

2008

# IDCR: Infectious Diseases in Corrections Report, Vol. 9 No. 24

Infectious Diseases in Corrections

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# IDCR

INFECTIOUS DISEASES IN CORRECTIONS REPORT

August 7, 2008

Dear Reader,

Over the past 10 years IDCR has strived to bring you the most up-to-date, relevant information on managing infectious diseases in the correctional setting. As we celebrate a decade of publication, we would like to personally thank you for your continued support and engagement. Unfortunately, **this will be IDCR's last issue as an independent publication.** While it is our every intention to continue publishing issues under a new umbrella organization, these plans have yet to be determined. Please read the letter from the editor to learn more.

**Important Things to Know:**

- Continuing medical education credit will continue to be available through August 2009. Please refer to the instructions and expiration date of the issue when applying for credit.
- **All** of our issues (February 1999-July/August 2008) will be available online at [www.IDCROnline.org](http://www.IDCROnline.org) **through 2014**. Click on the Archives link at the top of the web page for a complete list of archived issues.

We have made these arrangements to allow maximum access to IDCR content during this time of uncertainty. We apologize for any confusion or inconvenience these changes may cause. If you have any questions feel free to contact me at (401)453-2068 or [idcrme@gmail.com](mailto:idcrme@gmail.com).

Sincerely,

Elizabeth Closson  
Managing Editor



# IDCR

**INFECTIOUS DISEASES IN CORRECTIONS REPORT**  
JOINTLY SPONSORED BY NOVA SOUTHEASTERN UNIVERSITY HEALTH PROFESSIONS DIVISION

**FORMERLY HEPP Report**

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## ABOUT IDCR

*IDCR, a forum for correctional problem solving, targets correctional physicians, nurses, administrators, outreach workers, and case managers. Published monthly and distributed by fax and email, IDCR is ACCME accredited and free of charge. Since its founding in 1998, IDCR has served as an important resource for correctional health care providers by offering the newest and most relevant information on the management and treatment of infectious diseases within the correctional setting.*

*Continuing medical education credits are provided by Nova Southeastern University Health Professions Division. This publication is jointly sponsored by IDCR and NSU. This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of NSU and IDCR. NSU is accredited by the ACCME to provide continuing medical education for physicians.*

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## RAPID HIV TESTING: COMING TO A JAIL NEAR YOU?

- **Main Article:** Rapid HIV Testing: Coming to a jail near you?
- **101:** HIV 101 FDA-Approved Rapid HIV Antibody Screening Tests
- **Spotlight:** An Overview of Microbicides

### OBJECTIVES

- The learner will be able to explain the different types of FDA-approved rapid HIV tests, how they are used, and details related to their sensitivity and specificity.
- The learner will be able to discuss how to communicate rapid HIV test results and how to incorporate HIV counseling with the rapid testing process.
- The learner will be able to describe recent studies related to feasibility and cost analysis of rapid testing in jails.

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In accordance with the Accreditation Council for Continuing Medical Education Standards for Commercial Support, the faculty for this activity have been asked to complete Conflict of Interest Disclosure forms.

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#### Purpose Statement

The purpose of this monograph is to increase the knowledge of correctional health care providers on FDA-approved rapid HIV tests, communicating results offering HIV counseling for rapid testing, and on the benefits of implementing a rapid HIV testing program in a jail setting.

#### Instructions for Credit

To obtain credit read the Main Article, Spotlight, and HIV 101 sections. When completed with these items, complete the post test and evaluation on the last page of the monograph. You must receive a test score of at least 75% and respond to all evaluation questions to receive a certificate. Mail or fax the post test and evaluation to:

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## RAPID HIV TESTING: COMING TO A JAIL NEAR YOU?

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### Introduction

An estimated 1.2 million people in the United States are living with HIV/AIDS,<sup>1</sup> and an estimated 25% of these people are unaware of their HIV infection.<sup>2</sup> In response, the Centers for Disease Control and Prevention (CDC) in September 2006 issued their Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings, aiming to reduce barriers to HIV testing and increase the number of Americans who know their HIV status.<sup>3</sup> A centerpiece of these recommendations is a move to opt-out HIV screening for all patients ages 13-64 years in all health care settings, including correctional health care facilities. The basis

for this recommendation is that by increasing the availability of HIV testing the number of people who know their result will also increase and, as demonstrated, will subsequently reduce behaviors likely to transmit HIV, and will help reduce the spread of the virus.<sup>4,5</sup>

Although detection of HIV infection is a cornerstone of HIV prevention, testing alone is insufficient. According to the CDC, almost one-third of individuals in 2000 who tested and found to be HIV-infected did not return to receive their test result.<sup>6</sup> The turn-around time for conventional HIV testing has often been an insurmountable obstacle to HIV screening of at-risk populations such as those who are homeless or migratory. A failure to return for HIV test results is not unique to community HIV screening; the transient nature of those who are jailed has prevented wider spread HIV testing in this setting. A study of the HIV testing experiences of jail inmates conducted in Rhode Island found that 50% of those who had previously been tested for the virus had not received the result of the test even though a majority of prior HIV screening had been

performed in correctional settings.<sup>7</sup> Since becoming available in the United States in 2002, rapid HIV tests have allowed for the expansion of HIV screening in both medical and non-medical settings, including prisons and jails.<sup>8</sup> Rapid HIV tests yield results in less than 30 minutes and substantially increase the number of people who receive their test result by eliminating the need for a return visit, and are becoming increasingly utilized in non-clinical settings such as community-based screening events.<sup>9</sup> Rapid HIV testing is particularly suited to use in jails due to the transient nature of inmates in this environment. Testing can be conducted quickly, does not require extensive training of the tester, and the results are provided immediately. Another Rhode Island study found that among 95 jail inmates, 79% of whom had not received an HIV test result during a prior incarceration, 100% were informed of the results of their rapid HIV test during their current jail stay.<sup>10</sup>

### FDA-approved rapid tests

Since February 2002, six rapid tests have been approved by the Food and Drug Administration (FDA) (See HIV 101).<sup>11</sup> Four of these tests (OraQuick ADVANCE Rapid HIV-1/2 Antibody Test, Clearview HIV-1/2 STAT-PAK, Clearview COMPLETE HIV 1/2, and Uni-Gold Recombigen HIV Test) are approved for use with whole blood specimens obtained by finger stick or venipuncture. OraQuick ADVANCE may also be used with oral fluid samples. These tests have received waivers under the Clinical Laboratory Improvement Amendments (CLIA) that set quality standards for all testing on human specimens, enabling these tests to be used in settings that do not include laboratories when they utilize whole blood specimens or oral fluid.<sup>12, 13</sup> Settings using CLIA-waived tests only need to enroll in CLIA, pay a fee, and follow the test manufacturer's instructions for use.

The two tests that only use serum or plasma samples (MultiSpot HIV-1/HIV-2 Rapid Test and Reveal G3 Rapid HIV-1 Antibody Test) are classified as "moderately complex" under CLIA and are not waived, meaning they are subject to specific laboratory and personnel requirements. Similarly, when the four tests with waivers for use with oral fluid and/or whole blood specimens are used with plasma or serum samples (only plasma in the case of OraQuick ADVANCE), they are no longer CLIA-waived.

All of the FDA-approved rapid tests are interpreted visually. The test strip or membrane is covered with HIV antigens that bind HIV antibodies that may be present in the patient specimen. The test kits also contain colorimetric reagents that generally bind to a control region on the test strip and to HIV antibodies to create an indicator that is visually detectable.<sup>14</sup>

With the exception of the MultiSpot HIV-1/HIV-2 Rapid Test, which takes about 10-

## LETTER FROM THE EDITOR

### Dear Correctional Colleagues,

The air is velvet with humidity. The grass is lush and green. Daylight stretches away into the evening and warm breezes embrace us. We delight in the glory of summer, but know the time is limited, and one day soon, we'll feel the first crisp hint of fall. With fall will come a change, and as it goes with summer, so it goes with *IDCR*.

This will be *IDCR's* last issue as an independent non-profit (501c3) organization. We can look back in pride at our work - ten years of solid work almost to the day - first as *HIV Education Prison Project (HEPP)* and more recently as *IDCR*. We've written, edited and published more than 100 issues in our nine volumes of work over the past decade, on topics ranging from HIV testing and treatment of inmates to the management of chickenpox outbreaks in correctional institutions. We pushed the envelope. We took action. We advocated for better HIV care.

We can positively claim that our years of productive work have improved the care of inmates with HIV and the management of infectious diseases in prisons. We believe that we collectively contributed to improving the standards of health care in our specialized setting, just as we were able to build strong relationships across state (and institutional) lines and national borders. We celebrate our teamwork and look back on our work with pride and amazement, but these glorious, halcyon days, are coming to a close.

Dear reader, just as summer must end one day soon, we will publish this last issue of *IDCR* and move on to the next thing. *IDCR* will be reborn in a new form, under a different guise, as yet to be determined. We, the founders, editors, the *IDCR* editorial board, and the advisors of *IDCR*, appreciate your involvement as readers and hope that you enjoy the end of our glorious summer. We wish for you the best that the turning seasons may bring.

### Annie De Groot, MD

Executive Editor

## **RAPID HIV TESTING: COMING TO A JAIL...** (continued from page 2)

15 minutes to conduct, all of the rapid tests take less than 5 minutes to set up and perform.<sup>12</sup> The window periods for reading the results as measured from the last step of the testing process are listed in Table 1. If the tests are not read within these window periods, they are considered invalid. It is therefore important to make sure that personnel coordinate patient intake and processing to fit within these window periods.

### **Sensitivity and specificity**

All of the FDA-approved rapid tests have sensitivities and specificities that are comparable to conventional blood-based HIV enzyme immunoassays (EIAs) antibody tests.<sup>15</sup> Sensitivity is the probability that the test result will be positive given that the person is truly HIV-infected, while specificity is the probability that the test result will be negative given that the person is truly HIV-uninfected. While the sensitivity and specificity of a test are constant properties, the predictive value, or the usefulness of the test in classifying people with infection, varies depending on the prevalence of disease in the population being tested.<sup>16</sup> The negative predictive value of a rapid HIV test, or the probability that a person is HIV-uninfected given that his or her test is negative, is high at the HIV prevalence observed in most testing sites in the US.<sup>17</sup> However, the positive predictive value of a rapid test, or the probability that a person is HIV-infected given that his or her test is reactive, is lower in populations with low HIV prevalence (For more information on why this is true, visit: <http://www.cdc.gov/hiv/topics/testing/rapid/index.html>). Therefore, in correctional settings where the prevalence of HIV infection is generally higher than the general population, the positive predictive value of rapid HIV testing will likely exceed that of most community settings. Reactive rapid tests results, like conventional EIAs, are considered preliminary and require confirmatory testing to rule out false-positive results.<sup>16</sup> Confirmatory testing is usually done with a Western blot or indirect immunofluorescence assay.<sup>15</sup>

Recently, several clusters of higher than expected numbers of false-positive results have been noted in settings using rapid HIV tests of oral fluid.<sup>18</sup> As reported in the *Morbidity and Mortality Weekly Report (MMWR)*, the causes of these clusters have not been elucidated, but investigations are under way to determine what factors might be associated with this unexplained variability. Several programs using oral fluid-based testing have changed their procedures and now repeat the rapid test on whole-blood specimens from patients who have reactive oral fluid tests. This strategy allows the programs to take advantage of the convenience of oral fluid rapid testing while decreasing the number of preliminary false-positives. Regardless of the test used, it is important to remember that confirmatory testing is required to confirm all reactive rapid HIV tests.

### **Communicating the meaning of the rapid test result**

Because the negative predictive value of a rapid HIV test is high, a person who receives a negative HIV rapid test result can be told that he or she is not HIV-infected.<sup>14</sup> However, if a person has had a possible recent exposure to HIV (within 3 months), he or she could be in the acute phase of HIV infection and have not yet developed detectable HIV antibodies. Such persons should be counseled regarding the possibility of acute HIV infection and be retested within 3 months. If symptoms or high suspicion for acute HIV infection are present, testing for HIV RNA may be warranted.

Individuals with reactive rapid test results should be counseled on risk-reduction behaviors while awaiting the results of confirmatory testing. The CDC recommend conveying to the patient that the preliminary test is positive and that the individual should take precautions to avoid transmitting the virus to others while awaiting confirmatory testing.<sup>19</sup> If the confirmatory test result is negative or indeterminate, the individual should be retested after one month to rule out test error and the possibility of early HIV infection that may not yet be detectable by Western blot.<sup>20</sup> An indeterminate test may be an indication of early HIV infection and testing for acute HIV with an HIV RNA test may be necessary. Consultation with an HIV expert should be sought in such cases.

### **HIV counseling with rapid testing**

The FDA requires that individuals who undergo rapid testing receive an information sheet provided by each manufacturer with its rapid HIV test kits.<sup>14</sup> This sheet includes general information on HIV and AIDS as well as specifics about the test and what the results mean and don't mean. Clients should also receive prevention counseling. With conventional HIV testing, there are two visit opportunities for prevention counseling for clients who return for their results. With rapid testing, there may be either one or two opportunities for counseling depending on whether or not confirmatory testing is required and the patient returns for these test results.<sup>19</sup> Point-of-care testing requires that personnel have the ability and the privacy to provide positive test results on the spot. If an individual with a reactive rapid test does not return for confirmatory testing results, he or she should at least leave the initial visit knowing that there is a high probability of infection.<sup>14</sup>

### **Rapid HIV testing in jails**

While rapid HIV testing has been incorporated into the HIV screening procedures of jails across the United States, there are few published reports describing their application in this setting. Results of a CDC-supported effort to introduce rapid HIV testing for screening of jail inmates in Florida, Louisiana, New York, and Wisconsin provide some of the best data on this approach.<sup>8</sup> Between 2003 and 2006, 33,211 inmates, 6% of all those booked, were voluntarily HIV tested with a rapid test

between. More than 99% of these inmates received their HIV test results; 1.3% had a reactive test result and 97% of those who underwent confirmatory testing were found to be HIV-infected. For two-thirds of those found to be HIV-infected, the diagnosis was new. In these settings, rapid HIV testing was found to be feasible and did lead to the identification of over 250 individuals who were unaware of their HIV infection.

An analysis of the costs associated with this CDC demonstration project, including the cost of identifying previously undiagnosed HIV infection, has also been published.<sup>21</sup> This analysis focused on data collected from 2004 to 2005. Although the costs were extremely variable by site, the study found that the average cost of HIV testing for those without infection was between \$29.46 and \$44.98. The cost of testing was significantly higher for HIV-infected inmates and was estimated between \$71.37 and \$137.72 per inmate. The discrepancy in costs relative to HIV serostatus is due to the extra post-test counseling required for individuals who test positive for HIV. Most of the cost of rapid HIV testing was due to variable costs, including time for counseling and testing, nondurable goods and supplies, and test kits. Overall, the average cost per newly diagnosed HIV infection ranged from a low of \$2,451 to high of \$25,288. The high end of the spectrum of the cost per new HIV diagnosis is a function of greater travel and other expenses at one site coupled with a low overall HIV prevalence in that state.

### **Conclusions**

Rapid testing should be used to encourage behavior change to limit the spread of HIV infection and to link those who test positive into a system of care. Such testing reduces significant barriers to individuals learning their HIV status, allows for HIV testing opportunities in settings without committed laboratories, and facilitates patients receiving their test results at the testing visit. HIV screening of jailed inmates with rapid HIV tests is attractive given the quick turn around time for results and the accuracy of these tests. However, such testing is not without costs, including the expense of the tests themselves, the training of staff to perform the testing, and counseling and confirmatory testing, when necessary. The cost per new HIV diagnosis drops with increasing prevalence of HIV infection. Therefore, jails in areas with a higher prevalence of HIV infection may find rapid HIV testing to be more affordable than those where HIV infection is less common. In all settings, the benefits of the detection of undiagnosed HIV infection, including prevention of opportunistic conditions and secondary transmission of the virus, may well justify any added expense.

## RAPID HIV TESTING: COMING TO A JAIL... (continued from page 3)

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## SPOTLIGHT: AN OVERVIEW OF MICROBICIDES

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### Why are microbicides needed?

Over the last 15 years, there has been an increasing feminization of the HIV epidemic with the proportion of women infected dramatically rising. Women are at greater risk for HIV infection due to physiologic and socioeconomic reasons. The Centers for Disease Control and Prevention (CDC) estimate that 25% of new HIV infections in the United States (US) occur in women. In the US in 2004, HIV was the leading cause of death in black women aged 25-34 years and the 5th and 6th leading cause of death in all women aged 35-44 and 25-34, respectively. In parts of the world with more generalized epidemics, such as sub-Saharan Africa, women account for almost 60% of those living with HIV. These worrisome statistics point to a clear need for HIV prevention technologies aimed at protecting women from acquisition of HIV. The current prevention methods, condoms and male circumcision, pertain to men and must be initiated by males. Although a female condom is available, the cost is prohibitive and there may be poor acceptance from the woman's partner. Female initiated methods of prevention are an important part of a comprehensive HIV prevention plan, and methods that women can use to protect themselves from HIV infection are urgently needed.

### What are microbicides?

Microbicides are primarily vaginal products that are being developed to prevent the acquisition of HIV infection. To date, no effective microbicide exists, and work is ongoing to develop the concept of an intravaginal method of protection into an effective microbicide product. Microbicides are being developed in a variety of topical forms including gels, films, soft gel

capsules and intravaginal rings. The mechanisms of action of microbicide candidates differ; early generation products are non specific and directed at multiple organisms that cause sexually transmitted infections (STIs) including HIV, and later generation candidates contain antiretroviral agents and are directed specifically at disabling HIV. Developed in the 1990s, the first generation microbicides were expected to reduce the acquisition of HIV infection by killing or immobilizing pathogens and by boosting the vagina's natural defenses. These agents displayed in vitro activity against HIV and other sexually-transmitted pathogens, including HSV-2. The first generation products were coitally dependent, meaning that they needed to be applied just before intercourse. The newest candidate microbicides contain antiretroviral agents and are expected to prevent infection through blocking replication of HIV. These products are designed to be used independent of sex with dosing once daily for gel forms or once monthly in the case of microbicides formulated as intravaginal rings.

### Research to Date

Researchers have been working to develop microbicide products for over a decade; these efforts have resulted in Phase III clinical studies to test whether candidate products protect against HIV infection. To date, 6 candidate microbicide gels have or are being tested in 8 large scale trials. None of the candidates thus far have shown efficacy in these studies. The first trial tested the spermicide nonoxynol-9 (N-9) and results from this study were published in 2000. Unfortunately, in this study, harm was found and there were more infections in the women who used N-9 compared to those who used placebo gel.

More recently, results from trials testing 3 other first generation products have been announced. Two trials testing cellulose sulfate were halted due to fertility and potential harm (in one trial there was a trend toward more HIV infections in the women who received product compared to those who received placebo). Two trials testing the surfactant agent Savvy®

were stopped for fertility, and results from the single trial testing the product, Carraguard®, showed that while it was safe, it did not protect against HIV infection. The results from these large Phase III trials were considered to be significant setbacks to the microbicide field; it is hoped that the next generation antiretroviral containing microbicides being developed will be effective. Results from trials testing the remaining first generation products, BufferGel® and PRO2000 are expected in the next 1-2 years.

The second generation candidates are those containing compounds with antiretroviral activity. It is believed that since these products contain drugs with activity directed specifically against HIV, they will be more potent than the first generation products. The first generation products rely on contact with HIV to induce viral inactivation, and are inserted at the time of sex, a feature that is believed to decrease adherence to product. In contrast, since second generation products inhibit viral replication and rely on intracellular concentration of an antiretroviral agent, they can be used daily and do not need to be used at the time of sex, a feature that may improve adherence to product. These second generation products are being formulated as either daily gels or as intravaginal rings that will be inserted once per month. A gel made with the currently approved non nucleotide reverse transcription inhibitor tenofovir (Viread®) is currently being tested in a large trial in South Africa. Other drugs being developed as microbicides but are not yet in large trials include dapivirine (TMC 120) and UC-781, both of which are non nucleoside reverse transcriptase inhibitors. Unlike the non specific agents, there is the potential for antiretroviral containing agents to select for HIV resistance in the viruses in women who become infected while using them. Because this is a recognized concern, there will be careful monitoring for this in the efficacy trials.

To date, research has focused mainly on vaginal microbicides; however it is widely acknowledged that any product that is approved for vaginal use will be used rectally. Since the

**SPOTLIGHT: AN OVERVIEW OF...**  
(continued from page 4)

vagina and rectum are different environments, more research needs to be conducted on rectal microbicides. First, it is important to know about the safety of vaginal products if they are used rectally, and initial research to answer safety questions is being conducted. Determining efficacy of products to prevent acquisition of HIV through anal sex will also be an important part of microbicides research.

**Lessons learned**

The microbicide field has and will continue to be faced with multiple challenges. Many of the efficacy trials require thousands of participants in areas of documented high incidence and as a result have been conducted in sub-Saharan Africa. Early stage studies examining safety and acceptability have been conducted in mul-

multiple areas including North America, Europe, India and Africa. In the context of these clinical trials, it is important to educate communities about the importance of prevention research and build local awareness and political support to prevent trial delays and closures. Microbicide development to date has provided important lessons to be applied to future work. These include best ways to perform preclinical evaluation of products, the need to choose best-in-class for large scale trials, and concentration on ways to bolster and objectively measure adherence. High levels of adherence to product are essential to measuring effectiveness in the context of trials. Other challenges to microbicide development include manufacturing and delivery. Products must be acceptable, affordable and accessible to those who need them most. In the context of the correctional setting, access to proven microbicides may be limited in the same manner that access is limited to condoms and clean needles, how-

ever even in this case, correctional facilities could serve as settings for education about microbicides as part of interventions to prevent HIV.

Drug development is a long and costly process. Microbicide research is no exception and will take time. It is important to learn from past experiences and trials and to thoughtfully engage in future research.

**Path Forward**

With an estimated 33.2 million people infected worldwide and over 2.5 million people becoming infected in 2007, HIV prevention options are urgently needed. Microbicides will be an important part of any HIV prevention package particularly for women who are increasingly at risk. A safe and effective microbicide will enable women to take control of protecting themselves from HIV infection.

**Editors Note**

In resource blessed nations, antiretroviral treatment has been enormously successful in both preventing maternal to fetal transmission of HIV and in extending the lives of those who are HIV infected. In spite of these successes, it has become increasingly clear that on a global basis we cannot treat ourselves out of the HIV epidemic. The costs associated with drug procurement and delivery puts treatment beyond the reach of many of those who are in need. Furthermore, HIV has demonstrated an impressive ability to successfully evolve in response to each newly developed antiretroviral agent.

A brief glance backwards in history provides numerous examples of common infectious diseases that have been either eradicated or rendered uncommon due to advances in prevention, not treatment. In the early part of the 20th century, it would have been difficult to find a family that had not lost at least one member due to typhoid, diphtheria, smallpox, polio, pertussis, or measles. These and many other once common scourges have been controlled by improved sanitation and/or effective immunization efforts.

Thus far, efforts to develop an effective HIV immunization have been unsuccessful. Although efforts continue in this area and must eventually succeed, there is an urgent need for other prevention strategies to augment the use of barrier methods. In spite of decades of experience demonstrating that condoms are highly effective in preventing transmission of HIV and other sexually transmitted infections, most of those who are incarcerated have been denied access to these cheap and effective life-protecting devices. There are some notable glimmers of hope in this arena, including a pilot project that is slated to begin within the California Department of Corrections and Rehabilitation. Similarly, it is unlikely that the incarcerated will be on the forefront of access to immunization and microbicial approaches to HIV prevention. That notwithstanding, correctional health care providers must keep up on developments in this important field. Only by doing so will we be able to effectively advocate for our patients when science catches up with the promise. Human sexuality and physical expressions thereof do not end simply because one is confined behind bars. To pretend otherwise and to deny access to proven prevention measures for HIV or any other fatal illness is in this writer's point of view indefensible and nothing short of deliberate indifference.

JB

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**RESOURCES****CDC's Website on HIV Testing**

<http://www.cdc.gov/hiv/topics/testing/index.html>

**Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings.** CDC. *MMWR* 2006;55(RR14):1-17. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.html>

**FDA-Approved Rapid HIV Antibody Screening Tests – Purchasing Details.** US Department of Health and Human Services. CDC. 2008 <http://www.cdc.gov/hiv/topics/testing/rapid/rt-purchasing.html>

**Community HIV/AIDS Mobilization Project's (CHAMP) Project UNSHACKLE: Confronting HIV and Mass Imprisonment** <http://www.champnetwork.org/unshackle>

**Alliance for Microbicide Development** <http://www.microbicide.org/>

**NIH Office of AIDS Research (OAR) Microbicide's Research Working Group** <http://www.oar.nih.gov/initiatives/mrgw.asp>

**Microbicide Trials Network** <http://www.mtnstopshiv.org/>

**Global Campaign for Microbicides** [http://www.global-campaign.org/about\\_microbicides.html](http://www.global-campaign.org/about_microbicides.html)

**Department of Health and Human Services 2007 Adult and Adolescent Antiretroviral Treatment Guidelines** <http://aidsinfo.nih.gov/Guidelines/Default.aspx?MenuItem=Guidelines>

**International AIDS Society-USA Panel 2006 Recommendations of the Treatment for Adult HIV Infection** <http://jama.ama-assn.org/cgi/content/full/296/7/827>

**National HIV/AIDS Clinician's Consultation Center Warmline: National HIV Telephone Consultation Services** 1-800-933-3413

**PEPLINE: National Clinician's Post-Exposure Prophylaxis Hotline** 1-888-448-4911

**Perinatal Hotline: National Perinatal HIV Consultation and Referral Services** 1-888-448-8765

**CDC's Correctional Health Website** <http://www.cdc.gov/correctionalhealth/>

**American Correctional Health Services Organization** <http://www.achsa.org/index.cfm>

**American Academy of HIV Medicine** <http://www.aahivm.org/>

**HIV 101: FDA-Approved Rapid HIV Antibody Screening Tests**

Assay by Specimen Type*	Manufacturer	Sensitivity (95% CI)	Specificity (95% CI)	Window Period for Result Validity†
<b>Whole Blood (finger stick or venipuncture)</b>				
Clearview HIV 1/2 STAT-PAK	Inverness Medical Professional Diagnostics ( <a href="http://www.invernessmedicalpd.com">www.invernessmedicalpd.com</a> )	99.7% (98.9-100)	99.9% (99.6-100)	15-20 minutes
Clearview COMPLETE HIV 1/2	Inverness Medical Professional Diagnostics ( <a href="http://www.invernessmedicalpd.com">www.invernessmedicalpd.com</a> )	99.7% (98.9-100)	99.9% (99.6-100)	15-20 minutes
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test§	OraSure Technologies, Inc. ( <a href="http://www.orasure.com">www.orasure.com</a> )	99.6% (98.5-99.9)	100% (99.7-100)	20-40 minutes
Uni-Gold Recombigen HIV Test	Trinity Biotech ( <a href="http://www.unigoldhiv.com">www.unigoldhiv.com</a> )	100% (99.5-100)	99.7% (99.0-100)	10-12 minutes
<b>Serum or Plasma</b>				
MultiSpot HIV-1/HIV-2 Rapid Test	BioRad Laboratories ( <a href="http://www.biorad.com">www.biorad.com</a> )	100% (99.9-100)	99.9% (99.8-100)	Immediately to up to 24 hrs
Reveal G3 Rapid HIV-1 Antibody Test	MedMira, Inc. ( <a href="http://www.medmira.com">www.medmira.com</a> )	99.8% (99.0-100)	98.6% (98.4-98.8)	Must be read immediately

\* When tests may use other specimen types, it is listed as a table footnote.

† As measured from last step of testing process

\_ Can also be used with a serum or plasma sample

§ Can also be used with an oral fluid specimen or plasma sample

Data adapted from References 11 and 12 of the Main Article.

**NEWS AND LITERATURE REVIEWS****The paradoxical effects of using antiretroviral-based microbicides to control HIV epidemics: risk for HIV drug resistance**

This study examines the potential effects of microbicide use in preventing HIV infection and transmission. Researchers used a 10 year epidemiological model simulation to predict the effects of an antiretroviral-based microbicide public health intervention. Microbicides are being developed as a tool to prevent infections in women and to empower women. Paradoxically, the researchers found that the ARV-based microbicides may benefit men more than women and that this effect will be exacerbated if high-risk microbicides are used.

The same number of infections will be prevented whether the microbicide is high-risk or low-risk. However, low risk microbicides will generate fewer resistant cases, even if adherence is high. If resistance does emerge as a result of ARV-based microbicides, the resulting strains will only be resistant to the specific class of drugs in the product. Therefore, therapeutic options, including other classes of ARVs, for the individuals who acquire resistance will be reduced but not eliminated. Prevalence of resistance would be greatest in women (22% median; IQR 8-50%), but transmitted resistance would be 12 times greater in men (2.6% median; IQR 0.8-7%) than women. The researchers recommend monthly monitoring for seroconversion. However, they also found that although the monthly tests decrease the risk to participants during the trial, the use of microbicides increases resistance in the general population when frequent testing does not occur.

Wilson DP, Coplan PM, Wainberg MA, et al. *The paradoxical effects of using antiretroviral-based microbicides to control HIV epidemics. Proc Natl Acad Sci U S A* 2008;105(28):9835-40. Epub 2008 Jul 7.

**Alcohol abuse and dependence has big impact on cirrhosis in HIV/HCV coinfection**

Researchers discovered that alcohol abuse and dependence significantly increases the risk of advanced fibrosis/cirrhosis among those

with HIV, HCV and HCV/HIV coinfection. However, this effect was not observed in lesser degrees of alcohol consumptions, which were defined by NIAAA criteria. The study, Veterans Aging Cohort Study (VACS), was a longitudinal study of 6,090 age/sex matched HIV+/HIV- U.S. Veterans at 8 sites. Of the 4,678 veterans with complete data, 425 (9.1%) had advanced fibrosis/cirrhosis. This number includes 12.5% of the HIV+ and 4.4% of HIV- subjects. Researchers discovered a trend towards increased liver injury with hazardous or binge-drinking. However, they only observed a statistically significant increase in advanced fibrosis/cirrhosis in those with an IDC-9 diagnosis of alcohol abuse and dependence (AAD). Among these were 9.5% of the HIV infected, 15.6% of the HCV infected and 33.1% of the HCV/HIV co-infected. In multivariate analysis, after controlling for HCV and HIV, alcohol was the strongest correlate of advanced fibrosis/cirrhosis. Other significant correlates include age > 50 years, black race and HBV. Of the subjects with advanced fibrosis/cirrhosis, 38.7% had a diagnosis of ADD. Thus, the conclusion of the study is that alcohol abuse and dependence is particularly common among individuals with advanced fibrosis/cirrhosis.

Lim JK, Fultz SL, Goulet JL, et al. *Impact of Alcohol Abuse and Dependence On Liver Fibrosis in a Prospective Cohort of 6090 HIV+/Hiv- U.S. Veterans. Digestive Disease Week. San Diego, CA May 17-22, 2008*

**Role of week 4-rapid virological response (RVR) in prediction of sustained virological response to Peg-IFN plus ribavirin in HCV/HIV co-infected individuals**

This study was performed as a retrospective review of two prospective, open-label single center studies in HCV/HIV co-infected patients who attended a specialty outpatient clinic in Dublin, Ireland. The objective of the study was to evaluate the role of rapid virological response (RVR) in predicting sustained virological response (SVR) rates to hepatitis C virus (HCV) therapy. Virological response was assessed at four intervals: week 4 (RVR), week 12 (EVR – early virological response), week 24 (EOTR – end of treatment) and 24 weeks post-completion of treatment (SVR).

Continued on page 7



## SAVE THE DATES

### XVII International AIDS Conference (AIDS 2008)

Centro Banamex Convention and Business Centre  
Mexico City, Mexico  
August 3-8, 2008  
Visit: <http://www.aids2008.org/>

### Improving Health Outcomes for HIV-Positive Individuals Transitioning From Correctional Settings to the Community

Hawthorne, NY-August 12, 2008  
Rochester, NY-September 11, 2008  
Syracuse, NY-September 15, 2008  
Johnson City, NY-October 29, 2008  
Amityville, NY-November 10, 2008  
Buffalo, NY-November 25, 2008  
Contact:  
For more information or to register, email: [hivet@health.state.ny.us](mailto:hivet@health.state.ny.us)  
Visit: [http://www.health.state.ny.us/diseases/aids/training/addition.htm#health\\_outcomes](http://www.health.state.ny.us/diseases/aids/training/addition.htm#health_outcomes)

### American Correctional Association- 138th Congress of Correction

New Orleans, Louisiana  
August 8-13, 2008  
Visit: <http://www.aca.org/conferences/Summer08/home.asp>

### TB Program Managers' Workshop

Newark, NJ  
September 9-11, 2008  
Visit: [www.umdnj.edu/globaltb/coures/brochures/2008progmanworkshop.htm](http://www.umdnj.edu/globaltb/coures/brochures/2008progmanworkshop.htm)

### 2008 United States Conference on AIDS (USCA)

Miami, FL  
September 18-21, 2008  
Visit: [www.nmac.org/index/2008-usca](http://www.nmac.org/index/2008-usca)

### National Conference on Correctional Health Care

Chicago, IL  
October 18-22, 2008  
Visit: <http://www.ncchc.org/education/national2008.html>

### MRSA & HIV

Live Satellite Videoconference & Webcast  
Wednesday, October 22, 2008  
12:30 - 2:30 p.m. (Eastern Time)  
Visit: <http://www.amc.edu/hivconference>  
(518) 262-4674  
[ybarraj@mail.amc.edu](mailto:ybarraj@mail.amc.edu)

### The 48th Annual ICAAC/IDSA 46th Annual Meeting

Washington, DC  
October 25-28, 2008  
Visit: [www.icaacidsa2008.org/](http://www.icaacidsa2008.org/)

## NEWS AND REVIEWS...

(continued from page 6)

The researchers discovered that the achievement of RVR, a negative HCV-PCR, at week 4 of treatment is indeed predictive of SVR in this cohort of patients. The positive predictive value of RVR at week 4 for subsequent SVR in HIV-HCV co-infected patients was 100%, while the negative predictive value was 57%. Sixty percent of the 65 patients achieved SVR (25% genotype 1 / 4, 77% genotype 2 / 3). The significant variables associated with SVR were lower median pre-treatment HCV viral load, genotype 2 / 3 disease and achievement of RVR. The researchers suggest that with this evidence, it would be possible to identify, based on their HCV-PCR test at week four, which of the patients would only need 6 months of a full dose to achieve SVR. In addition, these findings further strengthen the groups previously published recommendation to individualize the duration of HCV therapy for HIV/HCV co-infected patients.

*Shea D O, Tuite H, Farrell G, et al. Role of week 4-rapid virological response (RVR) in prediction of sustained virological response to Peg-IFN plus ribavirin in HCV/HIV co-infected individuals. Journal of Viral Hepatitis 2008;15(7):482-89.*

### Randomized comparison of 12 or 24 weeks of peginterferon a-2a and ribavirin in chronic hepatitis C virus genotype 2 / 3 infection

Researchers discovered that the effectiveness of 12 weeks of combined peginterferon a-2a and ribavirin treatment is inferior to 24 weeks in patients infected with genotype 2 or 3. The study followed 382 genotype 2 / 3 infected patients at 31 centers in Denmark, Finland, Norway, and Sweden who were randomly selected for 12 or 24 week therapy. The sustained viral response (SVR) rates, 59% (12 week) and 78% (24 week), were significantly greater for those who were treated longer, regardless of fibrosis stage and genotype. In addition, 12-week patients experienced a higher relapse rate (33% versus 12%) than 24-week patients.

Post hoc analysis identified two groups of patients who responded favorably to short-term treatment; patients younger than 40 years who have achieved RVR and those 40 years or older with very rapid virological response, meaning HCV-RNA below 1000 IU/mL on day 7 in addition to achieving RVR. Age was determined to be a significant factor on the efficacy of treatment. Patients younger than 40 years of age had decidedly better outcomes than those 40 and over. Thus, if patients with favorable viral kinetic response to therapy were selected for 12 weeks of therapy, and the demographics were similar to those in the study, 40% of the total population would be suitable for short-term therapy, which would lead to a 20% reduction in pharmaceutical costs as well as a substantial reduction in side effects along with minimal change of SVR rates.

Findings from this study differ from previous reports on treatment shorter than 24 weeks for patients with these genotypes. Possible explanations of this difference include a greater proportion of unfavorable prognostic features included in this study population, differences in ribavirin dosage, and differences in treatment duration.

*Lagging M, Langeland N, Pedersen C, et al. Randomized comparison of 12 or 24 weeks of peginterferon a-2a and ribavirin in chronic hepatitis C virus genotype 2 / 3 infection. Journal of Hepatology. June 2008.*

### Khorrani, Pollard & Abir Files Class Action Civil Rights Lawsuit in Federal Court Against California Prisons for Failure to Properly Treat Inmates With Hepatitis C

The law firm of Khorrani, Pollard & Abir filed a class action law suit in Los Angeles on July 8 contending that the California Department of Corrections and Rehabilitation (CDCR) is unjustly excluding thousands of inmate from liver biopsies and hepatitis C anti-retroviral treatment, allowing them to progress to more advanced stages of liver damage. The suit sites the fact that the standard of care as set by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) requires that patients with Stage II Hepatitis be offered treatment. Contrary to this standard, the CDCR requires inmates to develop a more advanced stage of hepatitis C before they are willing to initiate treatment. Without Stage II treatment the likelihood of developing cirrhosis, liver failure, and liver cancer dramatically increases. The case was filed on behalf of Kevin Johnson, the lead plaintiff and a current inmate at California State Prison at Solano. It names the defendant as Robin Dezember, the director of the division of health services responsible for the health care policies for the CDCR.

"Despite an established standard of care, the California Department of Corrections and Rehabilitation has adopted protocols designed to exclude patients from diagnostic biopsies and treatment. This is in contrast to the care and treatment provided to the general population," says Khorrani. "This practice not only denies inmates proper care and allows their health to deteriorate, but also presents a health danger of further spreading the disease not only within the prison population but also in the general population once the infected inmates are released from prison."

*Marketwire-July 8, 2008. Accessed 22 July 2008. Available at: <http://www.marketwire.com/press-release/Khorrani-Pollard-and-Abir-LIp-876713.html>*

## SELF-ASSESSMENT TEST FOR CONTINUING MEDICAL EDUCATION CREDIT

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of Nova Southeastern University Health Professions Division, Inc. (NSU) and IDCR. NSU is accredited by the ACCME to provide continuing medical education for physicians.

NSU designates this educational activity for a maximum of 1 AMA PRA Category 1 Credit™. The target audience for this educational program is physicians. Physicians should only claim credit commensurate with the extent of their participation in the activity. Statements of credit will be mailed within 6 to 8 weeks following the program.

**Objectives:**

- The learner will be able to explain the different types of FDA-approved rapid HIV tests, how they are used, and details related to their sensitivity and specificity.
- The learner will be able to discuss how to communicate rapid HIV test results and how to incorporate HIV counseling with the rapid testing process.
- The learner will be able to describe recent studies related to feasibility and cost analysis of rapid testing in jails.

1. Which of the following is NOT an FDA-approved rapid HIV test for use with whole blood specimens or oral fluid specimens that has received a waiver under the Clinical Laboratory Improvement Amendments (CLIA) allowing use in settings that do not have access to a laboratory?
  - A. OraQuick ADVANCE Rapid HIV-1/2 Antibody Test
  - B. Clearview HIV 1/2 STAT-PAK
  - C. MultiSpot HIV-1/HIV-2 Rapid Test
  - D. Uni-Gold Recombigen HIV Test
2. With the exception of the MultiSpot HIV-1/HIV-2 Rapid Test all FDA-approved rapid HIV tests take how much time to set up and perform?
  - A. Between 5 and 20 minutes
  - B. Less than 10 minutes
  - C. Between 10-15 minutes
  - D. Less than 5 minutes
3. As a strategy for decreasing the number of preliminary false-positives using oral fluid-based testing, many programs have changed their procedures and now repeat the rapid test on whole-blood specimens from patients who have reactive oral fluid tests. True or False?
4. An indeterminate HIV test result may be an indication of early HIV infection, and therefore testing for acute infection with an HIV RNA test may be necessary. True or False?
5. According to the Spotlight article "An Overview of Microbicides" which of the following is NOT a characteristic of a second generation microbicide?
  - A. They contain compounds with antiretroviral activity
  - B. These products are being formulated as coitally dependent gels or intravaginal rings
  - C. There is the potential for antiretroviral containing agents to select for HIV resistance in the viruses in women who become infected while using them
  - D. None of the above

### IDCR EVALUATION

5 Excellent 4 Very Good 3 Fair 2 Poor 1 Very Poor

1. Please evaluate the following sections with respect to:
- |                | educational value | clarity   |
|----------------|-------------------|-----------|
| Main Article   | 5 4 3 2 1         | 5 4 3 2 1 |
| In the News    | 5 4 3 2 1         | 5 4 3 2 1 |
| Save the Dates | 5 4 3 2 1         | 5 4 3 2 1 |
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Why or why not?
  3. What future topics should IDCR address?
  4. How can IDCR be made more useful to you?
  5. Do you have specific comments on this issue?

**In order to receive credit, participants must score at least a 75% on the post test and submit it along with the credit application and evaluation form to the address/fax number indicated. Statements of credit will be mailed within 4-6 weeks following the program.**

**Instructions:**

- Applications for credit will be accepted until September 7, 2009.
- Late applications will not be accepted.
- Please anticipate 4-6 weeks to receive your certificate.



Please print clearly as illegible applications will result in a delay.

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