Provide STI care and treatment and necessary follow up or refer to the appropriate provider
- If sexually active, screen for syphilis at least annually
- Test for hepatitis B, vaccinate if not immune; refer for evaluation if chronic hepatitis B found
- Test for hepatitis C; refer for evaluation if chronic hepatitis C found
- Provide a prescription for condoms (male or female)
- Provide support and guidance on changing risk behaviors (guidance found on pages 19-32)

- Refer, if appropriate, to services such as SUD treatment and mental health counseling that can support behavioral changes (additional information found on pages 46-51)
- Determine need for pregnancy testing

#### Engage in Risk-reduction Discussions

Any patient engaging in sexual behaviors that put them at risk for STIs or HIV will benefit from discussions on behavioral changes that can reduce their risk of transmission. Guidance on having these discussions is found on pages 22-31.

## **HIV Partner Notification Services**

Intervention	Targeted Individuals	
	HIV negative	HIV infected
HIV partner notification services	$\checkmark$	$\checkmark$

# Why are HIV partner notification services an effective HIV prevention intervention?

When a Veteran tests HIV positive, the primary concern is their health and the health of individuals they may have exposed to the virus. In addition to immediately referring the Veteran for HIV care and treatment, you should strongly encourage the patient to inform sexual partners and needle-sharing partners of their HIV status.<sup>98</sup> This activity, know as partner notification, ideally occurs very soon after an individual receives an HIV-positive test result.

The goal of partner notification services<sup>‡‡</sup> is to maximize an HIV-infected individual's "portion of partners notified of their [HIV] exposure" and "early linkage of [their] partners to testing, medical

<sup>‡‡</sup> Also referred to as partner counseling and referral services.

care, prevention interventions and other services."<sup>99</sup> The delivery of partner notification services by a "public health professional (provider referral) effectively increases identification of a high-prevalence target-population for HIV testing."<sup>100</sup>

In some instances, the VA is legally permitted to disclose a patient's positive status to a sexual partner even if the patient does not consent. These circumstances are discussed in detail in Chapter V.

### How can I implement this intervention?

During patient appointments:

 Strongly recommend to HIV-infected patients that they inform all sexual and needle-sharing partners of their HIV infection. Let the patient know that their local health department can help them disclose this information to their partner if they (the patient) feel unable to do so themselves.

## Recommend Use of Partner Notification Services Available at Health Departments

The purpose of partner notification discussions with your patient is to help them understand that by telling their sex and/or injection drug use partners they have been exposed to HIV, this disclosure often will prompt the partner to undergo HIV testing and if they are positive, engage in early treatment and modify their behaviors so as not to infect others.

The health department can perform confidential partner notification on behalf of the patient should the patient be unable to notify their partner(s) themselves. In its 2008 Recommendations for Partner Services Programs for HIV Infection, Syphilis, Gonorrhea, and Chlamydial Infection, CDC strongly recommended that due to the effectiveness of partner notifications services and program costs, individuals with HIV "receive partner services with active health department involvement."<sup>101</sup> The professional and ethical

#### PRIMARY AND SECONDARY HIV PREVENTION INTERVENTIONS

responsibilities of VHA providers require them to make full use of partner notification services available through state and local health departments. Health departments have in-depth experience providing these services and knowledge of state laws and regulations governing partner notification. *Appendix H* lists state and territorial health departments' AIDS directors who can connect your patients to partner services available within their agency.

In the event that a patient asks you to be present while their partner is informed, the patient must provide written informed consent (see *Appendix I* for form information) for such a disclosure. Disclosure of one's HIV status to their partner(s) may put some patients at risk for intimate partner violence.<sup>§§</sup> As a provider you should assess your patient's risk of intimate partner violence using the instrument found on page 65 and provide appropriate guidance.

## Referrals to Support Services including SUD Treatment and Mental Health Treatment

Intervention	Targeted Individuals	
	HIV negative	<b>HIV</b> infected
Referrals to support services	$\checkmark$	$\checkmark$
including SUD treatment and		
mental health treatment		

# Why are referrals to support services such as SUD treatment and mental health treatment an effective HIV prevention intervention?

For some individuals, their HIV-positive status or their opportunity to remain HIV negative is secondary to challenges they face such as addiction, mental illness, poverty, unstable housing, and un/

<sup>§§</sup> Intimate partner violence consists of physical, sexual, psychological, and economic abuse occurring in sexual and non-sexual relationships and is not gender specific.

under-employment. Specific to HIV-infected individuals, the presence of such stressful events has been shown to affect not only the progression of HIV,<sup>102</sup> even in the advent of ART, but also one's level of ART adherence.<sup>103</sup>

Support services can provide HIV-infected Veterans and those at risk with critical programming that aids in day-to-day living and increases their chance for healthy lives. These services include:

- SUD treatment
- mental health treatment
- housing assistance
- domestic violence services
- nutritional guidance and food pantry access
- employment training
- legal assistance
- child care
- needle exchange programs (not available within VA)

Two key support services are SUD treatment and mental health treatment. A number of people living with HIV experience substance use and mental health disorders<sup>104,105</sup> and as well, these disorders can leave other individuals at risk for virus acquisition. For individuals with a SUD, factors that increase their risk for HIV transmission include:

- The use of unsterile syringes when injecting drugs
- Participation in sexual networks that are made up of other people at high risk for HIV transmission
- Unprotected sex, which may occur for a variety of reasons such as lowered inhibitions while high, the trading of sex for drugs, engagement in survival sex to meet basic needs (e.g., food, shelter)<sup>106</sup>

#### PRIMARY AND SECONDARY HIV PREVENTION INTERVENTIONS

"The cumulative science has shown that drug treatment reduces drug use, related risk behaviors, and the acquisition and transmission of HIV and other bloodborne pathogens."<sup>107</sup> SUD treatment can expose individuals to HIV prevention activities such as HIV testing, behavioral change interventions, and referrals to HIV care and treatment as well as services including medical care and mental health counseling. HIV prevention components within SUD treatment are crucial because while the number of people infected with HIV due to injection drug use has decreased,<sup>108</sup> 8% of the HIV cases diagnosed in 2009 were attributed to injection drug use (this percentage does not include HIV cases attributed to MSM contact and IDU or transmissions involving substance use such as unprotected sex while under the influence of a substance).<sup>109</sup> In addition, 50-90% of individuals who became HIV infected through injection drug use are also infected with hepatitis C,<sup>110</sup> a disease that can complicate the treatment of HIV.<sup>111</sup>

Like SUDs, mental health disorders are often intertwined with HIV transmission risks. Individuals with chronic mental illnesses may be at greater risk for HIV due to:

- deficits in social skills needed to negotiate safer sex with partners,
- sexual disinhibition,
- · cognitive impairment or poor judgment,
- hypersexuality or mania, or
- associated substance use.

An estimated half of people living with HIV/AIDS have been found to have mild-severe cognitive impairment.<sup>112</sup> If left untreated these problems can lead to increases in higher risk behavior, problems with medication adherence, and reduction in overall quality of life and quicker disease progression.

PTSD is an example of a mental health condition associated with stress-related risk behaviors that may place Veterans at risk for HIV. In attempting to cope with, self-manage, or 'numb' symptoms of PTSD, an individual may engage in substance use or abuse or associated unprotected sexual behaviors that may place him or her at risk for HIV. If PTSD is secondary to sexual assault or trauma, it may be much harder for an individual to engage in the self-efficacy and interpersonal skills necessary to negotiate safer sex practices such as consistent condom use with a sexual partner. In FY2010, 408,000 unique Veterans were treated for PTSD in VA specialty mental health programs<sup>113</sup> and in a study of OIF and OEF Veterans entering VHA care from 2002 to 2008, 37% received a new mental health diagnosis, including 22% diagnosed with PTSD.<sup>114</sup>

### How do I implement this intervention?

During patient appointments:

- Recommend HIV testing to all patients whose serostatus is undocumented in CPRS
- Assess the patient's need for support services and refer when appropriate

### **Recommend HIV Testing**

Guidance on recommending HIV testing to all patients and test administration is found in Chapter IV.

### Assess Support Service Needs and Provide Referrals

Discussions with patients on their medical history will help you better understand their support service needs. Questions to help you determine a patient's need for SUD treatment, STI testing and referrals to domestic violence services are found on pages 21, 22 and 65, respectively, and in *Appendices A and B*. As well, a PTSD screening tool is found in *Appendix J*. We suggest the questions below<sup>11</sup> to help you hone in on other support service needs:

- 1. In the last three months, did you feel you needed help for any of the reasons below:
  - \_\_\_\_ Mental health problems
  - \_\_\_\_ Family problems
  - \_\_\_\_ General health problems
  - \_\_\_\_\_ Alcohol and/or drug use problems
  - \_\_\_\_ Finding or keeping housing
  - \_\_\_\_ Finding or keeping a job that pays you enough to support you (and your family)
  - \_\_\_\_\_ Finding services for your kids
  - \_\_\_\_\_ Sexual identity/sexual attraction
- 2. Did you get help for these issues and if so, where?
- 3. Please tell me if any of these reasons kept you from getting help:
  - \_\_\_\_ Didn't know where to go/what service to use
  - \_\_\_\_ You were concerned that getting help would jeopardize your VA/VHA benefits
  - \_\_\_\_ You were concerned information about the issue(s) would go in your VA/VHA record
  - \_\_\_\_ The service cost too much money
  - \_\_\_\_ The service was too far away
  - \_\_\_\_\_ You had a bad experience with the staff last time

**<sup>11</sup>** A number of these questions are used with permission from the Center for HIV Identification, Prevention and Treatment Services. Retrieved from <u>http://chipts.ucla.edu/</u> wp-content/uploads/downloads/2012/02/Getting-Services.pdf

- \_\_\_\_ You thought the service couldn't help you
- \_\_\_\_ You had no money to get here
- \_\_\_\_ You had to wait a long time for an appointment
- \_\_\_\_\_ You were concerned the staff would contact your family
- \_\_\_\_ The service wasn't open when you needed it
- \_\_\_\_ You didn't fit the eligibility criteria for the service
- \_\_\_\_\_ You felt nervous/embarrassed to talk about the problem
- \_\_\_\_ Other (please specify)
- \_\_\_\_\_ Refused to answer

Successful referrals are more likely to occur when you:

- Plan the referral (e.g., take into consideration the needs of the patient such as language, gender, age, child care, transportation)
- Help patients access referral services (e.g., service provider's name, telephone number, address)
- Document referral and follow up<sup>115</sup>

Knowledge of services available through VHA and within the larger community is key to the referral process. Also vital are the professional relationships VHA providers develop with service staff. Through these relationships, providers can make informed referrals and gain the ability to track such referrals. To locate agencies and organizations outside of VHA that offer a range of support services, go to Project Inform's webpage of state HIV-hotline numbers (*www.projectinform.org/hotlines*).

## Reproductive Health Care for Women

Intervention	Targeted Individuals	
	<b>HIV negative</b>	HIV infected
Reproductive health care	$\checkmark$	$\checkmark$
for women		

# Why is reproductive health care for women an effective HIV prevention intervention?

At year-end 2009, 32% (approximately 189,587) of adults and adolescents living with HIV in the United States were female and more than 50% of them were infected through heterosexual contact.<sup>116</sup> Comprehensive reproductive health care protects the health of the woman, her partner(s), and that of her fetus should she become pregnant while at the same time exposing her to an umbrella of services containing HIV prevention components, such as:

- HIV testing
- STI testing
- Contraceptives (e.g., female and male condoms)
- Pap smears
- Specific cancer screenings
- Preconception counseling
- Obstetric care

### How can I implement this intervention?

During patient appointments:

- Recommend HIV testing for all patients whose serostatus is undocumented in CPRS
- Take the patient's sexual health history and help her understand her risk of HIV and STI transmission

- Familiarize yourself with the special reproductive health care needs of HIV-infected women
- Discuss the availability of reproductive health care available through VA's Women Veterans Health Program

#### **Recommend HIV Testing**

Guidance on recommending HIV testing to all patients and test administration is found in Chapter IV.

### Take a Sexual History

Taking the patient's sexual history (see pages 21-22 and *Appendix A* for a sample sexual history questions) will help you determine their need for a variety of OB/GYN services including STI testing, pregnancy testing, contraception, risk-reduction counseling (guidance on helping patients identify their risk behaviors and make behavioral changes is found on pages 19-32), and referrals for services outside OB/GYN.

### Understand the Reproductive Health Care Needs of HIV-infected Women

Many reproductive health care services become highly specialized when a woman is HIV infected. National guidelines and recommendations address the reproductive health care needs of HIV-infected women and women with HIV-infected partners, from preconception to postpartum as well as the care of their fetus and infant upon birth.<sup>117,118</sup>

VHA developed the Primary Care of Veterans with HIV manual to address the health care needs of HIV-infected Veterans, including those who are pregnant or may become so. *Appendix K* contains the manual's recommendations for pregnant HIV-infected women and the manual in its entirety can be accessed at <u>www.hiv.va.gov/provider/manual-primary-care/index.asp.</u>

#### The VA's Women Veterans Health Program

In 2010, 8% of Veterans in VHA care were female, a figure projected to nearly double by 2036.<sup>119</sup> Each VA Medical Center has a designated Women Veterans Program Manager who advocates for female Veterans and can coordinate their primary and specialty care. Should your patients want woman-focused health care (including reproductive health) or wish to augment their current primary care with this option, staff at the facility where they receive care can connect them to the facility's Women Veterans Program Manager. IV.

# **HIV Testing in VHA Settings**

Knowing one's own serostatus is a principal component of HIV prevention. CDC recommends HIV testing be a part of routine medical care, a standard of care endorsed by many agencies and organizations including the American College of Physicians. In 2009, VA aligned its HIV testing policy with CDC's recommendations and removed the requirement of written informed consent for testing.

Many people do not believe they are at risk for HIV and in turn find HIV testing irrelevant to their situation or age. Yet it is estimated that persons unaware of their positive status transmit 54-70% of new infections in the United States.<sup>120</sup> For the individual who tests positive, this knowledge can direct him/her to early care and treatment that can provide additional quality years of life. It also offers them the chance to reduce their risk of transmission by making healthful behavioral changes and when on treatment, decreasing their viral load. For individuals who test negative yet remain at risk due to behaviors, knowing their status affords them the opportunity to reflect on their health and make behavioral changes. It allows you, as their provider, to engage them in primary prevention activities specific to their needs.

Researchers determined that by implementing routine HIV testing and treatment, thousands of infections could be prevented. Using an HIV epidemic model based on data from the United States, researchers found "that expanding HIV screening and treatment could prevent 200,000 to 300,000 infections over 20 years or approximately 17% to 24% of new infections..."<sup>121</sup> Such a strategy is also cost effective as the care and treatment for one HIV-infected individual is estimated to cost approximately \$22,500 annually.<sup>122</sup>

Regardless of a Veteran's self-perceived risk for HIV, many are willing to be tested. In a survey administered October 2008 to February 2009 through the VA's My HealtheVet website, approximately 31,000 Veterans answered questions on health screenings offered to them in VHA settings. Just 9% of respondents indicated they had been offered an HIV test in the last 12 months while 73% reported they would be "very likely" to take an HIV test if offered.<sup>123</sup> During the same time frame, respondents were offered screenings for cholesterol (83%), glucose (65%), and hepatitis C (19%).<sup>124</sup>

## Guidance on Discussing HIV Testing with Patients

Stigmatization surrounding HIV still exists and continues to deter some individuals from testing. It can also impact a patient's disclosure of information to their health care provider. For Veterans in particular, it can result in non-disclosure because of the incorrect belief that elements of such information would result in a loss of VHA benefits. Therefore it is important to reassure patients that HIV testing and related information is in no way connected to these benefits.

Let patients know that HIV testing is a part of VA routine care and such testing is recommended for all Veterans. For some Veterans, this approach may decrease the "singled out" anxiety they experience when broached by their provider on HIV testing. Since it is no longer necessary to administer an HIV-risk assessment to each patient, you will likely learn about their risk behaviors when taking their medical history, including information on their sexual health and substance use (see pages 21-22 and *Appendices A and B* for sample questionnaires). For Veterans reporting high-risk behaviors and/or experiencing conditions associated with immune suppression (see *Appendix L* for a list of AIDS-defining conditions), more personal approaches to testing may prove fruitful. One such approach involves discussing how their behaviors put them at risk for HIV and how their medical care will be better managed if their serostatus is determined. When approaching patients on HIV testing, a variety of verbal prompts can be used:

#### All Patients:

"Based on current public health recommendations, the VA is offering HIV tests to all patients, as part of their routine medical care. In order to provide you with the best possible care, may I test you today?"

#### or

"Would you like to take an HIV test today?"

#### New Patients:

"In order to provide the most complete medical picture on all of our patients, I am offering HIV testing to all of my patients, regardless of whether they think they are at risk. This will help me to provide the best medical care I can for you. May I test you today?"

#### Continuing Patients:

"You have been a patient here for some time. Because of recommended medical guidelines, VA is offering HIV tests to all patients as part of their routine medical care just like we test for diabetes, cholesterol and high blood pressure. May I test you today?"

#### Patients with medical indication or risk profile:

"Based upon your current medical profile and some of the information you have shared with me, I think we should consider the HIV antibody test today. Current public health recommendations consider HIV testing a routine part of medical care. I would like to know your HIV status in order to provide you with the best medical care. May I test you today?"

### • **Pregnant patient**\*\*\* or one considering pregnancy: *"Because of the advances in the diagnosis and treatment of HIV, all physicians are talking with their patients about HIV/AIDS*

<sup>\*\*\*</sup> States have laws and regulations regarding HIV testing of pregnant women and newborns.

prevention. Lets talk about this now. Have you ever had an HIV test? If not, may I test you today?"

VHA research on the barriers to and facilitation of routine HIV testing in VHA primary care settings concluded, "patients and providers appear ready for implementation of routine HIV testing. Providers should use patient-centered communication strategies to ease patients' concerns about confidentiality and stigma associated with HIV disease."<sup>125</sup> As such, the researchers developed the "6 Rs," which are steps providers can follow when addressing HIV testing with their patients.

#### The Six **R's** of Patient-Centered Discussions on HIV Testing in VHA Primary Settings<sup>126</sup>

- 1. Raise the topic of HIV testing.
- 2. Reassure the patient that he/she is not showing clinical signs of the disease.
- 3. Provide Rationale that many patients infected with HIV are unaware of their status.
- 4. Respond to any questions that the patient may have about HIV disease.
- 5. Request permission to order the test.
- 6. Tell the patient when he/she can expect to get the Results.

## **HIV Test Administration**

#### VHA HIV testing sites and available testing methods

VHA sites offering HIV testing include primary care facilities, mental health clinics, SUD treatment programs, women's health programs/

clinics, nursing homes, CBOCs, programs for incarcerated Veterans, Stand Downs, domiciliaries, and homeless outreach programs. HIV testing methods at these sites vary, as VHA does not mandate all FDA-approved methods be available at each site. VHA testing sites may use traditional blood tests and/or rapid tests on blood or oral fluids.<sup>†††</sup>

HIV rapid testing may allow a greater proportion of individuals access to testing and to their timely results.<sup>127</sup> Rapid testing consists of testing for HIV antibodies using oral fluid or a blood sample (whole blood, serum or plasma). These tests can be used in either clinical or non-clinical settings with results available in less than an hour. Currently, there are six FDA-approved rapid HIV tests. A positive result on a rapid test must be confirmed by Western blot. In February 2010, the VHA released IL 10-2010-006: Use of Rapid Tests for Routine Human Immunodeficiency Virus (HIV) Screening, which recognized the role of rapid testing to increase "the number of Veterans tested for HIV as part of routine medical care, facilitate notification of Veterans of test results, and help with timely linkage to care."<sup>128</sup>

#### VHA staff authorized to order HIV tests

Across VISNs and facilities it varies as to who can order an HIV test for a patient. VHA Directive 2009-019: Ordering and Reporting Test Results defines an "ordering practitioner" as "...a practitioner authorized to enter and sign orders for diagnostic tests by privileges or acting under a scope of clinical practice." These practitioners mainly include physicians, physician assistants, nurse practitioners, and nurses. To determine who can order an HIV test within your facility, check your facility's policy or contact facility leadership.

<sup>+++</sup> VHA Directive 2009-019 states that test results are to be communicated to patients "no later than 14 calendar days from the date on which the results are available to the ordering practitioner."

#### Obtaining and documenting consent for HIV testing

Any health care professional authorized to order HIV testing, or any health professional whose scope of practice agreement or other formal delineation of job responsibility specifically permits them to order tests and/or obtain informed consent, can obtain consent for HIV testing.<sup>129</sup> Primary care physicians, physician assistants, nurse practitioners, and nurses often obtain HIV testing consent. VHA requires that a patient's verbal consent for HIV testing be documented in CPRS.

The updated VHA policy on informed consent requires that written HIV educational materials be given to patients being HIV tested. These materials must be provided to patients at the time of their consent for HIV testing or prior to the administration of the test. Any appropriate VA staff member, not just the provider ordering the test or obtaining consent, can provide the patient with these materials.

The material must contain the following elements:

- "A description of HIV disease;
- A description of HIV testing;
- A description of the expected benefits and known risks associated with HIV testing, including the possibility that VA may disclose test results to the public health authorities and to the patient's spouse or sexual partner (see 38 U.S.C. § 7332);
- A description of the reasonable alternatives to HIV testing, the anticipated consequences of choosing no HIV testing, and the availability of anonymous testing.

Note: Anonymous testing is not available everywhere in the United States;

- A description of the meaning of a positive and a negative HIV test;
- A description of how HIV is transmitted; and

• A description of measures to be taken for prevention of HIV transmission."<sup>130</sup>

VHA has developed such educational materials, which can be found at <u>www.hiv.va.gov</u> under the heading "Publications and Products." In addition to providing patients with these materials, any questions the patient has must be answered fully. Further information on VA's informed consent policy is found in Chapter V.

#### Informing patients of their HIV test results

Providers often want to know what information they should discuss with patients when delivering HIV test results and if the test results must be given in person.

#### VHA guidance on these issues is as follows:

# Q: What should I discuss with the patient when delivering HIV test results?

Delivering an HIV test result involves more than just telling the patient about the result. It should include time to make sure the patient understands the meaning of the result and making appropriate plans based on the results. The specific elements of the discussion will vary based on the test result and also on the needs of the particular patient. When delivering a negative test result, information should be given about the validity of the test result, especially if the patient has engaged in high risk behavior within 6 months of the test, as well as the need for possible retesting. It is also important to talk with the patient about how to decrease his or her risk for HIV. If the patient's risk factors for HIV infection include a substance use disorder, then he or she should be referred to appropriate treatment resources. Similarly, providers should discuss safer sex practices that decrease the risk of HIV infection.

When delivering a positive HIV test result, it is important to provide a referral for HIV care, to inform the patient about the importance of informing his or her spouse, and/or sexual or drug use partners, and provide information about how to avoid transmitting HIV to others. It is important to document the information provided to the patient, including: the results of the test; information about the patient's comprehension of and reaction to the results; and, information about follow-up referrals or services arranged.<sup>131###</sup>

Q: Do I have to deliver the HIV test results in a face-to-face meeting with the patient? (Sometimes our patients may not have another clinic visit scheduled in the immediate future and they may live several hours away from our medical center. Coming in for just the HIV results may be a hardship for some while others do not show up for appointments that were scheduled to deliver the test results.)

VHA practice has always been to deliver HIV test results in a face-to-face visit with the patient whenever possible. This is even more important when the test result is positive as it is critical to make sure that the patient has all the information that he or she needs to answer any questions about HIV and to offer much needed support.<sup>§§§</sup> It is also important to help get the patient into care for their HIV as soon as possible and to provide them with the information about how to prevent transmission to others.

However, there are times when it may be difficult or impossible after multiple attempts to get a patient in to discuss positive test results [a face-to-face visit for the delivery of a HIV positive test result is strongly encouraged]. At those times, it is appropriate to try to reach the patient by phone and speak with him or her directly. This is more easily done over

<sup>###</sup> When delivering a preliminary positive test result (as with a rapid test when same-day confirmation is not available), it should be explained to the patient that they have received a positive screen for HIV infection. Although a confirmatory test is needed, they should be instructed to take precautions to avoid transmitting the virus to other people.

<sup>§§§</sup> Providers are strongly encouraged to deliver HIV-positive test results in a face-to-face visit with their patient. HIV rapid testing can eliminate the need for a return appointment and thus facilitate face-to-face delivery of negative test results. Also, providers can deliver a patient's HIV-negative test result over the telephone or through the mail.

the phone when the provider is someone who already has a relationship with the patient. The information provided over the telephone should be similar to that which would be given in a face-to-face visit, and documented in the patient's electronic health record. The patient should be encouraged to come see the provider or the HIV clinic to which they are being referred for care as soon as possible.

In patients with negative results, contacting the patient by phone [or mail] may be acceptable if it would represent an undue burden for the patient to return for a visit just to receive the test results. However, the same information on risk reduction that would be provided in a face-to-face visit should be given to the patient, and documented in the patient's electronic health record. In addition, appropriate referrals for risk reduction and other needed services should be made and discussed with the patient. It is important to make sure that the patient's confidentiality is protected. If you need to leave a message with someone on the phone, please make sure that the reason for the call is not disclosed. It is not appropriate to leave a message on results on an answering machine or to inform a patient by email, as these are not secure means of communication.<sup>132</sup>

In addition, VHA Directive 2009-036: Testing for Human Immunodeficiency Virus in Veterans Health Administration Facilities addresses the delivering of test results under two distinct scenarios. First is the individual who tests HIV negative, yet is thought to be at increased risk for HIV transmission and second is the individual who tests HIV positive.

# Individuals who test HIV negative and are considered at risk for HIV transmission

For individuals with a negative result who are known or suspected to be engaged in behaviors (e.g., injection drug use, unprotected sex with a partner at increased risk, see subpar. 4e(5)) that place them at increased risk for HIV infection, delivery of negative test results must be accompanied by education about the risks of such behaviors. If appropriate to the patient situation, referral by the notifying provider to resources (e.g., mental health or substance use treatment) to reduce the risk of future HIV infection must be performed. Such individuals must also be advised of the need for periodic retesting (see VHA Directive 2009-019).

*Note:* Routine post-testing counseling is not required for individuals who are not known to be engaged in such behaviors. (VHA Directive 2009-036, section 4.e.(7)(b))

#### Individuals who test HIV positive

For confirmed positive results, the patient must be expeditiously referred for ongoing HIV-related care, including providing the patient with a contact name and number for ongoing HIV-related care, which needs to include any necessary prevention services and mental health counseling, as appropriate. Patients must be informed about the potential for sexual or parenteral transmission, or in the case of women of reproductive age, perinatal transmission. In addition, patients must be strongly encouraged to inform any sexual and needle-sharing partners about their status.

*Note:* Further information on these topics is available at <u>www.hiv.va.gov</u>. (VHA Directive 2009-036, section 4.e.(7)(c))

In some instances, your patient's disclosure of their HIV-infected status to their partner(s) may put the patient at risk for intimate partner violence. If you suspect your patient has experienced intimate partner violence or may be at risk, consider screening for it during the delivery of an HIV test result using the following questions:

- 1. Have you been hit, kicked, punched, choked or otherwise hurt by an intimate partner in the past year?
- 2. Have you been physically harmed or threatened by your partner?
- 3. Do you (or did you ever) feel controlled or isolated by your partner?
- 4. Do you feel frightened by what your partner says or does?

In any instance where a patient tests positive, you should encourage them to utilize partner notification services available at a local health department. For the patient who fears or has experienced intimate partner violence, health department partner notification services can be tailored to fit these circumstances. You can also offer your patient telephone numbers for local shelters and legal advocacy organizations, help them develop an emergency plan for use in the event of intimate partner violence, and offer follow-up visits.

#### **Repeating HIV testing**

All patients who are documented to be HIV negative and have risk factors or clinical indications of HIV must be tested for HIV at least annually, provided they consent.<sup>133</sup> Patients who have no risk behaviors and no clinical indications for HIV should generally not be retested, unless the patient requests it.<sup>134</sup>

#### **Post HIV-test referrals**

Veterans testing HIV positive "must be expeditiously referred for ongoing HIV-related care..." as well as provided with critical information regarding potential transmission risks and strongly recommended to engage in partner notification.<sup>135</sup> Their rapid entry into care, care most likely provided by an infectious disease provider, will provide them with early access to often life-altering treatment. For information on how to refer an HIV-infected patient into care, contact your facility's HIV lead clinician.

The overall health of some Veterans, regardless of their HIV test results, may be best served by referrals to specialized services for underlying psychosocial and physiological conditions. Such a referral may be for SUD treatment, which is a highly effective form of HIV prevention that reduces the incidence of drug-related behaviors associated with HIV transmission.<sup>136</sup> Mental health services can help prevent HIV transmission by addressing disinhibition, poor social skills and judgment, hypersexuality, hopelessness, and associated substance use. Mental health referrals are also helpful in the treatment of depression and other psychological factors that may contribute to poor adherence with antiretroviral regimens.

A referral for HIV case management may help an HIV-infected Veteran struggling with risk behaviors and result in better coordination of their HIV-related care and services. Other needed referrals may include dietary or nutritional support for the patient's general health and medication adherence support provided by pharmacy staff. For more information on support service referrals, see pages 46-47.

It is important to remember that the support you offer your HIV-infected and at-risk patients may not be effective until more critical underlying conditions such as mental illness and other acute or chronic conditions are addressed. Attempts to reduce a patient's risk for HIV transmission need to take into consideration all the psychosocial conditions and stressors of that patient as they relate to his or her ability to protect himself or herself.

> Guidance for VHA Substance Use Disorder Treatment Providers

SUD treatment providers should recommend HIV, hepatitis C and TB testing to all patients if such test results are undocumented in CPRS. Testing can take place within the SUD treatment program by staff authorized to order tests and obtain patient consent or through a referral to a VHA provider outside the SUD treatment program.

If a patient tests positive for HIV, he or she should be expeditiously referred to the infectious diseases clinic or their primary care provider in their VHA facility in order to receive further evaluation and treatment if indicated. Patients testing positive for hepatitis C or TB should also be referred to their VHA primary care provider for

care and treatment. For patients with or without these conditions who continue to engage in risk behaviors, they should receive risk-reduction counseling through the SUD treatment program and be prompted for retesting as clinically indicated.

## Guidance for VHA Mental Health Service Providers

Recommend HIV testing to all Veterans in your care and test within your mental health clinic/setting. Explain to your patients that such testing is part of VHA routine medical care, that you recommend it to all your patients, and that knowing their HIV status will allow you to make sure they are provided with the most comprehensive care possible. If testing is unavailable in your clinic, refer your patient to a VHA provider authorized to test and obtain consent.

For patients indicating they want an HIV test:

- assess their ability to provide informed consent,<sup>111</sup>
- order HIV test and obtain consent (refer the patient if you are unable to do so), and
- if you are not administering the HIV test, determine if they want you to accompany them to the testing or provide a time to see them while they are waiting for their result and immediately after receiving the results of their test.

In addition to offering HIV testing to all your patients, provide them with prevention tools such as free condoms and educational materials (found at <u>www.hiv.va.gov</u>). Make condoms available in places such as restrooms so patients can pick them up unnoticed. Educational materials can be placed in both the waiting area and provider offices

**<sup>¶¶¶</sup>** VHA Handbook 1004.01: *Informed Consent for Clinical Treatments and Procedures* contains specific procedures should a patient be judged to lack decision-making capacity.

so patients can read them while waiting for their appointment. Providing patients with these prevention tools signals that HIV is a topic they can discuss with their mental health service provider.

It is important to continually assess the HIV risk of Veterans receiving mental health services as it may change in response to changes in their psychological functioning and life events. Factors such as depression, hopelessness, manic presentations, and diminished judgment may increase patients' risk status, and may have to be addressed before a patient can change his or her risk behaviors. You can integrate general HIV prevention counseling and your evaluation of your patient's readiness to adopt behavioral changes, into their therapeutic goals.

Both substance-use and sexual health histories can be integrated into a mental health intake evaluation. When taking patients' medical history, include questions on specific sexual activities, substance use and sexual risk, use of condoms, and previous diagnoses of STIs (see pages 21 and 33 and *Appendices A and B* for sample questions). Again, it is important to emphasize with the patient that you routinely ask these questions of all your patients as you are concerned with all aspects of their health. As well, you can discuss VHA's confidentiality policy concerning personal medical information.

## Guidance for VHA Homeless Care Providers

Veterans are disproportionately represented among the U.S. homeless population. Of the homeless population, an estimated 20% are Veterans,<sup>137</sup> yet Veterans constitute approximately 9% of the U.S. population over 18 years of age.<sup>138</sup> In 2008, approximately 107,000 Veterans were homeless.<sup>139</sup> While the majority of these Veterans were from the Vietnam era,<sup>140</sup> OIF/OEF Veterans are experiencing

homelessness as well (VA estimates that 3,700 OIF/OEF Veterans have sought support through homeless outreach programs).<sup>141</sup>

Homelessness and HIV/AIDS co-occur at high rates. It is estimated that homeless individuals have at least three times the risk for HIV compared to the general population.<sup>142</sup> Risk factors such as severe mental illness, SUDs, and a history of injection drug use all occur at higher rates among urban homeless populations, leading to increased risk for HIV.<sup>143</sup> Homeless populations are also likely to have poor access to health care, SUD treatment, or condoms–all resources that can affect one's risk for transmission.<sup>144</sup>

VHA policy of HIV testing as a routine part of medical care means that such testing should be recommended to all homeless Veterans. Traditional blood-based HIV testing may not be effective with homeless Veterans as it requires a two-step process of venipuncture and laboratory analysis and future recontact for delivery of the results. Providers (and facilities) working with homeless Veterans should consider the use of HIV rapid screening procedures to mitigate the loss to follow up, and well as to strengthen linkage to long-term VA care.

A number of homeless Veterans attend Stand Downs, events specifically designed as safe venues where they can access health screenings and support services. Stand Downs may provide HIV testing (including rapid testing) and other prevention interventions such as referrals for HIV care and treatment, SUD screenings, hepatitis C testing, and condom distribution. Should a Veteran at a Stand Down test HIV positive, the staff person working with that Veteran should immediately refer him/her to HIV care, whether at the VHA facility closest to that Veteran or an accessible HIV community-based organization. When a Veteran undergoes non-rapid HIV testing at a Stand Down, staff should arrange an appointment with the facility closest to the Veteran so s/he can receive their test results and any necessary referrals.

## Guidance for VHA Emergency Department Staff

It is important to note that HIV prevention interventions can take place in an emergency department (ED), despite its often chaotic, fast-paced environment. This is particularly important because many Veterans in VHA care use VA EDs as a primary source of health care. Let ED patients know that HIV testing is a part of routine medical care at the VHA and you can test them right there. As such, there is a role for HIV rapid testing in EDs when laboratory quality assurance measures are in place. Also tell them that if they test positive or are at risk for the disease, you can refer them to VHA services outside the ED.

Other HIV prevention activities you can administer within VHA EDs include:

- writing condom prescriptions for patients who are at risk for transmission (risk may be determined by asking sexual health and substance-use history questions found on pages 21-22 and in Appendices A and B)
- making patient referrals to VHA or community-based resources such as infectious disease clinics, mental health clinics, and HIV case management services
- providing patients with HIV prevention and educational materials found at <u>www.hiv.va.gov</u>

All activities associated with patient visits to the ED should be recorded in CPRS.

## **VHA HIV Policies and Guidance**

V.

This chapter highlights HIV related policies, directives, informational letters (ILs) and handbooks developed by VHA. Links to all such documents referred to in this chapter are available in *Appendix I*.

## **Routine and Voluntary HIV Testing**

In August 2009, VHA implemented major changes to its HIV testing policy: VHA HIV testing is now a routine part of medical care and requires documented verbal consent from the patient. In the past, VHA's HIV testing policy was based on an assessment of an individual's risk behaviors and required written informed consent for testing as well as the provision of pre- and post-test counseling.

VHA Directive 2009-036 *Testing for Human Immunodeficiency Virus in Veterans Health Administration Facilities* clearly states that HIV testing be offered as a part of routine medical care if the Veteran consents. Below are selected elements of the directive:

- 1. All patients who do not have documentation of an HIV test in their health record must be tested for HIV at the first reasonable opportunity, provided they consent.
- 2. All patients who are documented to be HIV negative and who have risk factors or clinical indications of HIV must be tested for HIV at least annually, provided they consent.
- Patients will not be tested excessively (e.g., patients who have no risk factors and no clinical indications for HIV testing should generally not be retested), unless the patient requests such testing.
- 4. Voluntary verbal consent must be obtained and documented in CPRS.
- 5. Patients must be provided with written educational materials (found at <u>www.hiv.va.gov</u> under Publications and Product) about HIV testing prior to, or at the time, consent is obtained. Any questions the patient has about HIV testing must be fully answered before testing is performed.
- 6. Clinical providers performing point-of-care HIV testing must comply with applicable policies promulgated by the

Laboratory Director (see IL 10-2010-006: Use of Rapid Tests for Routine Human Immunodeficiency Virus (HIV) Screening).

- Results related to HIV testing must be provided to patients in accordance with VHA policies on notification of patients of laboratory testing results:
  - a. Mechanisms for notification of patients of their test results may be developed and implemented based on local assessment of needs and resources; documentation of such notification must be consistent with applicable VHA policy on patient notification of results.
  - b. For individuals with a negative test result who are known or suspected to engage in behaviors (e.g., injection drug use, unprotected sex with a partner at increased risk) that place them at an increased risk for HIV infection, delivery of negative test results must be accompanied by education about the risks of such behaviors. If appropriate to the patient situation, referral by the notifying provider to resources (e.g., mental health or substance use treatment) to reduce the risk of future HIV infection must be performed. Such individuals must also be advised of the need for periodic retesting. Routine post-test counseling is not required for individuals who are not known to be engaged in such behaviors.
  - c. For confirmed positive results, the patient must be expeditiously referred for ongoing HIV-related care, which needs to include any necessary prevention services and mental health counseling, as appropriate. Patients must be informed about the potential for sexual or parenteral transmission, or in the case of women of reproductive age, perinatal transmission. In addition, patients must be strongly encouraged to inform any sexual and needle-sharing partners about their status.

## Informed Consent for HIV Testing

Informed consent is a fundamental component of HIV testing at VHA facilities and as such, VHA's policy on informed consent (VHA Handbook 1004.01 Informed Consent for Clinical Treatment and Procedures, see *Appendix I*) has been updated to reflect the current VHA HIV testing policy.

Major changes to VHA's informed consent policy regarding HIV testing consist of:

- The elimination of the required signature consent for HIV testing.
- The requirement of verbal informed consent prior to HIV testing and its explicit documentation in CPRS.
- Elimination of the required mandatory HIV pre- and post-test counseling.
- The provision of written informational material to a Veteran prior to HIV testing. These materials are available at <u>www.hiv.va.gov</u>.
- An expansion of the types of practitioners authorized to obtain informed consent.

## Patient Confidentiality and Disclosure of HIV Status

Confidentiality of a patient's health information is protected in the VHA health care system by multiple Federal laws and regulations (see VHA Handbook 1605.1, Privacy and Release of Information). In addition to general health information privacy protections such as those provided by the Health Insurance Portability and Accountability Act (HIPAA), there are multiple confidentiality laws and regulations that are specific to VA and VHA. There are also special protections (described below) for VHA patients' HIV-related information.

Under normal circumstances, access to information contained in a VHA patient's health record is restricted to health care professionals involved in the patient's care and treatment (including non-VA physicians providing care); VA employees and contractors who need it for treatment, payment, or operations purposes; or an insurance company being billed for VHA's services to the patient. Outside of these categories of authorized individuals or entities, this information cannot be released to others (e.g., potential employer, family member) unless the patient provides special written consent for such a release (see *Appendix I* for a link to VA Form 10-5345: Request for and Authorization to Release Medical Records or Health Information).

In addition to these extensive general confidentiality protections, there are additional protections for HIV/AIDS information in a patient's VHA medical records. A federal law, 38 U.S.C. 7332, states that any patient's medical record maintained in connection with the performance of any program or activity (including education, training, treatment, rehabilitation, or research) relating to HIV testing and infection, drug abuse, alcoholism and alcohol abuse, or sickle cell anemia can be disclosed only with the specific written consent of the individual or as permitted by one of the limited exceptions listed in the text box on pages 77-78. Penalties for unauthorized disclosures include a fine of up to \$5,000 for the first offense and up to \$20,000 for each subsequent offense. Unauthorized disclosures also include verbal disclosures. It is important to recognize that as of 2012, this statute applies to HIV testing, regardless of the results; in other words, the fact that a VHA patient has had HIV testing, whether the result is positive, negative, or unknown, cannot be released out of VHA (e.g., to non-VHA health care providers or insurance companies) without the patient's written permission (except for some special situations described in the text box on pages 77-78).

Thus, although VHA can share most medical information with non-VHA clinicians or insurance companies without prior authorization, it cannot legally do so with a patient's HIV-related information unless the patient gives his or her permission in writing. It cannot even reveal the fact that a patient has been tested (regardless of the result) without the patient's written permission. In addition, while general health information about a VHA patient can be shared with family members or others who have a significant personal relationship with the patient, HIV-related information about a patient cannot be shared with family members or others without the patient's written authorization (with one important exception described below).

#### Title 38 U.S.C. Section 7332

38 U.S.C Section 7332 also addresses circumstances under which disclosure of individually identifiable HIV-related health information (including HIV testing) by VHA is allowed (but not necessarily mandated) without the consent of the patient:

- 1. To medical personnel to the extent necessary to meet a bona fide medical emergency.
- 2. To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation; however, such personnel may not disclose patient identities in any report or in any other manner.
- 3. In response to an appropriate request from a proper Federal, state, or local public health authority charged with the protection of the public health and to which Federal or state law requires disclosure of such information, if a qualified representative of such authority has made a written request for that record for a purpose authorized by such law. Such information may not be redisclosed for a purpose other than the one for which the original disclosure was made.

- 4. Where authorized by an appropriate order by a court of competent jurisdiction.
- 5. To a claimant against the VA or their representative.
- 6. If the patient is deceased and a written request for information is made by their next-of-kin or personal representative, but only in connection with survivors' benefits.
- 7. To components of VA providing health care services or benefits to the Veteran.
- 8. Between components of VA providing health care to a Veteran and the Armed Forces.

In addition to the circumstances set forth above, one more notable exception to the disclosure rule is set forth in 38 U.S.C. Section 7332. That section provides that a physician or "professional counselor" may disclose a patient's HIV infection status to the patient's spouse or sexual partner without the patient's consent, but only under the following conditions:

"After the physician or counselor has made a reasonable effort to counsel and encourage the patient to voluntarily provide this information to the spouse or sexual partner, reasonably believes the patient will not provide the information to the spouse or sexual partner, and disclosure is necessary to protect the health of the spouse or sexual partner."

It is also important to understand that even well intended actions can undermine the confidentiality of patient information.

Conversations with colleagues about patients, including their HIV status and risk behaviors, should be confined to the appropriate settings, which do not include public areas in clinical settings

such as hallways, nurses' stations, clinical front desks, or elevators. Even though the patient may remain unnamed throughout the conversation, certain identifying information may inadvertently reveal the identity of the patient.

#### **Educating patients regarding confidentiality**

When meeting with a patient for their first visit, you should explain to them who routinely has (and who does not have) access to their health information. You should emphasize that confidentiality protections for patient information are stricter within VHA than outside of VHA, and even stricter for HIV-related information. You can also clarify the patient's confidentiality rights and the circumstances under which VHA or a VHA provider can disclose their medical information without prior consent. For general (non-HIV-related) information, these circumstances include:

- for treatment, payment, or operations (except for HIV-related information)
- when necessary to protect the life or health of any individual (e.g., homicidal or suicidal intent, sexual or physical abuse of a minor);
- when a VA employee needs to know the information to perform his/her job;
- pursuant to a published routine use in the patient medical records system of records;
- pursuant to a valid request from law enforcement entities;
- when requested by a Congressional oversight committee or subcommittee; or
- pursuant to an order from a court of competent jurisdiction
- to a Congressional office in response to an inquiry from the Congressional office made at the request of the patient (not at the request of a third party, such as a family member).

For information protected under 38 U.S.C. 7332 (including HIV-related information), the only exceptions are those listed in the text box on pages 77-78 and the exception for spouses and sexual partners when the patient has refused to inform them. Without the patient's written authorization, VHA may not release HIV-related information to non-VA clinicians (except in a bona fide medical emergency), insurance companies, or family members.

#### **Partner Notification**

Patients who test HIV positive should be strongly encouraged to inform any sexual or needle-sharing partners of their status.<sup>145</sup> This disclosure process, called partner notification, may result in a patient asking you for advice and/or assistance with informing their partner(s). This assistance may involve you referring the patient to a local/state health department where partner notification services are available (see *Appendix H* for a list of state health department contact information), providing the patient with guidance on disclosure,<sup>\*\*\*\*</sup> and having the patient's partner(s) come to the facility and you being present while the partner is told.

Disclosure of a VHA patient's HIV-positive test result or status can be made to a spouse or sexual partner without the patient's consent only where efforts to have the patient provide such information to their partner have been unsuccessful or when the health of the partner needs protection. It is the professional and ethical responsibility of VHA providers to make use of available partner notification services by contacting the state or local health department in such instances in order to protect the health of the spouse or known sexual partner of a Veteran with HIV (see *Appendix H* for health department contact information).

<sup>\*\*\*\*</sup> Disclosures may be made where the individual who was tested has provided a specific written consent for such disclosure.

Should an HIV-infected Veteran being tested die, a disclosure may be made on the written request of the next of kin, executor, or personal representative if such disclosure is needed by the survivor to obtain benefits.

## HIV Case Reporting to State and Local Health Authorities by VHA Providers

All states have enacted laws requiring reporting of new HIV diagnoses to state or local public health departments. Although VA, as a Federal agency, is not obligated to comply with such state laws, such reporting is both allowed and encouraged. In a 2002 Advisory Opinion, VA's Office of General Counsel held that, "VA providers are not under legal obligation to comply with a state mandatory HIV reporting law. However, in the spirit of cooperation with state and local health authorities, VA providers are allowed and encouraged to comply with those official requests provided appropriate authorities make written requests, and VA regulations concerning release of medical information are followed."<sup>146</sup>

#### **Occupational Exposure and Universal Precautions**

While providing care to patients, you may encounter an exposure (e.g., through blood exposure, needlestick injury, wound care) to infectious pathogens such as HIV and hepatitis C. If you believe such an exposure has occurred, you must follow your facility's protocol for reporting the incident and evaluating and treating the exposed employee following current CDC guidelines. Each VHA facility must develop an occupational exposure protocol, which is readily available to occupational health staff and their surrogates when they are closed. Recommendations on post-exposure prophylaxis (PEP) following an occupational exposure to HIV are promulgated by the U.S. Public Health Service. The most recent PEP recommendations were released in 2005 (available at <u>www.aidsinfo.nih.gov</u>) and when they are updated, will be available at the same AIDSinfo website and in CDC's Morbidity and Mortality Weekly Report (<u>www.cdc.gov/mmwr</u>). In addition, the National HIV/AIDS Clinicians' Consultation Center operates PEPline, The National Clinicians' Post-Exposure Prophylaxis Hotline (1-888-448-4911). The hotline provides clinicians who manage occupational exposures with expert guidance on the treatment of healthcare worker exposure to HIV, hepatitis B and hepatitis C.

VHA has developed policy on testing a source patient when an occupational exposure has occurred. Stated in VHA Handbook 1004.01: Informed Consent for Clinical Treatments and Procedures:

#### f. Consent for Testing of a Source Patient after an Occupation Exposure

1. When an employee is inadvertently exposed to a patient's bodily fluids, tissues or excretions (e.g., blood, urine, sweat, saliva, pus, fecal matter) there may be transmission of infectious pathogens (e.g., HIV, Hepatitis C, Hepatitis B, MRSA), contaminants (e.g., radiated isotopes), toxins, or other agents. When such an occupational exposure occurs, optimal treatment for the employee may depend upon the source patient's medical condition(s). Testing to determine the source patient's medical condition(s) may only be performed with the source patient's (or surrogate's) explicit informed consent and that consent must be documented according to procedures as outlined in subparagraph 13c. Source patients have the right to refuse testing or procedures requested for the purposes of diagnosis or treatment of employees who have experienced an occupational exposure.

- 2. Informed consent for source patient testing may <u>only</u> be obtained after the occupational exposure has occurred. Consent may not be obtained prospectively, i.e., in case of a hypothetical or potential occupational exposure. For example, prior to a surgical procedure, patients may not be asked to provide consent to undergo Hepatitis C testing that might be needed if a member of the surgical team experiences a needlestick injury during the upcoming surgical procedure.
- 3. To prevent coercion or undue influence on the source patient, informed consent for testing of a source patient after an occupational exposure must be performed by an employee who does not have a personal relationship with the exposed employee (e.g., friend, family member, former spouse) and, whenever possible, by an employee who is not professionally related to the employee or patient. The exposed employee may never seek consent from the source patient without incurring consequences.

In addition to occupational exposure protocols, each VHA facility has standardized universal precautions, which are safety measures designed to prevent transmission of HIV, hepatitis B, and other bloodborne pathogens when providing health care or first aid.

Universal precautions involve the use of protective barriers such as gloves, gowns, aprons, masks, and/or protective eyewear, which reduce the risk of exposure of potentially infectious materials to the health care worker's skin or mucous membranes. In addition, it is recommended that all health care workers take precautions to prevent injuries caused by needles, scalpels, or other sharp instruments. According to CDC, universal precautions apply to blood; other body fluids containing visible blood; semen; and vaginal secretions. Universal precautions also apply to tissues and to the following fluids: cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids. Unless they contain visible blood, universal precautions do not apply to feces, nasal secretions, sputum, sweat, tears, urine, or emesis. Universal precautions do not apply to saliva except when visibly contaminated with blood or in dental settings where blood in saliva is common.

## **HIV Standard of Care**

VHA holds its providers accountable to the provision of the highest quality HIV care and treatment available. In order to meet this standard, VHA follows the most current DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents<sup>††††</sup> and has developed the Primary Care of Veterans with HIV<sup>‡‡‡‡</sup> clinical manual for VHA providers.

<sup>++++</sup> DHHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents retrieved from <u>http://aidsinfo.nih.gov/Guidelines</u>

**<sup>‡</sup>‡‡‡‡‡¥‡¥WHA Primary Care for Veterans with HIV retrieved from** <u>*www.hiv.va.gov/provider/*</u><u>*manual-primary-care/index.asp*</u>

## VI.

## Investigational HIV Prevention Interventions

Thirty years into the U.S. HIV epidemic, existing HIV prevention strategies continue to be refined while new strategies evolve based on research and real life application. VHA staff specializing in HIV prevention, HIV care and treatment, and policy monitor these developments for possible VHA implementation. Five promising prevention interventions under investigation are detailed in this section.

#### Vaccines

A fundamental component of the arsenal needed to bring the pandemic under control and ultimately, end it, is an HIV vaccine. At this time, there is no vaccine that prevents (preventive vaccine) or cures (therapeutic vaccine) HIV/AIDS. Research on the development of an HIV vaccine began immediately following the disease's discovery and receives support from the National Institutes of Health (NIH), the U.S. military, private companies, foundations, and research centers throughout the world.

As of 2011, the most hopeful vaccine research has come from the RV144 vaccine trial sponsored by the U.S. Military HIV Research Program. In 2009, this phase III clinical trial, consisting of more than 16,000 participants and taking place in Thailand, found its vaccine regime to be "safe and modestly effective in preventing HIV infection."<sup>147</sup> Researchers reported a 31% lower rate of HIV acquisition among the vaccine group, compared to the placebo group.<sup>148</sup>

For further information on HIV vaccine research, please visit:

- CDC HIV Vaccine Unit, <u>www.cdc.gov/hiv/topics/research/</u> vaccine\_unit/index.htm
- DHHS, http://sis.nlm.nih.gov/hiv/vaccine.html
- NIH, <u>www.niaid.nih.gov/topics/hivaids/research/vaccines/Pages/</u> <u>default.aspx</u>
- HIV Vaccine Trials Network, <u>www.hvtn.org/</u>
- International AIDS Vaccine Initiative, <u>www.iavi.org</u>

## Non-Occupational Post-Exposure Prophylaxis

Non-occupation post-exposure prophylaxis (nPEP) consists of providing ART to HIV-negative individuals after they may have been exposed to HIV during sexual activities and/or injection drug use.<sup>149</sup>

Findings from research on animal models and individuals receiving prophylaxis after an occupational exposure and during perinatal transmission have indicated that nPEP "might sometimes reduce the risk for HIV infections after nonoccupational exposure."<sup>150</sup> In one of the most-often cited studies, health care workers who sustained percutaneous exposure to HIV-infected blood and were promptly given zidovudine, experienced an approximately 81% decrease in the risk of HIV transmission.<sup>151</sup>

In order to determine if ART should be initiated in an individual who has experienced a non-occupational exposure, DHHS recommends an evaluation based on "the HIV status of the potentially exposed person, the timing and characteristics of the most recent exposure, the frequency of exposures to HIV, the HIV status of the source, and the likelihood of concomitant infection with other pathogens or negative health consequences of the exposure event."<sup>152</sup>

In 2005, DHHS issued the following nPEP recommendations: 5555

 For persons seeking care ≤72 hours after nonoccupational exposure to blood, genital secretions, or other potentially infectious body fluids of a person known to be HIV infected, when that exposure represents a substantial risk for transmission, a 28-day course of highly active antiretroviral therapy (HAART) is recommended. Antiretroviral medications should be initiated as soon as possible after exposure.

<sup>§§§§</sup> The DHHS algorithm for evaluating use of nPEP is found in Appendix M.

#### INVESTIGATIONAL HIV PREVENTION INTERVENTIONS

- For persons seeking care ≤72 hours after nonoccupational exposure to blood, genital secretions, or other potentially infectious body fluids of a person of unknown HIV status, when such exposure would represent a substantial risk for transmission if the source were HIV infected, no recommendations are made for the use of nPEP. Clinicians should evaluate risks and benefits of nPEP on a case-by-case basis.
- For persons with exposure histories that represent no substantial risk for HIV transmission or who seek care >72 hours after exposure, DHHS does not recommend use of nPEP.
- Clinicians might consider prescribing nPEP for exposures conferring a serious risk for transmission, even if the person seeks care >72 hours after exposure if, in their judgment, the diminished potential benefit of nPEP outweighs the risk for transmission and adverse events.
- For all exposures, other health risks resulting from exposure should be considered and prophylaxis administered when indicated.
- Risk-reduction counseling and indicated intervention services should be provided to reduce the risk for recurrent exposures."<sup>153</sup>

For further information on nPEP, visit HRSA's Guide for HIV/AIDS Clinical Care at <u>http://hab.hrsa.gov/deliverhivaidscare/clinicalguide11/</u> <u>cg-302 nonoccupational pep.html</u>. For information on PEP, contact the National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) at 1-888-448-4911 and <u>http://www.nccc.ucsf.edu</u>.

## Pre-Exposure Prophylaxis

In May 2012, the U.S. Food and Drug Administration (FDA) announced its support of the medication Truvada® for use as pre-exposure prophylaxis (PrEP). PrEP involves an HIV-negative individual at high risk for HIV infection taking an oral medication, in this case antiretroviral medication, on a daily basis in order to reduce their risk of becoming HIV infected.

The IPrEx study examined the use of PrEP among 2,499 adult MSM and transgender women who were HIV negative at study enrollment. Sponsored by the National Institute of Allergy and Infectious Diseases, the IPrEx study began in 2007 and took place in 11 international sites. Study participants were randomly assigned to receive either a combination tablet of tenofovir and emtricitabine (TFV/FTC) or a placebo tablet. The combination TFV/FTC tablet is an existing FDA-approved antiretroviral medication marketed under the trade name Truvada<sup>®</sup>. All study participants were provided with HIV prevention support services including counseling on safer sex practices, condoms, and treatment for STIs.

Of the 100 participants who became HIV infected during the course of the study, 64 received the placebo and 36 received TFV/FTC. This finding represents a 44% reduction in the incidence of HIV among the participants receiving PrEP and HIV prevention support services. In addition, those participants who adhered to the TFV/FTC regimen for 90% or more days prescribed experienced increased efficacy resulting in almost 73% fewer HIV infections.<sup>154</sup>

The TDF2 study and the Partners PrEP study both released findings in 2011 on the role of PrEP in preventing HIV transmission through heterosexual sex. TDF2 found that use of Truvada<sup>®</sup> reduced the risk of HIV infection by approximately 63%<sup>155</sup> while Partners PrEP found the use of Truvada<sup>®</sup> and tenofovir (trade name Viread<sup>®</sup>) significantly reduced HIV transmission among serodiscordant heterosexual couples.<sup>156</sup>

Based on research findings, CDC has begun development of U.S. Public Health Service guidelines on PrEP use. CDC is examining the critical elements of such guidelines, which include:<sup>157</sup>

- Populations for which PrEP is recommended, based on data from clinical trials
- Procedures for assessing the appropriateness of PrEP for individual patients, including initial screening for risk, existing HIV infection, and other health conditions
- Specific drugs and dosing for PrEP based on data from clinical trials
- Necessary support services to ensure adherence to PrEP
- Needed risk-reduction counseling to be delivered in conjunction with PrEP, as well as referrals and/or transition to other interventions
- Monitoring for side effects, clinical toxicities, HIV infection and possible drug resistance among those who become infected

While these guidelines are being developed, CDC has released interim guidance on PrEP use among MSM. This guidance can be found at <u>www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a1.htm?s</u> <u>cid=mm6003a1\_w</u>

#### For more information on PrEP, visit:

- CDC, <u>www.cdc.gov/hiv/prep</u>
- TDF2 study, <u>www.cdc.gov/botusa/HIV-Research.htm</u>
- Partners PrEP Study, <u>www.uwicrc.org</u>

## Microbicides

The development and widespread availability of effective microbicides will give women and men a personally controlled means to decrease their risk for HIV acquisition. Microbicides come in the form of gels, films or suppositories that can kill or neutralize viruses and bacteria.<sup>158</sup> Research has concentrated on the use of these gels in the vagina and rectum to inhibit HIV transmission. For women, whose main mode of HIV transmission is heterosexual contact, a prevention tool that can be used without the knowledge of their sexual partner(s), such as a microbicide, offers them a chance to better control their sexual health.

Of note is the successful CAPRISA 004 study that demonstrated that women who used a microbicide gel experienced 39% fewer HIV infections than a placebo gel group.<sup>159,160</sup> In this study, tenofovir, an antiretroviral medication in the form of a vaginal gel, was made available to HIV-negative, sexually active female participants. In women who had high adherence to gel use, the risk of acquiring HIV was reduced by 54%.

For more information on the state of microbicide research, visit the NIH-funded Microbicide Trials Network (MTN) at <u>www.mtnstopshiv.org</u>.

## Adult Male Circumcision

Researchers are determining if male circumcision can significantly reduce HIV transmission and other STIs. Thus far, the majority of male circumcision studies have focused on the transmission of HIV from females to males during penile-vaginal sex. In a systematic review and meta-analysis of 27 such studies conducted in Africa, the relative risk for HIV infection was 44% lower in circumcised men and an even lower relative risk was noted in circumcised men considered at high risk for HIV infection.<sup>161</sup>

Research focused on MSM circumcision has not proved as promising. Such a study in Peru and the United States concluded that "circumcision does not have a significant protective effect against HIV acquisition among MSM from Peru and the US, although there may be reduced risk for men who are primarily insertive with their male partners. This association needs to be investigated across diverse cohorts of MSM."<sup>162</sup>

The current CDC guidance on male circumcision states that "individual men may wish to consider circumcision as an additional HIV prevention measure, but they must recognize that circumcision...

- does carry risks and costs that must be considered in addition to potential benefits;
- 2. has only proven effective in reducing the risk of infection through insertive vaginal sex; and
- confers only partial protection and should be considered only in conjunction with other proven prevention measures (abstinence, mutual monogamy, reduced number of sex partners, and correct and consistent condom use)."<sup>163</sup>

CDC is expected to release recommendations on male circumcision in the near future.

For further information on the role of male circumcision in HIV prevention, visit <u>www.cdc.gov/hiv/resources/factsheets/circumcision.htm</u>.

VII.

\*\*\*\*\*\*

## Appendices

## Appendix A:

Sexual Health Questionnaire, New York City Department of Health and Mental Hygiene

		Medical Record #:		Date:		
ate of Birth: / / Sex: ge:M/F/T	Females GYN: G LMP Normal: YES	/ NOMenarche		018: # p term # a	eregnancie abortions	
ey Message for Patient						
EXUAL ACTIVITY	Circle the answer					
Sexual health is an important part of general health, so I always talk to my patients about it. If it's okay with you, I'd like to ask you some questions now.	Currently sexually a	ictive	Yes	No		
	Sexually active eve	r	Yes	No		
	Sexual partners	Sexual partners		Women	Both	
	Type of sexual activ	Type of sexual activity		Anal	Oral Set	
ONTRACEPTION	Circle or fill in the a	Inswer				
If you are not interested in becoming pregnant soon, regular use of safe and effective contraception is important. Many effective methods are available according to your health status and risk factors, as well as your personal preference.	Pregnancy/Fatherto		Yes	No		
	Contraception (birth If yes, what meth		Yes	No		
	If no contraception	used, why				
	Method satisfaction	Method satisfaction		Somewhat Satisfied	Not Satist	
		Interested in a different contraception method If yes, indicate type		No		
		Knowledge of emergency contraception ("morning-after") pill		No		
	Emergency contract	Emergency contraception use ever		No		
IV / STD HISTORY	Circle or fill in the a	mawer				
No matter what form of birth control you choose, always use latex or polyurethane male condoms or female condoms to prevent HIV and other sexually transmitted diseases (STDs).	Condom use in pas	t last year	Always	Sometimes	Neve	
	Condom use with la	st sexual activity	Yes	No		
	Type of condoms up		Male	Female		
	Diagnosis of HIV or Most recent HIV to HIV status Other STD(s)		Yes Date: +	No / / -	Unkn	
	Treated for HIV or o	ther STD(s)	Yes	No		
	Partner history of H If yes, which one	IV or other STD(s)	Yes	No		
	Has your current par tested for HIV If yes, result if know		Yes +	No 	Unkn	
COUNSELING AND RISK REDUCTION	PROVIDER NOTES					
ontraception Methods/Condom Use						
mergency Contraception						
IV/STD risk reduction						

# Appendix B: Substance Use Assessment Instruments

# Alcohol Use Disorders Identification Test (AUDIT-C)

Please circle the answer that is correct for you.

- 1. How often do you have a drink containing alcohol?
  - (0) Never
  - (1) Monthly or less
  - (2) Two to four times a month
  - (3) Two to three times a week
  - (4) Four or more times a week
- 2. How many drinks containing alcohol do you have on a typical day when you are drinking?
  - (0) 1 or 2
  - (1) 3 or 4
  - (2) 5 or 6
  - (3) 7 to 9
  - (4) 10 or more
- 3. How often do you have six or more drinks on one occasion?
  - (0) Never
  - (1) Less than monthly
  - (2) Monthly
  - (3) Weekly
  - (4) Daily or almost daily

## SCORING AUDIT:

Add scores from all three items.

Score > 4 - In hepatitis C infected patients, we recommend that a score > 4 be used as an indicator for further assessment of substance use. Note that in the general population, a score > 8 indicates a high likelihood of hazardous use or dependence and requires obtaining additional substance use history or offer of referral.

## **Drug Use Questionnaire**

1. Please indicate how often you have used each of the following drugs in your lifetime:

Drug	Never Used (Y/N)	Used 1-5 times (Y/N)	Used more than 5 times (Y/N)	Year last used	Used in last 6 months (Y/N)
Marijuana/hashish					
Cocaine					
Methamphetamine/ speed					
Heroin					
LSD/PCP					
Ecstasy/MDMA					

2. Have you ever injected any drugs, even once?

□ Yes

3. Have you ever used prescription drugs such as painkillers or sedatives for non-medical purposes?

🗆 Yes

□ No

4. Have you ever had treatment for alcohol or drug dependence?

🗆 Yes

□ No

- a. If yes, how many times?
- b. Last time treated?

## SCORING THE DRUG USE QUESTIONNAIRE:

Question 1: Positive if any drug used >5 times in life or any drugs used in past year Questions 2-4: Any yes is positive A positive screen requires 1 item be positive

If any of the instruments are positive, obtain additional substance use history through interview or refer to a SUD treatment practitioner (for more information, see the VA/DOD Clinical Practice Guidelines for the Management of Substance Use Disorders, at <u>www.healthquality.va.gov/</u> Substance Use Disorder SUD.asp).

# Appendix C: HIV/AIDS Basics

## What is HIV?

HIV stands for the human immunodeficiency virus:

- H-Human. This virus infects human beings.
- I Immunodeficiency. This virus attacks a person's immune system. The immune system is the body's defense against infections, such as bacteria and viruses. Once attacked by HIV, the immune system becomes deficient and doesn't work properly.
- V-Virus. A virus is a type of germ too small to be seen even with a microscope.

HIV is a virus. Some viruses, like the ones that cause colds or flu, stay in the body for only a few days. HIV, however, never goes away. A person who is infected with HIV is said to be "HIV positive." Once a person is HIV positive, that person will always be HIV positive.

## What does the virus do?

All viruses must infect living cells to reproduce. HIV takes over certain immune system cells that are supposed to defend the body. These cells are called CD4 cells, or T cells.

When HIV takes over a CD4 cell, it turns the cell into a virus factory. It forces the cell to produce thousands of copies of the virus. These copies infect other CD4 cells. Infected cells don't work well and die early. Over time, the loss of CD4 cells weakens the immune system, making it harder for the body to stay healthy.

## What is AIDS?

AIDS was first reported in the United States in 1981 and has since become a major worldwide epidemic. AIDS stands for acquired immunodeficiency syndrome:

- A-Acquired. This condition is acquired, meaning that a person becomes infected with it.
- I –Immuno. This condition affects a person's immune system, the part of the body that fights off germs such as bacteria or viruses.
- D-Deficiency. The immune system becomes deficient and does not work properly.
- S –Syndrome. A person with AIDS may experience other diseases and infections because of a weakened immune system.

AIDS is the most advanced stage of infection caused by HIV. Most people who are HIV positive do not have AIDS. An HIV-positive person is said to have AIDS when his or her immune system becomes so weak it can't fight off certain kinds of infections and cancers.

Even without one of these infections, an HIV-positive person is diagnosed with AIDS if his or her immune system becomes severely weakened. This is measured by a lab test that determines the number of CD4 cells a person has. A CD4 cell count less than 200 in an HIV-infected person counts as a diagnosis of AIDS. It can take between 2 to 10 years, or longer, for an HIV-positive person to develop AIDS, even without treatment.

## How is HIV spread?

HIV is spread though four body fluids:

- semen
- vaginal fluid
- blood
- breast milk

HIV is **NOT** spread through:

- tears
- sweat
- feces
- urine

## How is HIV spread through sex?

You can get infected from sexual contact with someone who is infected with HIV. Sexual contact that can transmit HIV includes:

- vaginal sex (penis in the vagina)
- anal sex (penis in the anus of either a man or a woman)
- oral sex (penis in the mouth)

If you have sex, the best thing to do is to practice "safer sex" all the time. To do so, always use a condom, dental dam, or other latex barrier and avoid "rough sex" or other activities that might cause bleeding. If you use lube with a condom, make sure it is water based, not oil-based. Oil-based lube causes latex condoms to break. See more tips for using condoms.

If you have unprotected sex with someone who is infected, it doesn't mean that you will be infected, too. But there is always a chance. Using a condom reduces your risk.

## HIV is NOT spread by:

- hugging or massage
- masturbation
- fantasizing
- dry kissing
- phone sex
- cyber sex
- sex toys you don't share
- · daily living with someone who has HIV

## How is HIV spread through blood?

You can become infected if you have contact with the blood of someone who is infected with HIV. Blood-borne infection with HIV can occur through:

- sharing needles when shooting drugs
- · tattoos or body piercings with unsterilized needles
- accidental needle sticks
- blood transfusions
- splashing blood in your eyes

## HIV is NOT spread by blood passed through insect bites.

*Note*. From U.S. Department of Veterans Affairs. *HIV/AIDS Basics* (modified). Retrieved from <u>www.hiv.va.gov/patient/index.asp</u>

Appendix D: Behavioral Change Theories and Models Transtheoretical Model of the Stages of Change Theory & Motivational Interviewing

# **Transtheoretical Model of the Stages of Change Theory**

Developed in 1982, the Transtheoretical Model of the Stages of Change Theory originally focused on determining the behavioral change stage of cigarette smokers so they could be offered an appropriate smoking cessation intervention. This theory has successfully served as the basis of multiple HIV prevention interventions recognized by the CDC as "best evidence interventions."<sup>1111</sup> Interventions using this theory help identify personal risk factors and barriers to risk reduction. Results from interventions using this model have shown significantly lower rates of new STIs and increased rates of condom use.<sup>164</sup>

The theory consists of 5-6 stages an individual faces when addressing a behavioral change. These stages do not occur in a linear fashion, but a cyclical one<sup>165</sup> and consist of:

• **Precontemplation:** At this stage, the person has no intention of changing the behavior (i.e., never uses condoms) in the near future. Authors of the theory state that many individuals at this stage do not recognize their behavior as a problem. If the person expresses no intention to change their behavior within the next six months, they are termed a precontemplator.<sup>166</sup>

**<sup>1111</sup>** According to the CDC, "best-evidence HIV behavioral interventions include interventions that have been rigorously evaluated and have shown significant effects in eliminating or reducing sex- or drug-related risk behaviors, reducing the rate of new HIV/STD infections, or increasing HIV-protective behaviors. These interventions meet the Prevention Research Synthesis (PRS) efficacy criteria for best evidence and are considered to provide the strongest scientific evidence of efficacy." Retrieved from www.cdc.gov/hiv/topics/research/prs/print/best-evidence-intervention.htm.

- **Contemplation:** This stage involves identification by the person that they want to change the behavior, but no commitment has been made to this change. An individual could be in this stage for an extended period of time (i.e., 18 months). During this time they may examine the pros and cons of behavior change and the effort it will take to address it.<sup>167</sup>
- **Preparation:** "is a stage that combines intention and behavioral criteria...Individuals in this stage are intending to take action in the next month and have unsuccessfully taken action in the past year...Although they have made some reductions in their problem behaviors, individuals in the preparation stage have not yet reached a criterion for effective action, such as abstinence from smoking, alcohol abuse, or heroine use."<sup>168</sup>
- Action: "is a stage in which individuals modify their behavior, experiences, or environment in order to overcome their problems. Action involves the most overt behavioral changes and requires considerable commitment of time and energy."<sup>169</sup>
   A person is considered to be in the action stage if they can successfully alter their problem behavior for a period of one day to six months.<sup>170</sup>
- **Maintenance:** At this stage, an individual should be free of the problem behavior for more than six months."<sup>171</sup> In the maintenance stage, people work to prevent relapse and consolidate the gains attained during action. <sup>172</sup>
- **Termination:** While not reflected in all of the literature, termination is considered a sixth stage. Here, a person is "presumed to have no temptation to relapse and a complete sense of self-efficacy concerning their ability to maintain healthy behavior."<sup>173</sup>

Relapse is the norm for most attempts at behavior change.<sup>174</sup> Relapse is more likely to occur during the action stage<sup>175</sup> than the maintenance stage although maintainers can experience temptations to relapse for years.<sup>176</sup>

## **Motivational Interviewing**

Motivational interviewing (MI) is another method used to help an individual recognize and evaluate behaviors that may put him/ her at risk for HIV acquisition or transmission.<sup>177</sup> It has been defined as "a collaborative, person-centered form of guiding to elicit and strengthen motivation for change."<sup>178</sup> When applied to HIV prevention behavioral counseling, it has been shown to reduce HIV sexual risk behaviors associated with HIV acquisition or transmission.<sup>179</sup> Many MI interventions are short enough (5-10 minutes) that they can be delivered during a routine clinical encounter.<sup>180</sup>

MI involves conversations between a provider-patient/ counselor-client that focus on how the patient feels about making changes in their life. Highlighting ambivalence is a key target of this intervention as this is most often what a patient feels about changing risky behavior. It is through collaborative conversations between the patient and provider that an exploration of ambivalence and an emphasis on patient's strengths can help foster intrinsic motivation to change risky behavior.<sup>181</sup> Activities associated with MI include:<sup>182,183</sup>

- Respecting autonomy, such as by asking permission to discuss health behaviors
- Collaborative, empathetic and non-judgmental interactions about patient's behavior change goals
- Evoking ideas, needs, values, reasons, abilities around behavior change from the patient. Open questions and reflections are helpful for this.
- Understanding patient goals
- Helping the patient personalize his/her risk
- Increasing the patient's "strength of expressed motivation for a target behavior change"
- Discussing the patient's idea of their own longevity (i.e., connecting personal determination to one's wishes for longevity)
- Providing personal risk feedback
- Exploring readiness for action
- Rolling with resistance to change, and leaving the door open for future discussions

Appendix E: Examples of HIV Prevention Behavioral Interventions

There are a number of primary and secondary HIV prevention interventions that target behavioral change. Below is a brief sample of such interventions and most are found in CDC's Compendium of Evidence-based HIV Prevention Interventions found at <u>www.cdc.gov/</u> <u>hiv/topics/research/prs/compendium-evidence-based-interventions.htm</u>.

## Partnership for Health Intervention\*\*\*\*\*,184

- Target population: HIV-positive men and women
- **Goal:** Eliminate or reduce unprotected anal or vaginal sex
- Effectiveness: Significant reduction in unprotected anal and vaginal sex among patients who had two or more sexual partners<sup>185</sup>
- Activities: Providers talk briefly (3-5 minutes) with patients using prompts such as educational posters and informational brochures (available in English and Spanish) over a number of office visits, and focus on self-protection, partner protection, and disclosure<sup>186</sup>
- Intervention preparation: 4-hour training program for providers that helps them develop skills to talk with their patients about safer sex during regular office visits

# Healthy Living Project<sup>187</sup>

• **Target population:** HIV-positive individuals at risk of transmitting HIV

<sup>\*\*\*\*\*</sup> For further information on this intervention and training opportunities, visit The Diffusion of Effective Behavioral Interventions (DEBI) project at <u>www.</u> <u>effectiveinterventions.org/en/HighImpactPrevention/Interventions/PfH.aspx</u>

- **Goal:** To reduce transmission behaviors up to 25 months post-intervention
- **Effectiveness:** Reduced transmission overall at 20-month follow-up
- Activities: This intervention included 15, 90-minute individual counseling sessions, grouped into three modules of five sessions each, with a 3-month break between each module. The modules included coping skills, reducing transmission, and improving health outcomes

# HIV Prevention for Gay and Bisexual Men Receiving Hepatitis B Vaccination<sup>188</sup>

- **Target population:** Gay and bisexual men receiving a hepatitis B vaccination at a municipal health clinic
- **Goal:** Reduce unprotected anal intercourse among the target population
- Effectiveness: Reduced unprotected sexual intercourse
- Activities: An individually-tailored 15-minute counseling session

# Brief Alcohol Intervention for Needle Exchangers (BRAINE) <a href="http://www.englishift.isy">ttt://www.englishift.isy</a>

- **Target population:** Active injection drug users who also have heavy alcohol use (originally offered in a needle exchange program setting and it potentially effective in other settings)
- Goal: Reduce alcohol use and reduce or eliminate IDU use
- **Effectiveness:** Among participants receiving two 60-minute sessions, it reduced sharing of injection equipment

<sup>+++++</sup> For further information on BRAINE, contact Dr. Michael D. Stein, Division of General Internal Medicine, Rhode Island Hospital, 593 Eddy Street, Providence, RI 02903, <u>mstein@lifespan.org</u>

• Activities: BRAINE is an individual-level intervention consisting of two 60-minute sessions offered approximately two months apart. Using motivational interviewing, the counselor and client assess the client's risk behaviors, personal motivation to change, and barriers to changes; and develop a "change plan."

## **Positive STEPs**

- Target population: HIV medical providers
- **Goal:** Implementing risk-reduction interventions with HIV-positive patients in clinical settings
- Effectiveness: Significant improvement in providers successfully implementing risk reduction interventions, which resulted in decreased sexual risk behavior
- Activities: Administration of 9-question behavioral screener; provider-initiated discussion of safer sex and drug use behavior; risk-reduction planning; giving brochures with prevention messages and strategies to patients, availability of patient educational materials in exam rooms and clinic waiting rooms
- Intervention preparation: 4-hour intervention training for HIV medical providers and staff focused on enhancing communication skills, practicing brief behavioral counseling, and delivering prevention message. Booster training is provided at 1-2 months post-intervention.

# Appendix F: Condom Use Guidance

## Male Condom Guidance<sup>190,191,192,193</sup>

- Condoms should be stored in a cool, dry place out of direct sunlight and should not be used after the expiration date.
   Condoms in damaged packages or condoms that show obvious signs of deterioration (e.g., brittleness, stickiness, or discoloration) should not be used regardless of their expiration date.
- Carefully handle the condom to avoid damaging it with fingernails, teeth, or other sharp objects.
- Use latex or polyurethane condoms, not natural skin condoms. Research shows that HIV can pass through natural skin condoms.
- Use a new condom for every act of vaginal and anal sex throughout the entire sex act (from start to finish).
- Put the condom on before genital contact as pre-ejaculatory fluid, which comes from the penis, may contain HIV.
- Put the condom on the tip of the erect penis with the rolled side out.
- If a penis is uncircumcised, pull back the foreskin before putting on the condom.
- If the condom does not have a reservoir tip, pinch the tip enough to leave a half-inch space for semen to collect. Holding the tip, unroll the condom all the way to the base of the erect penis.
- Ensure that adequate lubrication is used during vaginal and anal sex, which might require use of water-based lubricants (e.g., Astroglide). Oil-based lubricants (e.g., petroleum jelly, shortening, mineral oil, massage oils, body lotions, and

cooking oil) should not be used because they can weaken latex, causing breakage.

- If you feel the condom break at any point during sexual activity, stop immediately, withdraw, remove the broken condom, and put on a new condom.
- Do not use two male condoms or a male condom along with a female condom. If the two condoms rub together, the friction between them can cause the male condom to be pulled off, the female condom to be pushed in, or either condom to break.
- After ejaculation and before the penis gets soft, grip the rim of the condom and carefully withdraw. Then gently pull the condom off the penis, making sure that semen does not spill out.
- Wrap the condom in a tissue and throw it in the trash where others will not handle it.

# Female Condom<sup>#####</sup> Guidance<sup>194,195</sup>

- Condoms should be stored in a cool, dry place out of direct sunlight and should not be used after the expiration date. Condoms in damaged packages or condoms that show obvious signs of deterioration (e.g., brittleness, stickiness, or discoloration) should not be used regardless of their expiration date.
- Carefully handle the condom to avoid damaging it with fingernails, teeth, or other sharp objects.
- Do not use a female condom with a male condom.
- Do not use a female condom with a diaphragm.

**<sup>‡‡‡‡‡</sup>** Currently the only FDA-approved female condom available is the FC2, manufactured by the Female Health Company. FC2 is available under the VHA national formulary.

- The condom can be inserted up to eight hours before sex.
- Use a new condom for each act of sexual intercourse.
- Put the condom in before genital contact as pre-ejaculatory fluid, which comes from the penis, may contain HIV.
- Inspect the condom and make certain it is completely lubricated on the outside and the inside. Add water-based lubricant onto the penis and/or the inside of the female condom to increase comfort and decrease noise. It is important to use enough lubricant so that the condom stays in place during sex. If the condom is pulled out or pushed in, that is an indicator that there is not enough lubricant.
- The female condom is inserted into the vagina with fingers, much like a tampon that has no applicator. To do so:
  - a. Hold the condom at the closed end and squeeze the flexible inner ring with thumb and middle finger so it becomes long and narrow. With the other hand, separate the outer lips of the vagina. Gently insert the inner ring end as far into the vagina as possible, using the index finger to push up the inner ring until the finger reaches the cervix (similar to how a diaphragm would be inserted).
  - b. Before having intercourse, make certain the condom is in place. When in place, it will cover the opening of the cervix and line the vaginal walls. A general indicator of correct insertion is that the individual will no longer feel the ring.
  - c. The open end of the condom must always remain outside the vaginal opening. Before having intercourse, make certain that the condom is straight and not twisted.

- If you feel the condom break at any point during sexual activity, stop immediately, remove the broken condom, and put in a new condom.
- If the penis is inserted outside the condom pouch or if the outer ring (open ring) slips into the vagina, stop and take the condom out. Insert a new condom before you start sex again.
- To remove the condom, twist the outer ring and gently pull the condom out to avoid any spillage.
- Wrap the condom in a tissue and throw it in the trash where others will not handle it.

# Dental Dam Guidance<sup>196</sup>

A dental dam is a square piece of latex that can help prevent contact with body fluids present during oral sex. An alternative to using a dental dam would be to cut open a male latex condom or a female condom to make a barrier.

- A dental dam should be used for each act of oral sex; it should never be reused.
- To use a dental dam, first check it visually for any holes.
- If the dental dam has cornstarch on it, rinse this off with water (starch in the vagina can cause an infection).
- Cover the women's genital area with the dental dam.
- For oral-anal sex, cover the opening of the anus with a new dental dam.

# Appendix G: Condom Use Negotiation Guidance

## How to talk with your partner about condoms and safer sex

Sometimes people don't like to use protection for sex, so it can be helpful to think about how you might respond if you're ever with a partner who doesn't want to use a condom. Remember, you have a right to protect yourself and your health, and using condoms is a way to take care of your partner too – so you're not being selfish at all.

Talk this over with your partner before you start to have sex. The two of you might even want to select and buy condoms together. When it's hot and heavy it might be easy to have sex without a condom "just this once."

Plan ahead and have condoms with you if you think you might want to have sex. Don't rely on your partner to have condoms.

A partner might have specific reasons for not wanting to use condoms. Look over this list to get ideas about how to respond if you ever feel pressured to have sex without a condom:

• "I don't have any kind of disease! Don't you trust me?"

"Of course I trust you, but anyone can have an STI and not even know it. This is just a way to take care of both of us."

• "I don't like sex as much with a rubber. It doesn't feel the same."

"This is the only way I feel comfortable having sex but believe me, it'll still be good even with protection! And it lets us both just focus on each other instead of worrying about all that other stuff..."

"I'm [or you're] on the pill."

"But that doesn't protect us from STIs, so I still want to be safe, for both of us."

"I didn't bring any condoms."

" I have some, right here."

"I don't know how to use them."

" I can show you – want me to put it on for you?"

"Let's just do it without a condom this time."

"It only takes one time to get pregnant or to get an STI. I just can't have sex unless I know I'm as safe as I can be."

"No one else makes me use a condom!"

"This is for both of us...and I won't have sex without protection. Let me show you how good it can be – even with a condom."

*Note.* Reprinted with permission from the American Social Health Association (ASHA). Retrieved from <u>www.ashastd.org/std-sti/condoms/talking-with-a-partner-about-condoms.html</u>. For more information on ASHA, visit <u>www.ashastd.org</u>.

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# Appendix I: VA HIV Policy and Guidance Resources

## Directives

VHA Directive 2009-036: Testing for Human Immunodeficiency Virus in Veterans Health Administration Facilities <a href="http://www1.va.gov/vhapublications/ViewPublication.asp?pub\_ID=2056">www1.va.gov/vhapublications/ViewPublication.asp?pub\_ID=2056</a>

VHA Directive 2008-082: National HIV Program www1.va.gov/vhapublications/ViewPublication.asp?pub\_ID=1811\_

VHA Directive 2009-019: Ordering and Reporting Test Results <a href="http://www.va.gov/vhapublications/ViewPublication.asp?pub\_ID=1864">http://www.va.gov/vhapublications/ViewPublication.asp?pub\_ID=1864</a>

VHA Directive 2011-023: Guidelines for the Use of Antiretroviral Agents and the Prevention and Treatment of Opportunistic Infections in HIV-infected Adults and Adolescents

http://vaww1.va.gov/vhapublications/ViewPublication.asp?pub\_ID=2414

VHA Directive 2008-003: Treatment of Antiretroviral Induced Facial Lipoatrophy in Human Immunodeficiency Virus (HIV) Infected Patients

www1.va.gov/vhapublications/ViewPublication.asp?pub\_ID=1640

VHA Directive 2007-022: National Hepatitis C Program www1.va.gov/vhapublications/ViewPublication.asp?pub\_ID=1586

# **Informational Letters**

VHA Informational Letter 10-2001-012: Access to Condoms as HIV Prevention <u>http://vaww.hiv.va.gov/policy-index.asp</u> <u>http://vaww.vhaco.va.gov/pubarchives/docs/10200112.DOC</u> VHA Informational Letter 10-2001-002: Case Reporting of Human Immunodeficiency Virus (HIV) to State and Local Health Authorities by VA Facilities and Providers

http://vaww.vhaco.va.gov/pubarchives/docs/10200102.pdf

VHA Informational Letter 10-2010-006: Use of Rapid Tests for Routine Human Immunodeficiency Virus (HIV) Testing

www1.va.gov/vhapublications/ViewPublication.asp?pub\_ID=2168

# **Manuals & Handbooks**

VA Primary Care of Veterans with HIV www.hiv.va.gov/provider/manual-primary-care/index.asp

VHA Handbook 1004.01: Informed Consent for Clinical Treatments and Procedures

www1.va.gov/vhapublications/ViewPublication.asp?pub\_ID=2055

VHA Handbook 1605.1: Privacy and Release of Information www.va.gov/vhapublications/ViewPublication.asp?pub\_ID=1423

# Recommendations

Management and Treatment of Hepatitis C Virus Infection in HIV-Infected Adults: Recommendations from the Veterans Affairs Hepatitis C Resource Center Program and National Hepatitis C Program Office

www.hiv.va.gov/provider/guidelines/hcv-coinfection.asp

# **Educational and Information Material for Patients**

VA National HIV/AIDS website www.hiv.va.gov

## Notice of Privacy Practices

www1.va.gov/vhapublications/viewpublication.asp?pub\_id=1089

## Forms

VA Request for and Authorization to Release Medical Records or Health Information (10-5345)

www.va.gov/vaforms/medical/pdf/vha-10-5345-fill.pdf

# **Staffing Lists**

VHA HIV Clinical Case Registry Coordinators

http://vaww.publichealth.va.gov/docs/quality/CCR HIV Coordinators.pdf

# Appendix J: Primary Care PTSD Screen

In your life, have you ever had any experience that was so frightening, horrible, or upsetting that, in the past month, you...

1. Have had nightmares about it or thought about it when you did not want to?

2. Tried hard not to think about it or went out of your way to avoid situations that reminded you of it?

□ NO

- Were constantly on guard, watchful, or easily startled?
   YES
   NO
- 4. Felt numb or detached from others, activities, or your surroundings?

**□**NO

# Current research suggests that the results of the PC-PTSD screen should be considered "positive" if a patient answers, "yes" to any two items or the single hyper-arousal item (item #3).

# Appendix K: VHA Recommendations for Care of Veterans who are Pregnant and Living with HIV

•						
Pregnancy						
Recommendations	Comments					
Refer to an obstetrician who has expertise working with HIV-infected women; for centers that do not have such expertise available, consultation is available through the ( <b>National</b> <b>Perinatal HIV Consultation and</b> <b>Referral Service</b> ; the number of the hotline for the service is 888-448-8765)	<ul> <li>Goals include maximal suppression of HIV RNA to prevent HIV transmission and to optimize the patient's health.</li> </ul>					
<ul> <li>For pregnant women or women who may become pregnant, give folate (folate dosage should be 4-5 mg QD for women who take TMP-SMX, to overcome the folate-antagonist effects of TMP-SMX) ART during pregnancy: <ul> <li>Test for HIV resistance before initiating ART</li> <li>Give combination ART with goal of maximal virologic suppression</li> <li>Recommended agents for use during pregnancy*: <ul> <li>ZDV + 3TC, combined with NVP or LPV/r</li> </ul> </li> </ul></li></ul>	<ul> <li>Higher risk of perinatal transmission with:</li> <li>High viral load</li> <li>Low CD4 count</li> <li>Advanced HIV infection</li> <li>Poor nutrition</li> <li>Drug use</li> <li>STD</li> <li>Vaginal delivery (if HIV RNA &gt;1,000 copies/mL)</li> <li>Invasive monitoring</li> <li>Prolonged rupture of membranes</li> <li>Chorioamnionitis</li> </ul>					

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Pregnancy	
Recommendations	Comments
<ul> <li>Alternative ARVs during pregnancy:</li> <li>NRTIs: ABC**, ddl, FTC, d4T</li> <li>NNRTIs: none</li> <li>PIs: IDV/r, NFV, RTV, SQV/r</li> <li>Insufficient data: TDF, ETR, ATV, DRV, FPV, TPV, ENF, RTV, MVC</li> <li>Avoid use of EFV, DLV: risk of teratogenicity, especially during first trimester</li> </ul>	<ul> <li>Without ART, risk of transmission is 25%; with PI-based ART, risk of transmission is 1% in the United States.</li> <li>Pharmacokinetic changes during pregnancy may alter serum levels of some ARVs; check USPHSTF guidelines for recommended dosage adjustments; consult with pharmacologist. (Many experts recommend increase in LPV/r dosage to 600/150 mg BID during 3<sup>rd</sup> trimester)</li> <li>Some evidence suggests ART may increase rates of preeclampsia.</li> <li>Consider scheduled cesarean section delivery if HIV viral load is &gt;1,000 copies/mL near time of delivery</li> </ul>
Breast-feeding	
Recommendations	Comments
Breast-feeding is not recommended in the United	

States (to avoid risk of HIV

transmission through breast milk).

\*Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States; November 2, 2007. \*\*If possible, check for HLA-B\*5701 before treatment with ABC.

# Appendix L: AIDS-Defining Conditions

- Bacterial infections, multiple or recurrent<sup>\$\$\$\$\$</sup>
- · Candidiasis of bronchi, trachea, or lungs
- Candidiasis of esophagus<sup>11111</sup>
- Cervical cancer, invasive<sup>\*\*\*\*\*\*</sup>
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (>1 month's duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes), onset at age >1 month
- Cytomegalovirus retinitis (with loss of vision)\*\*\*\*\*\*
- Encephalopathy, HIV related
- Herpes simplex: chronic ulcers (>1 month's duration) or bronchitis, pneumonitis, or esophagitis (onset at age >1 month)
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (>1 month's duration)
- Kaposi sarcoma<sup>++++++</sup>
- Lymphoid interstitial pneumonia or pulmonary lymphoid hyperplasia complex\*\*\*\*\*,†+++++
- Lymphoma, Burkitt (or equivalent term)

<sup>§§§§§</sup> Only among children aged <13 years. (CDC. 1994 Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. MMWR 1994;43 [No. RR-12].)

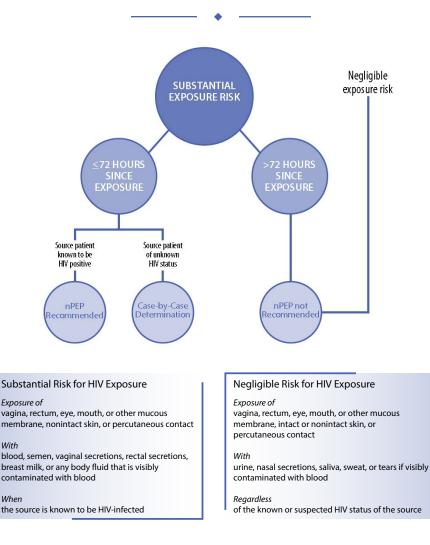
**<sup>¶¶¶¶¶</sup>** Condition that might be diagnosed presumptively.

<sup>\*\*\*\*\*\*</sup> Only among adults and adolescents aged >13 years. (CDC. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 1992;41 [No. RR-17].)

- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain
- Mycobacterium avium complex or Mycobacterium kansasii, disseminated or extrapulmonary \*\*\*\*\*\*\*
- Mycobacterium tuberculosis of any site, pulmonary \*\*\*\*\*\*, tittitt disseminated \*\*\*\*\*\*, or extrapulmonary \*\*\*\*\*\*
- Mycobacterium, other species or unidentified species, disseminated<sup>\*\*\*\*\*\*</sup> or extrapulmonary<sup>\*\*\*\*\*\*</sup>
- Pneumocystis jirovecii pneumonia\*\*\*\*\*
- Pneumonia, recurrent\*\*\*\*\*\*,+++++++
- Progressive multifocal leukoencephalopathy
- · Salmonella septicemia, recurrent
- Toxoplasmosis of brain, onset at age >1 month\*\*\*\*\*\*
- Wasting syndrome attributed to HIV

*Note*. From the Centers for Disease Control and Prevention. (2008). AIDS-defining conditions. *Morbidity and Mortality Weekly Report: Recommendations and Reports, 57*(RR10), 9. Retrieved from <u>http://www.cdc.gov/</u> <u>mmwr/preview/mmwrhtml/rr5710a2.htm</u>

# Appendix M: DHHS nPEP Exposure Risk Algorithm



*Note.* From the U.S. Department of Health and Human Services. (2005, Jan.). Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States. *Morbidity and Mortality Weekly Report, 54*(RR02), 1-20. Retrieved from <u>http://hab.hrsa.gov/</u> <u>deliverhivaidscare/clinicalguide11/cg-302\_nonoccupational\_pep.html</u>

# Appendix N: Activities Supporting VA HIV Prevention and Program Evaluation

- Make HIV educational materials readily available to patients and staff (see Appendix I for information on obtaining such materials);
- Provide training in HIV prevention to all new staff;
- Provide 'refresher' training to staff periodically;
- Monitor feedback from patients;
- Monitor the uptake of HIV testing, number of prescriptions written for condoms;
- Examine CCR data for program planning and training purposes;
- · Monitor progress in integrating HIV prevention;
- Make use of local clinical reminders available through CPRS
- Cultivate contacts with colleagues in other VHA departments who are part of the HIV continuum of care for patients; and
- Develop relationships with local community-based organizations and health department staff who provide HIV prevention and care services in the larger community—this is particularly important for Veterans living in rural areas who may have limited access to VA mental health and SUD treatment resources.

# VIII.

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U.S. Department of Veterans Affairs

# VA HIV Prevention Handbook

A Guide for Clinicians (2nd Edition)



Office of Public Health Veterans Health Administration Department of Veterans Affairs