



New Jersey **AIDS**LINE

SAVE THE DATE:

April 13, 2004: N.J. Hospital Association, Princeton

Reducing HIV/STD Transmission in Infants, Adolescents and Women/ Title IV HIV Case Study Day

Sponsors: UMDNJ-CCOE-AIDS and NJDHSS-DHAS

For information and to register: <http://www.pware.com/0646a> or call 800-227-4852

April 22, 2004: Ellis Island, Princeton; April 26: Atlantic City;

New Jersey HIV/AIDS Healthcare Conference [repeated conference re: background & utilization of antiretroviral resistance testing]

Sponsors: U. of S. Florida College of Medicine, NY/NJ AIDS Education & Training Center; UMDNJ; and Fisher Medical Communications

For information and to register: www.cme.hsc.usf.edu or call (800) 852-5362.

May 12, 2004: N.J. Hospital Association, Princeton

2nd Latino Medical Conference, "Addressing the New Jersey Healthcare Challenges: Access, Data and Cultural and Linguistic Competency."

Sponsors: UMDNJ-N.J. Medical School, Office of Multicultural Affairs, School of Public Health, Institute for the Elimination of Health Disparities, Office of Affirmative Action/EEO and Center for Continuing and Outreach Education; and NJDHSS-DHAS

For information and to register: <http://www.umdj.edu/lmc/index.html> or call 732-235-9375.

June 10, 2004: Iselin

HIV Clinical Update 2004: the State of HIV in NJ and Beyond

Sponsors: UMDNJ-CCOE-AIDS and NJDHSS-DHAS

For information and to register: <http://www.pware.com/0646a> or call 800-227-4852

December 8, 2004: Cherry Hill

15th Annual HIV Medical Update

Sponsors: UMDNJ-CCOE-AIDS and NJDHSS-DHAS

For information and to register: <http://www.pware.com/0646a> or call 800-227-4852



Center for Continuing & Outreach Education
Division of AIDS Education
30 Bergen Street, ADMC 710
PO Box 1709
Newark, New Jersey 07101-1709

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New Jersey

AIDS LINE

Volume 1, Issue 1 WINTER

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“Welcome to the newly updated New Jersey AIDSLine! The Center for Continuing and Outreach Education, Division of AIDS Education, at the University of Medicine and Dentistry of New Jersey, is proud to bring you this publication for New Jersey health care providers, which will focus on New Jersey-specific issues in HIV/AIDS.”

As the AIDS Education and Training Center representatives for New Jersey, we have been providing HIV/AIDS information to our professional colleagues across the state since 1989. We are pleased to embark on a new partnership with the New Jersey Department of Health and Senior Services, Division of HIV/AIDS Services, to bring you what we hope will be a useful addition to the cornucopia of information that you are presented with on HIV. The purpose of

New Jersey AIDSLine will be to filter and present HIV/AIDS relevant information from a New Jersey perspective. With each issue, we will consider a central theme and present content related to it, as well as provide resources for HIV/AIDS related information including clinical trials and education and training opportunities.

This first issue will focus on the emerging technology of Rapid HIV Testing. We will examine how this shift in communicating HIV serostatus, which can now be delivered as an almost instantaneous message, will impact New Jersey’s fight against a tenacious epidemic in its third decade.

It is our hope that you find New Jersey AIDSLine a useful resource. We look forward to your comments and feedback, and invite you to contribute your listings of relevant clinical trials, conferences, and resources for health care providers.

Dion Richetti, DC, Director of CCOE-Division of AIDS Education



This Issue's FEATURE ARTICLE

HIV AND RAPID DIAGNOSTIC TESTING IN NEW JERSEY

BY LINDA WHITE, MS

The purpose of this article is to provide an overview of rapid HIV testing and its implications for HIV counseling, testing and referral (CTR) in New Jersey. Topics covered include: rapid testing in occupational exposure and pediatric HIV/AIDS; the CDC’s RESPECT-2 and current HIV-counseling standards; FDA-approved rapid tests available in the US; and, finally, the availability of free rapid testing in New Jersey.

Prevalence of HIV/AIDS in New Jersey

With the 5th highest adult and the 3rd highest number of pediatric AIDS cases, New Jersey ranks high among states

affected by the global HIV/AIDS epidemic. In addition, women account for 28% of all reported AIDS cases in New Jersey; the highest proportion in the country.

Minority communities face a disproportionate share of this burden. One in every 73 African Americans and one in every 184 Latinos in New Jersey are living with HIV/AIDS. African Americans have the highest rates of infection: 65% of all cases among women; 70% of all cases among children; and 52% of all cases among men. As a result, Essex County, with the State's highest proportion of African American residents (43%), has the highest rate of persons living with HIV/AIDS in New Jersey

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(1,131 per 100,000). This disparity is further magnified within the incarcerated population where approximately seven out of every ten HIV/AIDS cases affect African Americans.

NJ ADULT/ADOLESCENT CUMULATIVE HIV/AIDS CASES by Race/Ethnicity as of June 2003²				
RACE/ETHNICITY	MALE		FEMALE	
	Cumulative Cases	% of Total	Cumulative Cases	% of Total
White	11,699	28	3,411	18
Black	21,890	52	12,247	65
Hispanic	7,701	18	2,873	15
Asian	193	<1	74	<1
Other	257	<1	108	<1
TOTAL	41,740	100	18,713	100

Because many cases of HIV/AIDS are either not diagnosed or not reported, it is likely that the true prevalence rate is substantially higher than

presented above. It has been estimated that for this reason approximately one third of all HIV/AIDS cases are not accounted for. Fortunately, recent technological advances in HIV testing are likely to significantly increase the number of people who are aware of their HIV status. This, combined with continuing improvements in treatment, has the potential to substantially improve HIV/AIDS prevention and care. Patients and healthcare providers can now learn the results of HIV testing in as little as ten minutes. This eliminates the need to return for a second visit but will require modification of conventional HIV counseling, testing and referral (CTR) protocols.

AVAILABILITY OF RAPID HIV TESTING IN NEW JERSEY

Although more than sixty types of rapid HIV tests are in use worldwide, only four are currently FDA-approved for use in the US. SUDS was approved by the FDA but is currently not available. An overview of the currently available tests is provided in the following table.

ALL CURRENTLY FDA-APPROVED AND AVAILABLE RAPID HIV TESTS			
TEST NAME	OraQuick Rapid HIV-1 Antibody	Reveal Rapid HIV-1 Antibody	Uni-Gold Recombigen HIV
Manufacturer	Orasure Technologies www.orasure.com	MedMira www.medmira.com	Trinity Biotech www.Trinitybiotech.com
Specimen Type	Whole blood	Serum, plasma	Whole blood, serum or plasma
Date of FDA Approval	November 2002	April 2003	December 2003
Testing Procedure/ Equipment Required¹	Fingerstick or purple-top tube blood sample is stirred into vial of developer solution. OraQuick device is then inserted into the developer vial.	Venous blood sample is centrifuged to isolate serum or plasma. Buffer solution placed in test cartridge followed by serum or plasma and finally a detection agent	One drop of whole blood, serum or plasma is placed directly onto testing device. Results are read directly from this device.
Timing	20-40 minutes	1-3 minutes	10 minutes
CLIA Category²	Waived	Moderate complexity	
Interpreting results	Non-reactive/Negative	1 reddish band at control location No band in patient's location	1 pink/red band in control region No pink/red band in test region of device
	Reactive/preliminary positive	2 reddish bands: one at control location and 1 at test location	1 pink/red band in control region Pink/red band in test region of device
	Invalid	No band in control location or pink/red background	Pink/red background No pink/red band in test region of device
Sensitivity	(probability of testing positive if infection is truly present) 99.6% whole blood	99.8% serum 99.8% plasma	100% whole blood 100% serum 100% plasma
Specificity	(probability of testing negative if infection is truly present) 100% whole blood	99.1% serum 98.6% plasma	99.7% whole blood 99.7% serum 99.7% plasma

¹Any organization that performs a rapid HIV test in order to provide results to patients is considered to be a laboratory under the Clinical Laboratory Improvement Amendment (CLIA) of 1988 and must comply with all regulations including any applicable state requirements. A list of laboratory contacts in New Jersey and additional information is available online (www.cms.gov/clia).

²Three categories of tests have been established: waived complexity, moderate complexity, and high complexity. CLIA specifies quality standards for laboratories performing moderate and/or high complexity tests. Waived laboratories must still enroll in CLIA, pay the applicable fee and follow manufacturers' instructions..

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Five healthcare facilities in New Jersey currently provide the OraQuick test at no cost to patients: Robert Wood Johnson Medical Center (New Brunswick), St. Michael's Medical Center and Newark Beth Israel Medical Center (both in Newark), Jersey Shore Medical Center (Neptune), and Jersey City Medical Center (Jersey City).

The OraQuick Rapid HIV-1 Antibody Test is a qualitative immunoassay to detect antibodies in fingerstick whole blood specimens and is intended for use as a point-of-care test. Test kits are sold in multiples of 25 or 100. Each test kit contains a single-use device, as pictured below, and a single-use vial containing a pre-measured amount of a buffered developer solution.



A whole blood specimen is collected by fingerstick or purple-top and transferred into the vial of developer solution, followed by the insertion of the test device. After 20 minutes, but no longer than 40 minutes, results can be read from the result window. All valid tests will show a reddish-purple line in the C (control) zone. If antibodies are detected, a second reddish-purple line will appear on the test strip, and the test should be considered a preliminary positive result. As discussed below, this must be confirmed through further testing. If a second reddish-purple line does not appear, the test can be considered negative.

Although rapid HIV tests are becoming increasingly simple to perform, only clinical laboratories with adequate quality assurance programs have approval to purchase the tests. Instructional materials provided with the tests must be fully understood by the person responsible for carrying out the test. The FDA also requires that clients receive the "Subject Information" pamphlet provided with the test. Manufacturers of rapid HIV tests have developed stringent requirements for sites providing these tests, including maintenance of reference blood samples with verified HIV-positive and ambiguous results,

and ongoing staff training. Details about other restrictions that apply to rapid HIV testing are outlined in the package inserts and CLIA guidelines (*see table footnote*).

IMPACT OF RAPID HIV TESTING IN TIME-SENSITIVE SITUATIONS

Rapid HIV testing is valuable when immediate results are needed in decisions concerning short-course antiretroviral therapy when a woman presents in labor with unknown HIV status, and for post-exposure prophylaxis for health care workers with possible occupational exposure to HIV.

HIV antibody screening was originally designed to process high volume batches to evaluate donated blood or to confirm suspected infection. Patients and clinicians had to wait up to 2 weeks for results. With comparable accuracy, it is now possible to know whether a patient is HIV-negative or "preliminary" positive within 10 minutes. This rapid turnaround, and the availability of effective prophylactic therapy, has important implications in the treatment and prevention of HIV infection.

Occupational Exposure

Rapid HIV testing in cases of possible occupational exposure can considerably reduce anxiety among healthcare providers. There are over 800,000 needle stick injuries in U.S. hospitals each year. Rapid and accurate evaluation of source patients facilitates decision-making and protects against the adverse effects of unnecessary antiretroviral agents.

Perinatal HIV Transmission: New Jersey's Most Successful HIV Prevention Initiative

Recent clinical studies report that prevention of perinatal HIV transmission, through antiretroviral prophylaxis and obstetric intervention, has reduced the risk of mother-to-child transmission to only 2%. Without intervention, approximately one in four infants of HIV-infected mothers are likely to become infected. In New Jersey, the rate of perinatal HIV transmission has dropped from 21% in 1993 to 3% in 2001. This medical success, and the fact that vertical transmission is responsible for almost all cases (94%) of pediatric AIDS in New Jersey, highlights the vital importance of determining maternal HIV status early in pregnancy.

To maximize the benefits of prophylactic therapy, all at-risk women would ideally be

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tested during the initial prenatal visit. Despite expanded efforts to increase HIV screening in prenatal care, many pregnant women do not learn their HIV status before delivery. Unfortunately, 25% of HIV-infected women in New Jersey do not receive prenatal care.⁴ Others may not have received their test results or have refused testing. National estimates show that the mothers of 40% of HIV-infected infants had not been diagnosed prior to labor and delivery. This represents the major missed opportunity to reduce perinatal transmission, as the obstetrical team cannot initiate antiretroviral treatment in labor and delivery without knowledge of the woman's HIV status. The standard of care in New Jersey requires that all pregnant women, including those with unknown HIV-status who present in labor, receive HIV counseling and the option of voluntary testing.⁵ The CDC established similar recommendations in 2004 (see box below).

Fortunately, antiretroviral therapy is effective in reducing vertical transmission even when used intra- or postpartum. Treating newborns within hours of birth can reduce mother-to-child transmission by half. Utilizing rapid testing during labor and delivery is an effective means of determining the need for therapy or for obstetrical interventions, such as elective cesarean delivery, avoidance of artificial rupture of membranes, and avoidance of breastfeeding

In collaboration with the National Pediatric and Family HIV Resource Center, the NJ Department of Health and Senior Services is disseminating recommendations for counseling and treatment of women who present in labor of unknown HIV status.

NEW! Rapid HIV Testing during Labor & Delivery for Women of Unknown HIV Status: A Practical Guide and Model Protocol (released by the CDC on January 30, 2004)

Working Group members included

- Sindy Paul, MD, MPH: Division of HIV/AIDS Services; New Jersey Department of Health and Senior Services; Trenton
- Carolyn Burr, EdD, MSN, RN: François-Xavier Bagnoud Center; University of Medicine & Dentistry of New Jersey; Newark
- Elaine Gross, RN, MS, CNS-C: François-Xavier Bagnoud Center; University of Medicine & Dentistry of New Jersey; Newark

Links to this and related documents will be found on http://www.cdc.gov/hiv/rapid_testing/index.htm#women

RAPID HIV TESTING AND RISK REDUCTION COUNSELING

Receiving immediate test results is likely to substantially increase the number of people who are aware of their HIV status: a greater number of those tested will actually receive results, and there is likely to be a greater response to voluntary testing.

Twenty-five percent of patients with reactive test results (and 30% with negative results) from NJ publicly funded testing sites did not return to learn their HIV status in 2002. Nationally, even greater proportions of HIV-positive (30%) and negative (39%) test results are not received. Under these circumstances much of the benefit of testing is lost; people who know they are infected are more likely to practice risk-reduction behaviors.

One study highlights that, under certain circumstances, even small decreases in waiting can be significant. When the turnaround time was 107 minutes, 55% of emergency room patients did not wait for the results of HIV tests. When the wait was reduced to 48 minutes only 20% did not wait. Nationally, the CDC estimates that 697,495 more people would have learned of their HIV status if rapid, rather than conventional, testing had been used.

Although the likely outcome of more people being tested and receiving test results is improved HIV prevention and care, the question remains whether single visit HIV counseling associated with rapid testing is as effective as conventional 2-visit counseling. Experience with the first rapid test (SUDS [Single Use Diagnostic System for HIV-1]), used with single visit counseling has shown that this change from conventional two-visit sessions is both feasible and well-accepted by clients and counselors. A randomized trial sponsored by the CDC is currently concluding analysis and will provide more definitive answers. More information on this trial as well as sample counseling protocols and materials are available online at: www.cdc.gov/hiv/projects/respect-2

CTR standards for HIV prevention are based on the principles of protecting confidentiality, obtaining informed consent, and providing the option of anonymous testing. HIV counseling encompasses two key elements;

I) Providing information: The following information can be communicated either in person, by printed materials, or by video

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presentation. The topics covered are the same as those recommended in conventional testing, however, it is important to inform clients that any preliminary positive results of rapid HIV testing must be confirmed and would require a second visit.

- Benefits and consequences of taking the HIV test
- How HIV is transmitted and how it can be prevented
- The meaning of test results in explicit, understandable language
- Where to obtain further information and, if applicable, HIV prevention counseling
- Where to obtain other services including, if necessary, treatment

II) Prevention Counseling: The primary focus of prevention counseling is to reduce the client's personal risk for HIV acquisition or transmission and should include the following fundamental elements:

- Maintaining HIV risk reduction as the central focus of the session
- Performing an in-depth personalized risk assessment
- Clarification of any identified misconceptions about HIV risk
- Acknowledging and providing support for positive steps already made
- Negotiating a concrete, achievable behavior-change plan that will reduce identified risks
- Avoiding a "one-size-fits-all" approach through flexibility in the counseling technique and process

For the majority of clients, there are two test-associated opportunities for prevention counseling when using conventional testing techniques: pre-test and post-test counseling. However, as mentioned above, a significant number of clients do not return for the second counseling session, when they would receive their results. With rapid testing, most clients receive one pre-test and one post-test session in a single visit. Only those with preliminary positive results return for a second session. Counselors can, however, elect to recommend additional prevention counseling if warranted by an individual's risk assessment.

Conveying Reactive (Preliminary Positive) Rapid HIV Test Results

Reactive or "preliminary positive" results from

rapid HIV tests must be confirmed through subsequent testing using either Western blot or immunofluorescence assay.

Conveying a preliminary positive result to a patient poses specific challenges and was not always considered worthwhile because of the issues involved in reporting false positive results. These concerns led to recommendations to withhold results until initial tests had been confirmed. Eventually, however, the possibility that some patients might not return for confirmation came to outweigh the potential harm.

It is now recommended that patients be informed in simple, non-technical terms of the reactive test result. Counseling should be provided to reduce the risk of possible transmission to others. A return visit should be scheduled, and the critical need to return for confirmatory results must be strongly emphasized.

Conveying Negative Rapid HIV Test Results

Negative results of rapid HIV tests can be conveyed immediately to clients and do not need to be confirmed. If the client has possibly been exposed to HIV within the past 3 months, however, it may be too early to detect HIV antibodies. In this case, retesting should be carried out.

CONCLUSION

With over 60,000 reported cases of HIV/AIDS, and many yet to be diagnosed, New Jersey must stay on the forefront of all advances in the diagnosis and treatment of this disease. Early reports from the Robert Wood Johnson rapid testing program suggest that more people are willing to undergo testing when they know results will be available immediately. With more people aware of their HIV status and more opportunities to present risk-reduction strategies, rapid HIV testing has the potential to substantially increase the impact of HIV/AIDS prevention and care in New Jersey.

¹ 45,237 adult and 764 pediatric cumulative reported AIDS cases as of 2002, CDC

² Division of HIV/AIDS Services (DHAS), NJ Department of Health & Senior Services

³ Janssen R, et al, *AJPH* Vol. 91(7):1019, July 2001

⁴ New Jersey Department of Health and Senior Services, Division of AIDS Prevention and Control. New Jersey HIV/AIDS cases reported as of December 31, 2002.

⁵ Centers for Disease Control and Prevention. Update: HIV Counseling and Testing Using Rapid Tests – U.S., 1995. *MMWR* 1998(47) 211-215.

⁶ As with any screening test, positive predictive values (the probability that infection is truly present, given that test results are positive) may be low when disease prevalence is low, therefore, all initial reactive results must be confirmed.

BREAKTHROUGH IN RAPID HIV TESTING

On March 26, 2004, the FDA announced its approval of the first Rapid HIV Test for use with oral fluid, a new OraQuick test from OraSure Technologies, Inc.
Look for more information in the next issue of AIDSLine or check the CDC Rapid HIV Testing webpage:
http://www.cdc.gov/hiv/rapid_testing/

Training *Highlights*

NEW! HIV/AIDS Medical Update Series

This series of 1-hour HIV medical education programs has been developed to provide timely, expert, accessible training to health care professionals on HIV/AIDS care

Target audience: physicians, nurses, and other health care professionals and paraprofessionals throughout New Jersey who treat or provide services to persons with HIV/AIDS

Location: your health care site, by arrangement, between January and August 2004

Sponsors: Center for Continuing and Outreach Education-Division of AIDS Education at UMDNJ (UMDNJ-CCOE-AIDS), and the American Academy of CME, Inc. (AACME). The AACME is providing CME and CEN.

For information and to request on-site presentation(s): complete a brief request form available from Deborah Bottinick at the AACME, at (609) 921-6622 or DBOTTINICK@ACADEMYCME.ORG.

Topics available:

- **Diagnosis and Initial Management of HIV/AIDS: What the Primary Care Physician Should Know**
- **HIV/AIDS and Hepatitis C Co-Infection**
- **Immunizations for HIV Positive Adults**
- **Managing Occupational Exposure**
- **Prophylaxis and Treatment of Opportunistic Infections in Patients with HIV Disease**
- **Medical Intervention to Reduce the Risk of Vertical HIV Transmission**

The program is supported by an unrestricted educational grant from the New Jersey Department of Health & Senior Services, Division of HIV/AIDS Services, and replaces the "Roving Symposia"[™] previously presented by the Academy of Medicine of New Jersey.

RESOURCES

NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES, DIVISION OF HIV AND AIDS SERVICES

<http://www.state.nj.us/health/aids/aidsprv.htm> offers epidemiological reports, policies, and clinical guidelines for HIV/AIDS care and services in New Jersey.

New Jersey HIV/AIDS Semi-annual Newsletter, 12/01/03 [report through 6/30/03]

<http://www.state.nj.us/health/aids/aidsqtr.htm>

Free CME: articles and credit (1.0 hours) provided through *New Jersey Medicine* (the Medical Society of NJ)

- Syringe Exchange (09/03)
- Contraindicated Antiretroviral Drug Combinations (09/03)
- HIV Counseling and Testing in Pregnancy (09/03)
- HIV Disease Surveillance (09/03)
- HIV and Hepatitis C Co-Infection (09/03)
- Immunizations in HIV-Infected Patients (09/03)
- Recommendations for Reducing the Risk of Occupational HIV Transmission (09/03)
- Rapid Diagnostic Testing for HIV (09/03)
- HIV Resistance Testing (09/03)
- Updated Recommendations for Reducing Vertical HIV Transmission (09/03)

AIDS Education Training Center

<http://www.aids-etc.org>

AETC National Resource Center offers HIV treatment guidelines and key journal articles and news releases, links to all AETCs, training materials and curricula, and evaluation tools.

NEW! Rapid HIV Testing during Labor & Delivery for Women of Unknown HIV Status:

Links to these documents will be found on:

http://www.cdc.gov/hiv/rapid_testing/index.htm#women

A Practical Guide and Model Protocol
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- Elaine Gross, RN, MS, CNS-C: François-Xavier Bagnoud Center; University of Medicine & Dentistry of NJ; Newark



Training Highlights

CONFERENCE HIGHLIGHT: RYAN WHITE ALL-TITLES CONFERENCE, NOVEMBER 19, 2003

On November 19, 2003, the Division of AIDS Education at the UMDNJ-Center for Continuing and Outreach Education coordinated New Jersey's biennial Ryan White CARE Act All Titles Conference in Princeton, NJ. Jointly sponsored by the NJDHSS Division of HIV/AIDS Services and the NJ Statewide Coordinated Statement of Need Planning Taskforce, the conference was designed to assist recipients of Titles I-IV and Part F funding in developing and strengthening service linkages and collaborations as a proactive response to potential changes in CARE Act funding and/or regulations.

The conference was planned in part as a data-gathering tool for the New Jersey 2004 Statewide Coordinated Statement of Need document. In attendance were 204 participants representing not only north, central and southern regions of New Jersey, but also each of the Titles as well as members of health care, social service and administration professions and infected and affected consumers of Ryan White services. Conference participants were asked to answer a series of questions designed to assess both the ability and needs of each Title to maintain continuity of care and services for HIV+ consumers. The transcribed comments from all

discussion sessions will be provided for the participants and administrators of each Title, and incorporated into the SCSN document later in 2004.

Throughout the day, thought-provoking presentations on anticipated changes to the Ryan White CARE Act were given by faculty including Marsha Martin, DSW, from AIDS Action and Mary Boland, DrPH, MSN, RN, from UMDNJ-FXB Center. For the final presentation, Carmine Grasso, MSW, MPH, Director of the NJDHSS Care and Treatment Unit, disclosed a number of planned systemic changes to the state's ADAP program in 2004, and the projected elimination of the Title II-funded HIV Care Consortia. Mr. Grasso devoted his remaining time to fielding questions, which ranged from explaining the state's rationale for the changes to addressing potential implications for affected organizations and consumers.

Program evaluations ranked this conference as one of the most informative, provocative and well-designed All Titles program in years.

Photo from
Ryan White Conference
(left to right)

Marsha Martin, DSW
Executive Director,
AIDS Action, Washington, DC

Carmine Grasso, MPH, MSW
Director of Care & Treatment,
NJDHSS-DHAS

Sindy M. Paul, MD, MPH
Medical Director, Division of
HIV/AIDS Services at NJDHSS



What are the Clinicians Saying?

KAREN STRALKUS, RN
PROGRAM COORDINATOR
ROBERT WOOD JOHNSON'S HIV COUNSELING & TESTING PROGRAM

In mid January NJ AIDSline had the opportunity to meet with Karen Stralkus, RN, Program Coordinator for Robert Wood Johnson's HIV Counseling and Testing program. This was one of the first publicly funded sites in New Jersey to perform the rapid HIV test. The following excerpts are from this interview between Ms. Stralkus and myself.

I am very grateful to Karen Stralkus for taking the time to meet with me and share the important developments experienced in the early stages of Rapid HIV Testing in New Jersey.

Laura De Noble, MA, Editor



Editor: Please briefly describe the steps in which the Oraquick test is administered.

K.S.: First, the client is escorted into a private office with one of the counselors. The counselor obtains a signed consent form; a fingerstick whole blood specimen is then collected and transferred into the vial of developer solution. The sample is then inserted into the test device. A timer is then started.

While waiting for results, the counselor will speak with the client about his/her level of risk and ways in which to lower it. During this time, the counselor will also explain what a preliminary positive and negative result means. The counselor will ask the client what they believe would happen if the result were either preliminary positive or negative. By the end of this discussion- the results will be ready for reading.

Editor: Please describe what your process is after giving a negative result.

K.S.: If the result is negative, the counselor will provide up to six months of follow up for "high risk" individuals, in order to assess any future risks and lower the present found risks.

The counselor will also provide the individual with ideas or goals of how to lower their risk level. For example, if a "high risk MSM" (Men who have sex with Men) has a negative result- the counselor will encourage him to use flavored condoms during oral sex.

Editor:...if the result is positive...

K.S.: Whenever a preliminary positive result appears, the counselor takes a tube of blood is taken and sends off to the state lab in order for the Western Blot (confirmatory) test to be performed. At this point, the individual is told that they should return within 48 Hours to have their status confirmed. They are told that if they will be engaging in any sexual activity- they need to use condoms while waiting for the results because they could possibly pass the virus on. RWJ's CTS will then follow the client for up to 6 months; providing referrals for needs such as psychiatric services, housing, medical care, and peer support groups. The client will also be provided with information regarding clinical trials. The counselor also offers the client a "safe environment" where the individual may choose to disclose his or her status to partners, friends or family members.

HIV/AIDS OPEN CLINICAL STUDIES IN NEW JERSEY

This month's section on clinical trials will exclusively feature the SMART Trial
To find out more on SMART (Strategies for Management of Anti-retroviral Therapy)
 please visit their website: www.smart-trial.org

The purpose of this study is to compare the long-term clinical consequences of two strategies of antiretroviral therapy management. Patients will be randomized to one of two arms: Drug Conservation (DC) is a strategy aimed at conserving drugs through episodic use of antiretroviral treatment for the minimum time to maintain CD4 cells greater than or equal to 250. Viral Suppression Arm (VS) is a strategy aimed at suppressing viral load as much as possible immediately following randomization and throughout follow up irrespective of CD4 cell count.

Participants will be enrolled over a three year period. CD4 cells must be over 350. They must be able to give informed consent. They must be over 13 years of age. Participants must be willing to initiate, modify, or stop antiretroviral therapy, in accordance with the randomized assignment. And if they are participating in sexual activity that could lead to pregnancy, they must be willing to use acceptable contraception methods.

Northern New Jersey Community Research Initiative	Southern New Jersey AIDS Clinical Trials	New Jersey Medical School/ UMDNJ-University Hospital Clinical Research Group
<p>TEL: 1-800-652-7448 / 973-483-3444</p> <p>Sites in: Newark Paterson Perth Amboy Princeton Hillsborough Randolph Union New Brunswick</p>	<p>TEL: 856-963-6890</p> <p>Sites in: Camden Neptune Voorhees Trenton</p>	<p>TEL: 973-972-1268</p> <p>Sites in: Newark</p>



*If you would like the opportunity to recruit for your clinical trial in NJ AIDSLine, please contact editor Laura De Noble at 973-972-1972 or email denoblrl@umdnj.edu

COUNSELING AND TESTING SITES IN NEW JERSEY BY COUNTY

Atlantic

Atlantic City Health Department, 609-347-6457

Bergen

Bergen County Counseling Center, Hackensack, 201-487-3243

Camden

Camden County Health Department Blackwood, 856-374-6355
Camden AHEC (Mobile Unit), 856-963-2432

Essex

*St. Michaels Medical Center, Newark, 973-877-5525
East Orange Health Department, East Orange, 973-266-5454
Newark Community Health Center, Newark, 973-483-1300
UMDNJ-STOP (Mobile Unit), Newark, 973-972-8216
*Newark Beth Israel Medical Center, Newark, 973-926-3960

Hudson

*Jersey City Medical Center, Jersey City, 201-915-2545

Hunterdon

Hunterdon County Department of Health, Flemington, 908-806-4893

Mercer

Henry J. Austin Health Center, Trenton, 609-278-5946

Middlesex

*Robert Wood Johnson Medical Center, New Brunswick, 732-235-7114
Raritan Bay Medical Center, Perth Amboy, 732-324-5346

Monmouth

*Jersey Shore University Medical Center (Monmouth Regional
Screening Center), Neptune, 732-774-0151,
CheckMate Inc. (Mobile Unit), Asbury Park, 732-774-3100

Morris

Morristown Memorial Hospital, Morristown, 973-971-8910

Ocean

Ocean County Health Department, Toms River, 732-341-9700 ext. 7502

Passaic

St. Joseph's Hospital and Medical Center, Paterson, 973-754-4720

Union

Hyacinth Foundation, Plainfield, 908-755-0021
Plainfield Community Health Center, Plainfield, 908-753-6401 ext. 138
Elizabeth General Medical Center, Elizabeth, 908-965-7300 or 908-965-7605

* Rapid Testing Site

CONTACT INFORMATION

**UMDNJ-Center for Continuing
& Outreach Education,
Division of AIDS Education**
30 Bergen Street, ADMC 710
PO Box 1709
Newark, New Jersey 07101-1709
973-972-3690 / 973-972-3371
denoblr@umdnj.edu

Editor

Laura De Noble, MA

Contributing Writers

Linda White, MS

David Rosen, MSW, LCSW

Kimi Nakata, MSW, MPH

Medical Advisor

Sindy Paul, MD, MPH

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