

AIDS

INFO SOURCE

Treatment Issues & Information

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RESISTANCE AND RESISTANCE TESTING

A New Tool For New Treatment Complications

Daniel S. Berger MD

The new millennium has brought new complexities of treatment and created more challenges to HIV experts treating individual patients. More of our patients have been living longer but changes in their treatment cocktails are often needed. At times treatment must be altered because of intolerable side effects, but at times drug resistance has developed.

The term resistance refers to reduced ability for the antiviral medications to suppress HIV replication, which ultimately leads to rising viral load, sometimes despite a consistency in taking one's medications. To explain the viral ability to replicate over and beyond the barricade of antiviral drug defense is to explain mutant HIV strains. The viral ability to replicate is a result of its ability to mutate or change its genetic make-up, which then eludes and evades the antiviral effect of specific drugs. In other words these mutational strains of HIV are resistant to the effects of antiviral drugs that the individual patient is taking. How high a

Finally, the prevalence of AIDS-related complications including MIV, CMV, or Wasting Syndrome are remarkably less than several years ago. Overall, patients are much better off than in years past. More good news stems from the work to develop less complicated drug regimens for the patients. Simplifying drug cocktails to twice daily

Artwork by Dan Kreider

viral load reaches before we describe a patient to have resistance is not clearly defined and is often subject to a physician's opinion.

Physicians who specialize in treatment of HIV should understand differences in mutations caused by various antiretroviral agents. These include recognizing which drugs have common mutations that confer cross-resistance between other drugs, usually belonging with the same antiviral class. Additionally, the physician should

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UNPROTECTED SEX DANGERS

BAREBACKING:

by Gregory M. Sarlo, Psy-D
Doctoral Licensed Clinical Psychotherapist



While on my merry way of surfing the net for new information, I went into a few chat rooms and visited a few web sites anonymously. I found out that every Friday and Sunday night in San Francisco and in our own home town in Chicago, somebody named Marshall and Mark host a party for other gay men who share a similar sexual interest: No condoms required. If I were to attend, admission is \$8 dollars. After paying the eight dollars, I

would be handed literature stating that this was a barebacking party, the house rules would read as follows: It is assumed that all guests are HIV positive and made the decision to attend this party. There would be no discussion of status, illness, or medicine. Partygoers must also sign a statement of their intention not to infect anyone with HIV, whether or not they mean it. This relieves the host of any responsibility under the new law that criminalizes HIV transmission.

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Resistance and resistance testing

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Although the development and utilization of resistance testing is a new milestone among HIV therapeutic armamentarium, there are various questions and unresolved issues regarding genotypic and phenotypic testing

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know his or her patient's HIV treatment history, to apply all the facts towards construction of a patient's new antiviral regimen when and if they have developed resistance to their current treatment. Finally, if an individual had intolerable toxicities to a specific antiviral drug, decision-making is further influenced and one tends to avoid utilizing drugs that may provide similar toxicity. All of these and other factors are taken into account when constructing a patients' regimen - after resistance has developed. However, now in the arsenal of weapons to help configure these new regimens, are

tests that can help weed out some of the wrong possibilities. They include genotype and phenotype testing.

Genotype testing identifies the various mutations within an individual's blood that are known to cause resistance to specific HIV drugs. The most efficient use of this test is taking a sample of a patients' blood while they are on therapy but their viral load must exceed 1000 copies/ml. Remaining on therapy while the test is administered insures that mutant virus is present and can be captured for the test to be of greater accuracy.

Phenotype testing measures the virus' ability to replicate in varying concentrations of drugs in the test tube. Therefore, phenotypic testing should directly examine or test a patients' HIV and their response to treatment with specific drugs. This test should also be performed while the individual is taking his current treatment regimen.

Although the development and utilization of resistance testing is a new milestone among HIV therapeutic armamentarium, there

are various questions and unresolved issues regarding genotypic and phenotypic testing. Both tests show improved virologic outcome but no study has compared the two tests to demonstrate whether one test should be preferable over the other.

There are multiple studies recommending resistance testing for treatment failure. One instance of investigating the utility of the phenotype test was in the Vero 3001 trial. Here 274 patients who failed their first protease inhibitor regimen and could have had more than one set of nucleosides used in the past were studied. In this study the subjects had either their next cocktail chosen by either their physician or phenotype guided regimen. While there were various problems with the results of this study, including a high patient drop out rate from the trial, of the remaining analysis 38% of patients with phenotype guided regimens vs. 23 % of standard-of-care regimen showed viral loads less than 400 copies after 16 weeks. Therefore it may be concluded that patients in this circumstance would benefit having resistance testing done.

In other instances, such as in patients starting their first regimen, there are questions as to whether a resistance test should be preformed before starting initial therapy.

On the brighter side of resistance, various levels of resistance may or may not result in treatment failure..

There is the rationale to test someone who is recently infected since that individual may have been exposed to resistant virus. Having this knowledge can prevent failure of the first regimen only if there was exposure to resistant virus. However, there has to be resistant species predominating so that it

can be measured. We have not been performing genotype or phenotype testing in naive subjects since we have not witnessed treatment failures of initial regimens thus far. Also chronically infected individuals but naive to antivirals often have predominant wild type virus (non mutated virus) so that the likelihood of isolating resistance is low. In this situation, the utility of this test is also limited.

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Mission Statement

It is the mission of *AIDS Info Source* to provide free, timely, accurate, educational information pertinent to all persons living with HIV disease, their caregivers and healthcare professionals. *AIDS Info Source* attempts to service every educational aspect of the disease without regard to ones race, religion or sexual orientation.

Barebacking

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Recently I discussed this with someone who has attended such a party. He gave me the low-down on what follows. After he signed in, he was instructed to take off his clothes and stuff them into a bag labeled with his first name and last initial, with a sense of trepidation, he proceeded downstairs into a large bedroom occupied by dozens of men in various positions of sexual activity. There were no condoms in sight.

Since its public debut over three years ago, barebacking also called raw skin-to-skin sex has been simultaneously condemned and sensationalized by the media. The debate is stuck between two hyper-polarized camps, with anti-barebackers screaming, “Dangerous Sex Fiends”, while barebackers counter with “Condom Nazis”. Meantime, a new sexual subculture has emerged, organized around a new no-condoms creed. Driven underground but swelling in numbers, this community flourishes in private houses and especially on the Internet, where its’ members not all purported to be HIV+ can fantasize, experiment, and connect with others, free from the stigma attached to openly soliciting unsafe sex.

The notion that the new drugs may be contributing to a climate of sexual disinhibition became a media phenomenon last summer after Michelangelo Signorile’s article, “Bareback and Reckless” which appeared in the July issue of *Out* Magazine. Many have excused themselves by claiming HIV is a manageable disease. The following month, the New England Journal of Medicine published a letter suggesting that protease inhibitors have altered the perception of perceived risk of contracting HIV for many gay men. Twenty-six percent of the men surveyed reported being less concerned about becoming HIV-positive because of the new treatments. Fifteen percent had already had unprotected anal sex because of their decreased concern.

Dramatic reductions in viral load as a result of the new treatments could create new rationales for unprotected sex. Wishful thinking may lead some men to conclude that undetectable levels of the virus in their blood is equivalent to being HIV negative. The new treatments have led some men to conclude that the consequences of HIV infection for themselves or their negative partners have been minimized. Michael, webmaster of Xtreme’ Sex, a barebacking web site, says that now HIV is merely a minor inconvenience and that is not the catastrophe “negatives” think it is.

Since the start of the epidemic, individuals who are positive or negative were advised correctly regarding the necessity of using condoms during intercourse. This is also prudent if both partners are positive. . Some individuals express that the dangers of re-infection aren’t actually proven but better safe than sorry. Physicians explain the risks of re-exposure to HIV; their disease can become complicated with resistant virus and result in further progression. Further infections can also impose trauma and immune stress.

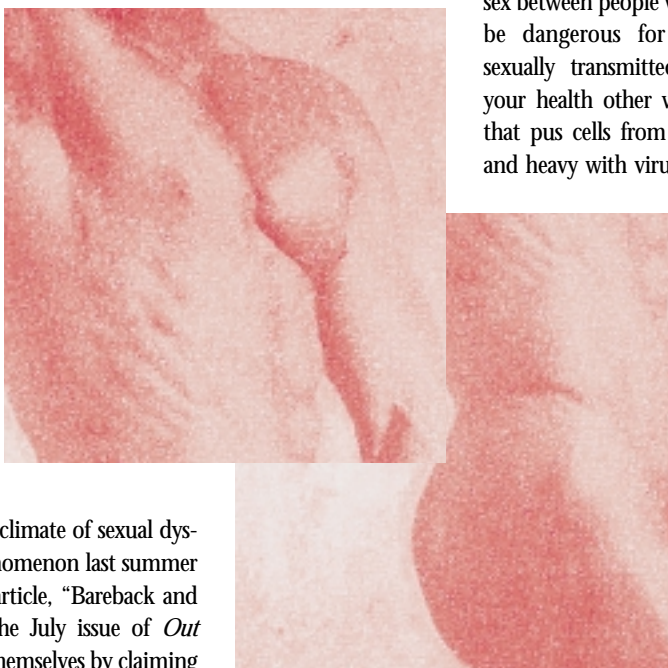
But despite their doctors’ reservations, many HIV-positive people reject this advice and don’t use condoms for positive-positive sex because they have not seen the evidence or danger

hit them in the face. Of course, unprotected sex between people who are HIV-positive can be dangerous for other reasons. Other sexually transmitted diseases can threaten your health other ways. It has been shown that pus cells from other STD’s are loaded and heavy with virus and HIV. Additionally,

one can become infected with Hepatitis C, of which currently there is no existing effective treatment. Persons co-infected with HIV and Hepatitis C are left with potentially having to face liver cancer and cirrhosis, down the road.

It has been difficult for many to have a quiet, rational

discussion about this topic. For many, barebacking pushes emotional buttons. The issue is compounded lately by the sensationalism and often misrepresentation. It is no secret that barebacking is a sensitive and complex issue that carries with it emotional baggage. While barebackers seem to represent a distinct minority of gay men who have unprotected sex, their reasons for doing so are irrational despite that many gay men share the desire, consciously or not. It has been stated to me that barebacking is the ultimate act and sharing virus with others is a sexual “high”. One feels sorry for persons thinking this way: why can’t they derive sexual pleasure in a way that is not medically injurious? How can they believe that the ten years of medical hard work and research will bail them out? One example patient in San Francisco, who physicians published his case in the prestigious New England Journal of Medicine, was not able to be bailed out.



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Reflections

After the 1999 National Conference on Women and HIV/ AIDS

by Pam



The 1999 National Conference on Women and HIV/ AIDS was held in Los Angeles, California from October 9-12. The conference was attended by people who are infected and/or affected by HIV/AIDS from across the United States and Canada. There were about 600 scholarships available and I was of several women from Chicago who received one.

At first, it was difficult to make the choice to go to Los Angeles. A vacation on the West Coast is one thing; but, to go and search for answers in dealing with the virus within is another thing altogether. After a great deal of soul-searching I chose to go and look for information and hopefully some new treatments or breakthroughs.

At first, it was difficult to make the choice to go to Los Angeles. A vacation on the West Coast is one thing; but, to go and search for answers in dealing with the virus within is another thing altogether. After a great deal of soul-searching I chose to go and look for information and hopefully some new treatments or breakthroughs.

I arrived at the convention center and immediately recognized some familiar faces from past conferences and even some women from Chicago. I met a woman who was circulating material concerning a website she published dealing with HIV positive women who are sexually active. Her internet "magazine" is entitled DENTATA. I recognized the name because my boyfriend had submitted a love poem about me to the magazine and it had been published in the premier issue. I knew that Susan was a lesbian and had initially thought she would be a rough looking "dyke". When I realized this lady was the publisher; I was shocked. To my surprise Susan was a demure, sweet young lady. I introduced myself and we laughed and delighted in the "world" we lived in.

This "small world" atmosphere had begun earlier when I checked into my hotel and had discovered who my roommate was. Beri and I had first met over four years ago, in Chicago, in a support group I was the facilitator of. Beri is a former IV drug user who had been in denial of being at risk for several years. She had come to the support group in an effort to face the truth and accept that she had the virus. Beri and I had

discovered we had someone in common. I had gotten the virus from having sex with an old boyfriend who was an IV drug user. Beri had known him prior to our relationship and had been the first person to start him on IV drug use. Now over four years after learning this information we both were at the National Conference and were roommates. The anger and hurt one deals with in accepting the virus is eventually replaced with a determined will to live.

As you will discover through reading this article; it does not matter how you acquire the virus. What matters is how you live with it. I met another old acquaintance who typifies this will to live. She is positive; her husband is negative and she is also the mother of twins who are negative. I first met her at another convention a few years ago when her twins were just babies. She writes for a magazine in California and leads what most people would consider a normal life. The subject of pregnancy and HIV/AIDS is intense and controversial. It was the focus of several seminars and I learned a great deal of facts.

The transmission of HIV from a pregnant woman to her fetus is known as perinatal transmission. This can occur prior to delivery, during delivery or from breast feeding. In 1997 an estimated 7,000 HIV infected women gave birth in the United States. Without intervention 15-30% of these infants could become HIV positive. Recent studies have shown that administering the drug AZT prior to delivery can reduce this risk to less than

10%. These findings have given HIV positive women the opportunity to have healthy babies. The most important factor being that the pregnant woman knows she is HIV-positive prior to giving birth. This has created a dilemma amongst HIV-positive women/families. It goes back to the desire to lead a normal life. A few years ago I got pregnant and could not go through with it. Now, women have a real choice to make. I have a good friend who is pregnant. Both her and her husband are HIV- positive and they have chosen to have a baby. The reduction in probability of having an infected baby and the progress made in medications have given people with HIV/AIDS the possibility of living a long, productive and yes, normal life.

Leading a normal life with HIV/AIDS is an extremely important issue. However, more important than that is prevention of the virus altogether. Women are one of the fastest growing groups to be infected with the virus. The disease is becoming increasingly common amongst younger women- especially women of color. In 1996 AIDS became the third leading cause of death in women of reproductive age and the number one cause of death of African-American women of that age. The symptoms that could serve as warning signals of infection may be ignored because many women do not perceive themselves at risk. Symptoms include recurrent yeast infections, pelvic inflammatory disease, abnormal changes in cervical tissue, genital warts, and severe mucosal herpes infections. It is possible for a person infected with HIV to not show signs for extended periods of time. Some people within a few weeks of becoming infected show flu-like symptoms. I remember getting sick and having strep throat but not in a million years did I ever dream I was infected. I listened to the news and knew of the epidemic, but never dreamed I was at risk. I was having unprotected sex with my boyfriend and did not know of his IV drug use. I found out because I went with a girlfriend who thought she was possibly positive and we both were tested. She was negative and I, the one "without" risk was positive. Safe sex through condom use and several other methods is vital. I attended a HIV lesbian seminar to learn what I could about the virus' transmission in this area. I found out that only 5 cases have been reported to the

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OUT OF AFRICA

Editorial by Daniel S. Berger, M.D.

Center for Disease Control. I wanted to know about safe-sex practices during oral sex. Most case workers and sex educators will advise the use of a barrier during oral sex. They recommend a dental dam or plastic wrap to prevent mouth to vaginal contact.

It is very uncommon for these measures to be utilized. Another recommended preventative is to have sex in the light to see what your partner looks like. Although, most people do not like to think about it. It is imperative that people practice safe-sex methods and regularly get tested for sexually transmitted diseases or STDs. A perfect example of how the risk factor comes into play occurred one night at the hotel I stayed at. I was enjoying a soak in the hot tub, next to the pool, with several other women from the conference. All of us were HIV-positive and there were men getting in the hot tub and asking us for dates etcetera. They were unaware that we were attending the conference. One man brushed against my leg "accidentally" and I jumped out of the water and left. I am mentioning this because no one knows who has it. The danger is out there.

There were other people at the conference who I enjoyed speaking with. One group was called M.A.P. - Mothers of AIDS Patients. These mothers were a joy to behold. They each gave me a hug and we discussed my parents' support and I left their table with tears in my eyes and a wonderful feeling of support.

I was told of a story about a very ill woman who attended the conference against her doctor's wishes. She felt the need to be there to either add support or receive it. She passed away during the conference and was an amazing example of courage.

One woman proudly told me that this conference was a history making moment. She had learned that never before had so many HIV-positive women come together in one event.

Leaving Los Angeles and the convention I was filled with emotions. I had overcome my original fear of going and come away with some useful information and a rejuvenated sense of hope. I did not find a miracle cure. I do know that the battle is always with me. But, most of all, I found that women with HIV/AIDS have a great deal of support, and the opportunity to live a normal life.

I write this article after the XIII International Conference on AIDS held in DURBAN, South Africa (July 10). This has been the first International Conference on AIDS in many years that I have opted not attended. Choosing not to attend was difficult but there were several reasons. I felt uneasy going to an area of the world that requires many extra precautions. One would have to take anti-malaria prophylaxis, as well as, multiple vaccinations against a variety of possible infections. If one were to get sick, being a physician accustomed to diseases of the Western world, there was a pervasive feeling of uneasiness at tackling the possible exotic diseases of Africa, not to mention being too far from home to obtain proper medical care, should the need arise. Additionally, there were many warnings issued from the International AIDS Society regarding safety issues. Many assaults, robberies, rapes and car jackings have been occurring in South Africa. Would the authorities in Durban be able to ensure the safety of the attendees? One can only hope that nothing dreadful occurs. Due to modern day technology, one can go on the Internet after many of the programs are presented and obtain all the necessary information. This also provides a large cost savings. The venue at such far a location carries with it costly international airfares, and hotel costs are often excessive. Much of the benefit to attending conferences such as this is the academic interaction and discussion with many of my colleagues; this I was not able to replace. However, my mother planned to undergo serious surgery and treatment, which left me uneasy about not being there for her, let alone being out of the country.

Much of the conference centered over the dire situation HIV-positive Africans find themselves in. While poverty and stigma have been blamed for fueling the AIDS epidemic affecting some 35 million people worldwide, it is the inaccessibility to life-saving drugs that dominated the 13th International AIDS Conference. With 35 percent of adults infected with the HIV virus, the highest rate in the world, the African nation has an urgent need for help.

Many people in Africa either believe the epidemic does not exist, or that it occurs to only persons "misbehaving". It was important for the conference to be held in Africa so that others from the west can see the conditions in their society that are prevalent, as well as the discrimination, isolation, rejection, stigmatization and lack of human rights, still present.

During the Conference it was announced that the Bill and Melinda Gates Foundation had joined forces with the U.S. pharmaceutical company Merck & Co. to donate \$100 million to fight AIDS in Botswana over five years. Subsequently, other pharmaceutical companies followed suit. One hopes that their generous gesture is implemented quickly and speedily; but unfortunately for many, this happened all too late. More needs to be done in other countries and sooner rather than later.

One only need to remember the frustration among our community and persons affected with HIV during the early years of the epidemic in the United States. Alternative theories regarding the cause of AIDS were common. During those years there was the prevailing hopelessness and lack of treatment for HIV infection; new opportunistic infections were a daily occurrence for those infected. The hospitals were riddled with AIDS and desperation abounded for those caught in the HIV net.

In an effort to control HIV throughout the world, there should be more interested parties actively participating, coming to the table. Ideally, there should be generic versions of antiretroviral drugs available in those societies unable to pay for the current costs. Funding for education regarding transmission and prevention during pregnancy and otherwise should be prominent. Governments, The Vatican, and Church in Africa, as well as those agencies around the world should cooperate. Enthusiastic advocacy for funding, treatments, education, prevention need to be initiated with force.

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The Role of Interleukin-2 in Combination with Antiretroviral Therapy

Does IL-2 Have A Hidden Antiviral Benefit?

By Matthew Sirinek, MD

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The development of combination antiretroviral therapy has led to dramatic and lasting decreases in HIV levels in the blood. While these treatments have led to a profound reduction in the incidence of opportunistic infections and death in the past five years, they appear to fall short of restoring the immune system to normal levels.

Currently available therapies primarily work to suppress HIV replication, not necessarily stimulate the functioning of the immune system. With a combination of new immuno-modifying therapies used together with current anti-HIV medications, we may be able to further increase immune system functioning, helping the body to fight HIV more effectively.

Interleukin 2 (IL-2) has shown promise in increasing immunologic activity as an adjunct to HAART. IL-2 is known to play a central role in the generation of strong immune responses. It is naturally produced by T cells (and other immune cells) and stimulates the production of more T cells, as well as B cells, natural killer cells and monocytes. Some studies have shown that IL-2 activated T cells also have an improved capacity to suppress HIV replication.

The immune system also has reservoirs of latent (or dormant) T cells where HIV can remain unreached by medications. As IL-2 activates these latent cells, the "hidden" HIV becomes susceptible to the drugs. In essence, IL-2 can help purge HIV from places medications can't reach. Therefore, IL-2 has demonstrated an ability not only to increase T cell counts, but also may aid the medications in suppressing the HIV virus.

IL-2 is commonly administered as a subcutaneous injection either once or twice daily. It is given for five consecutive days every eight weeks for one year. In the eight-week intervals between treatments, the patients simply continue to take their HIV medications as usual. While patients are taking IL-2 for those 5 days, they

may experience side effects associated with an activated immune system. These include fatigue, fevers, chills, night sweats, nasal congestion, rash, and other flu-like symptoms. Some patients have developed small red, inflammation and/or painless nodules at the

Interleukin 2 (IL-2) is known to play a central role in the generation of strong immune responses.

sites of injection that can last for a few weeks. These side effects can be somewhat controlled with ibuprofen and tylenol given as needed. After each 5 day cycle, patients usually quickly recover to normal functioning.

A recent landmark study of IL-2 treatment in combination with potent HIV cocktails was published in JAMA (July 12, 2000-Vol. 284, No.2). The results uniquely demonstrated that patients on IL-2 treatment had an anti-HIV advantage. The group of individuals on treatment with IL-2 were demonstrated to result in lower viral loads, as well as the immune system benefit. All study patients had T cell counts between 200-500 and HIV viral loads less than 10,000 copies/ml. They were taking at least 3 HIV medications to suppress the virus. The participants in the study were then randomized to either receive subcutaneous IL-2 plus their HIV medications vs. HIV medications alone and without IL-2 (control group).

T cell counts and HIV viral load was measured for 1 year. The mean percentage increase in T cell counts was 112% for the IL-2 treated patients vs. 18% for patients receiving only HIV medications. T cell percentage increased 12% for the IL-2 patients vs. 2.6% for the control patients. 67% of the patients receiving IL-2 were able achieve a viral load below 50 copies/ml compared to only 36% for control patients. All three of the measurements demonstrate that

intermittent therapy with IL-2 combined with continuous antiretroviral therapy produced a substantially greater increase in T cells and a larger decrease in HIV viral load than with antiretroviral therapy alone.

At NorthStar Medical Center, we are currently conducting a clinical trial using a new formulation of IL-2 called "Monomeric IL-2". This form of IL-2 is structurally different from the traditional IL-2 used in most studies. The one advantage it may have over the traditional IL-2 is that it may not cause the degree of inflammation or undesirable nodules at the injection sites that sometimes occur with traditional IL-2. The study is still open and looking for patients on effective HIV cocktails who have T cells between 300-500 and HIV viral loads less than 10,000. Individuals looking to participate should not have had previous experience with IL-2 and must be off hydroxyurea for at least 4 months to be eligible. Qualified patients are randomized to either 3 doses of the new IL-2, 2 doses of the regular IL-2, or being observed on their antiviral cocktails as a control group however these patients will indeed be eligible for treatment with traditional

The study is still open and looking for patients on effective HIV cocktails who have T cells between 300-500 and HIV viral loads less than 10,000.

IL-2 after completing the study of 24 weeks. The IL-2 will be administered twice-a-day for five consecutive days every 8 weeks for three cycles over 6 months. Blood samples will be collected at certain intervals throughout the study, and patients will be required to fill out a diary.

All patients are allowed to take over-the-counter medications to control side effects during each 5 day treatment. (If you are interested in screening for this study call Dr. Sirinek at (773) 296-2400).

CHIC, CHIP, & ADAP --- WHAT YOU NEED TO KNOW

You are HIV+, you live in Illinois, and you are faced with a crisis---medical coverage and you do not qualify for Public AID. What do you do?

By Michael Martino

The State of Illinois has available the following three programs that allow HIV+ individuals to gain access to their healthcare and medication needs when because of income/assets or disability status they do not qualify for Public AID: Illinois AIDS Drug Assistance Program (ADAP); Continuation of Health Insurance Coverage Program (CHIC); Comprehensive Health Insurance Plan (CHIP)

ADAP The Illinois State Drug Assistance Program provides drugs related to the treatment of HIV for those residents that either do not have insurance or have prescription coverage which pays less than 80% the cost of medication (requiring the individual to pay greater than 20% the cost of prescriptions). ADAP provides a drug formulary benefit which can support a triple (or quadruple) combination anti-retroviral therapy prescribed by your doctor. The program has a list of 61 HIV-related drugs that it covers, including all anti-retrovirals. There is a \$1000 per month cap for your ADAP prescription coverage; however this is more than sufficient to cover most physician prescribed therapies. The medications are mail-ordered through Statlanders Pharmacy and sent to any Illinois address you designate. The qualifications for the program are: Completed application; Illinois resident; HIV+; Income of less than 4x the federal poverty level; Either no insurance coverage or prescription coverage that pays less than 80%. You must send with your application proof of your income, recent CD4 or Viral Load count, and a copy of a valid Illinois ID or recent utility bill. The program is completely confidential. To obtain more information or an application, contact: Illinois Department of Public Health HIV/AIDS Section-ADAP 525 W Jefferson St, 1st Floor Springfield, IL 62761 or call 800-825-3518.

CHIC The Continuation Of Health Insurance Coverage Program is a specific insurance program offered through the Department of Public Health to assist HIV+ individuals who have left their employment and need to continue health insurance coverage through COBRA. The program will pay the monthly premium of the group plan (up to a maximum of \$300) for the qualified individual. In order to be eligible for the program you must be HIV+, a resident of Illinois, have a health insurance plan which covers prescriptions, and meet income and asset standards (income of less than 2x the poverty level and assets not to exceed \$10,000). Enrollment in the program requires a completed application submitted with verification of wages-income-assets, valid Illinois ID or utility bill, and a letter from a licensed physician confirming a diagnosis of AIDS. To receive additional information of submit a completed application, contact: Department of Public Health AIDS Activity Section 525 West Jefferson Street, 1st Floor Springfield, IL 62761 (217) 525-5983 and refer to the CHIC program.

CHIP The Comprehensive Health Insurance Plan is an insurance program offered through the State of Illinois for individuals with qualifying health conditions that are not able to obtain individual insurance plans or participate in group health insurance programs (as are typically offered through an employer). The program is a Blue Cross Blue Shield PPO plan, that is offered at affordable rates based upon age and county of residence. This program is especially ideal for self-employed individuals who because of income and assets would not qualify for Public AID. There is a six-month waiting period

before benefits would start for treatment associated with HIV unless the individual applied for the plan within 63 days of prior group health coverage. The program provides complete medical coverage including prescription benefit. Another highlight of this program is that if someone is on Medicare because of disability status, that individual would be able to apply for this insurance plan as secondary coverage—which again will include prescription coverage. Eligibility requirements include a valid Illinois ID, verification of HIV status, a completed application, and proof of denial for insurance coverage related to HIV and/or participating in an inferior insurance plan. To receive additional information contact: AIDS Activity Section, 400 West Monroe Street, Suite 202, Springfield, IL 62704; 1(800) 962-8384.

To participate in any of these programs does not require the assistance of a social worker. You can contact the programs direct and complete and submit applications on your own. Remember to make copies of any paperwork and applications submitted.

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STUDIES

- *Most studies provide for antiviral drugs, labs and Dr./study visits and are free of charge to the patient during the study.*
- *Think about being part of a study, or referring a friend, that is not on effective treatment*
- *Gain access to the newest generation of up and coming treatments.*

Tenofovir DF (PMPA Prodrug) Protocol 903

Tenofovir is part of a new class of agents called nucleotide reverse transcriptase inhibitors. This study is for naïve patients, or patients that have never been on HIV therapy. It is a randomized double-blind in combination with 3TC and Sustiva vs. D4T, 3TC and Sustiva. The study is a 48 week study, but promises to continue till the drug's approval.

PMPA Prodrug - Tenofovir Protocol 907 (Phase 3)

This is a part of the new class of agents called nucleotide reverse transcriptase inhibitors. The study keeps patients on their already stable cocktail but adds this new potent agent to the regimen. This phase III, 48 week study is for patients who have been on stable therapy and who have viral loads between 400 and 10,000.

Second Generation Non-nucleoside Phase 2 Protocol 083

This is the new second generation non-nucleoside reverse transcriptase inhibitor (DPC-083) - study that is randomized double-blind of two doses of DPC 083 in combination with open-label nucleoside analog reverse transcriptase inhibitors in HIV-1 infected patients who are failing treatment with a non-nucleoside reverse transcriptase inhibitor-containing regimen. This new agent is considered a true second generation NNRTI, promising to be an effective antiviral against resistance mutants of other currently available non-nukes

Lipodystrophy and/or Elevated Lactate Levels Switch Study

This study is to assess the regression of hyperlactatemia (elevated lactic acid levels in the blood) and to evaluate the regression of lipodystrophy in HIV-1 positive individuals (TARHEEL Protocol). Experienced patients will be switched, open label to zigen from d4T. Naïve patients will be placed on Combivir. Intensification will be permitted in the event of loss of virologic control.

L2-7001 - Interleukin-2

This is a phase II, 6 month study examines 3 doses of a new formulation of IL-2, that appears to be three times more potent and with less side effects than the currently used IL-2. The study eligibility includes patients with T cell counts between 300 and 500 cells. Viral loads should be less than 10,000 copies. Patients will be randomized to receive either the L2 form of IL2 or Proleukin IL2 twice daily (split dosing) for 5 days every two months. Some patients will be asked to be tested for IL2 blood levels.a

FTC (Emtricitabine) vs d4T

FTC is a new potent nucleoside analog. In-vitro studies demonstrated FTC to be more potent than 3TC. This study is a randomized double blind study comparing two arms: FTC +ddI and Sustiva vs d4T + ddI + Sustiva. Patients must be antiretroviral naïve and have viral loads greater than 5000 copies/ ml.

Lipodystrophy and Fat Redistribution Syndrome

This research involves testing to examine the various relationships of a variety of factors that may contribute to the development of lipodystrophy and fat redistribution. The initial stage of the study is retrospective and examines the patient's past medical history. The second phase of the study will include DEXA testing for body composition as well as single slice abdominal cat scanning to examine visceral (internal) body fat development.

Protease Failure – Study NZTA4008

This is a phase IV study for patients who are failing their initial protease inhibitor containing regimen in combination with 3TC and AZT or d4T. This study investigates three alternative regimens utilizing the drugs: Abacavir, Sustiva, ddI and Hydroxyurea. Patients are randomized to an open label regimen and must have CD4 T cell count > 200 cells and viral load between 400 and 50,000 copies/ml.

Substitution with Sustiva – Study DMP 266-049

This is a phase IV, open label randomized study to determine the safety and duration of effect of regimens comparing continued therapy with protease inhibitors vs protease inhibitor substitution with Sustiva. Randomization will occur in 3:1 ratio, substitution vs. continued treatment with protease inhibitors. Patients will have skin-fold/anthropomorphic (weight and body circumference measurements) to determine whether the patient has lipodystrophy. Laboratory tests include lipid profiles (cholesterol and triglycerides).

“Nice Study:” Crixivan combined with Norvir

This is a phase IV study for patients who remain with viral loads below 500 and who are on Crixivan with two other Nuc's. The study is for 24 weeks. 3 of 4 patients will have their Crixivan dose reduced to one pill twice daily in combination with 400 mg of Norvir, both to be taken with food. One patient of every 4 will continue on their regular Crixivan dosing but will eventually be changed to the Crixivan /Norvir combination regimen at 12 weeks.

PMPA PRODRUG Study (phase 2)

PMPA is a potent *nucleotide* reverse transcriptase inhibitor that inhibits HIV production in HIV infected cells. A 48 week phase II, randomized double-blind study to evaluate the safety and antiviral activity of the addition of PMPA Prodrug to stable combination regimens. Patients must have a viral load > 400 and < 50,000 copies/ml and must be on stable antiretroviral therapy (including protease inhibitors) of no more than 3 active agents for 8 weeks. Hydroxyurea as a fourth drug is permitted. Patients currently taking adefovir cannot be enrolled.

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The following list of studies are available at the NorthStar Medical Center Dan Berger, MD and Associates

For further information or participation please call 773-296-2400



Salvage for Protease Inhibitor Failures with MKC-442

MKC-442 is a potent non-nucleoside reverse transcriptase inhibitor (NNRTI) that inhibits HIV production. This 48 week randomized, double-blind study is enrolling patients failing protease inhibitor combinations and compares antiretroviral activity and tolerability of D4T, DDI, and Hydroxyurea with and without MKC-442. The study will involve 3 arms. Patients with viral loads >5000 and < 50,000 copies/ml will be randomized to receive either MKC-442 or placebo in combination with D4T, DDI and Hydroxyurea. Patients with viral loads > 50,000 copies/ml will receive open-label MKC-442. Patients must have failed a protease-containing regimen and be NNRTI naive.

DMP 266 - Sustiva + Crixivan

DMP 266 is a potent non-nucleoside reverse transcriptase inhibitor (NNRTI) that inhibits HIV production in HIV infected cells. A 2 year phase II/III multicenter, randomized, open-label study to compare antiretroviral activity and tolerability of three different combination regimens (DMP 266 + Crixivan, DMP 266 + AZT = 3TC, Crixivan = AZT + 3TC) in HIV-infected patients. Patients must be asymptomatic or mildly symptomatic,

have a CD4 cell count greater than or equal to 50 cells/mm, and a viral load greater than or equal to 10,000 copies/mL. Patients will have received no prior treatment with DMP 266, 3TC, nevirapine, delavirdine, or any protease inhibitor.

Passive Immunotherapy with CMV Intravenous Immunoglobulin

CMV IVIG is a preparation that contains high titers of antibodies of CMV (Cytomegalovirus). CMV is often a cause of opportunistic disease in AIDS. This off-label treatment is available to patients with CMV disease (i.e., CMV Retinitis, esophagitis, gastritis, or systemic disease, etc).

HIV Anemia with Weekly Procrit - Protocol PR98-29-002

Erythropoietin (Procrit) is a protein hormone, normally produced by the kidneys, and has been shown to significantly increase red blood cell count. This is a 16 week open label study using weekly injections of Procrit for patients with hemoglobins less than 11 g/dl. There is no placebo treatment and all qualified patients receive open label drug. The specific dosing requirement is titrated during the study.

Passive Immunotherapy with Intravenous Immunoglobulin

IVIG is a lyophilized preparation of intact immunoglobulin G (IgG) from pooled plasma and is not chemically altered. This broad range of antibodies is capable of neutralizing microbes and toxins against bacterial and viral antigens of various infectious diseases. This off-label treatment is available to patients with recurrent bacterial infections and/or history of an opportunistic disease. IVIG is administered monthly with close monitoring.

Interleuken-2 (IL-2)

Open-label interleuken-2 is a cytokine (natural substance produced by cells) that may stimulate T-cells increases. This off-label use of this drug for patients with CD4 T-cells greater than 100. The drug is administered by subcutaneous injection daily for 5 consecutive days every 8 weeks.

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Barebacking

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He failed every possible cocktail available, since the newly infected HIV was resistant to all available antivirals. How many barebackers are HIV-negative? In the terminology of barebackers, there are gift givers, persons who seek to infect others with HIV, and bug chasers, who want to get infected and join the viral brotherhood of man. Naturally this is the most ridiculous form of logic proposed by barebackers. One client mentioned "In a way it's a relief," he says, echoing a sentiment heard too frequently from newly infected men. "I don't want to wonder anymore. That awful waiting is gone. So now, if I do find someone, the relationship can be 100 percent real with nothing in the way. That's what I want: 100 percent natural, wholesome and real. Maybe now that I'm HIV positive, I can finally have my life." These individuals with these sentiments don't understand the sadness, pain and side effects that HIV positive individuals have to endure, day by day. They don't understand the dramatic consequences and change that occurs in the struggle of individuals to survive with their HIV status and remain healthy despite their HIV infection and damaged immune systems. This is not a joke.

There are also those who are HIV negative who are riding bareback who feel that the protease inhibitors provide them with the impetus to ride bareback. There are those who take on attitudes that post-infection they can take on the new drugs and their life will be fine. Those individuals appear to have no concern for the facts: the drug regimen can be excruciating for some, they can be taking up to and over twenty pills a day; the cost of the drugs is exorbitant; no one knows how long the antivirals will be effective at controlling HIV or the possible damage to the body over prolonged periods of time; there are substantial number of individuals who cannot tolerate the drugs and for some the drugs are ineffective; the virus can mutate around the drug and create a strain of HIV that is drug resistant, and further it is likely that there are drug resistant strains floating among the community now. They fail to realize those patients who are still getting sick, and some individuals are still dying, despite all the technology. With these considerations, safer sex is more important now than it was ever.

From a psychological point of view, the man who stops at the neighborhood bar after work to unwind feels more relaxed after a few drinks. Now he can laugh or cry freely neither of which he could release without a drink. Similarly, risky sex is a

means of suppressing affect or emotion and release of what is tightly controlled or suppressed.

When promiscuous and risk taking sexual activity in our community is used as one's only available means for release, the pursuit of sex increasingly becomes governed by itself. Often gay men can become addicted to the risk taking. In the case of barebacking, an individual can become addicted to an intense level of excitement or risk which requires varied and changing new sexual partners or objects that in turn, will pay off in perpetual thrills. . So sexual behavior can start out as being completely safe from mutual masturbation and accelerate to more risky behaviors

such as barebacking. This occurs when the object is found as no longer exciting. At this point there becomes an incessant search of higher levels of excitement and thrills. Unfortunately for many the quest for excitement at this point may begin to dominate one's life. It may overshadow even strong ties of enjoyment in the most enduring relationships. All other affects become eclipsed in the endless pursuit of greater thrills. Only the perpetual excitement suffices, and that hunger governs the quest for new sexual partners and more riskier sex. Similarly like the drug addict or alcoholic who has a near death experience before ending up in treatment.

Nevertheless, even within the barebacking community there seems to be guidelines, but one questions these so called "guidelines". By no

means can any rationale professional endorse these behaviors, or pretend that medically these precautions are effective. These so called guidelines have included: not using poppers because they dilate blood vessels in the body making it easy for transmission; always use plenty of lubricant to help prevent small tears in tissue and "pulling out early" in the hopes of not transmitting HIV. Some ration the barebacking experience to limit exposure; some use after-care by washing so that you don't trap bacteria and the virus; monitor health care immunity, remember the more stressed, the influence of alcohol or other drugs, fatigue, sleep deprivation, or being ill, increase the chance of becoming infected. We encourage individuals to talk with a professional in the medical field or discuss them with your favorite psychologist in an effort to explore the underlying motivation behind such behavior as barebacking. But, as this article has pointed out, if there isn't anything to fear, according to those who bareback, then why the need to impose some of these so called precautions? Are these individuals fooling themselves or are they the fools? Take your pick.

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Resistance and resistance testing

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For the most part, it's true that most gay men are, at the least, trying to be safe and would no doubt reject the bareback philosophy outright. Nevertheless, the glamorization of bareback sex a glamorization fueled by the absence of fear. This has a direct effect on gay men of all ages who are struggling with safer sex. They may be safe most of the time but there are those times when we all have our weaknesses. Those times often times are coupled with the use of drugs, alcohol, and other substances that lead to a loss of inhibitions. The intrinsic dangers of the "alphabet drugs" are becoming more prevalent and increase these inherent dangers. The community is in imminent peril; one can't help believing that these irrational individuals are taking over our society and imposing more health risk to our community. One recalls, that during the late eighties and nineties the gay community was respected; it was considered the safest community because of our awareness and knowledge. Barebacking has now changed that.

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Finally, in patients highly experienced to antiretroviral drugs, where no drugs are very active then the test will not be of benefit for an improved virologic response. One prospective study presented at the 7th Conference on Retroviruses and OI's confirmed that no viral benefit was derived from the use of such tests at 16 weeks when compared to the standard of care (Melnick et al).

On the brighter side of resistance, various levels of resistance may or may not result in treatment failure. Often HIV specialists may use drugs that increase the levels of other antiviral agents so as to overcome resistance, as is the case with protease inhibitors. Additionally, it has been shown that even while there may be viral resistance occurring in a given patient on their regimen, the potency of HIV is reduced (despite the presence of resistance); this is sometimes referred to as reduced viral fitness. In other words, if viral fitness is reduced there is still benefit of resistant regimens in many patients. Notably, while viral resistance is rampant, opportunistic infections are rare and patients continue to do well with continued increases in CD4+ T cells (disconnect syndrome).

Nonetheless, we applaud the arrival of yet another weapon in which to combat HIV disease and effect better treatment through the use of resistance testing. There are indeed many instances for which to use either genotype or phenotype testing to assist in our ability in constructing better and more effective regimens for patients. However, more studies of using this relatively new test need to be completed.

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VITAMIN CO-OP AVAILABLE AT BROADWAY VITAMINS -

Why shop at a Vitamin super store? For people in need, a Vitamin Co-op is available providing "at cost" vitamins and nutritional supplements.

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Utilize the co-op by appointment only. Contact: Dorothy Tanner 773/404-9000.

Progenics Pharmaceuticals Inc's PRO 542 and Trimeris Inc's T-20 when used in combination

may be a powerful new treatment against HIV. Both drugs effect HIV's ability to fuse with and ultimately stop HIV entry into the cell. Laboratory testing presented at the XIII International Conference on AIDS in Durban South Africa, showed an extremely potent response. While being used together, dosages were reduced to one-tenth the amount of each drug.

Cut or un-cut.

In a report published by the New England Journal of Medicine (March 20, 2000) Ugandan and American investigators presented a study of heterosexual transmission of HIV among 415 couples. One of the findings included the fact that among circumcised male partners (50 men), no HIV seroconversions occurred vs 16.7% among 137 uncircumcised male partners. The finding that circumcision afforded protection against HIV infection may be explained by the foreskin being prone to microulcerations and provide increased surface area that is susceptible to HIV. This may also explain why there is a lower risk of female to male transmission of HIV in the US where most men are circumcised.

L-Carnitine therapy demonstrated encouraging findings

in 4 patients treated for peripheral neuropathy (not to be confused with acetyl- carnitine being used for lipodystrophy). After 6 months of treatment there was observed improved skin innervation. Although this study findings, (presented at the 3rd International Workshop on Salvage Therapy in April 12-14, 2000), are limited by the small number of patients (20 patients are now continuing in this study) we hope that larger investigations are done to provide patients with additional treatment options for peripheral neuropathy symptoms.

Immunologic as well as anti-HIV benefit with interleukin 2.

reported in the July 12, 2000 issue of the Journal of the American Medical Association. The study was conducted among 82 patients with CD4 T-cell counts ranging from 200-500 cells. Patients on IL-2 showed greater range of increased CD4 cells and more patients on the IL2 treated group (67% vs 36%) achieved viral loads of fewer than 50 copies/ml. This is the first study published to show enhanced control of viral replication with IL-2. See Dr Sirinek's article in this issue.

Dupont Pharmaceuticals is ready to launch a phase 2 study of their new second generation non-nucleoside reverse transcriptase inhibitor.

After having less than superior effects from an earlier compound DPC 961, Dupont shifted their efforts to another agent in their pipeline - DPC 083. Dupont Pharmaceuticals is planning this phase II study at multiple sites in Europe, but at only 5 sites in the US; NorthStar will be one of the sites conducting the study.

IML (International Male Leather) weekend and circuit parties this summer

has realized an increased incidence of STD's among the gay community in Chicago. Obvious unsafe sexual practices are becoming more commonplace. Although anecdotal, we have seen near epidemic proportions of STD's during this Summer. This has also been reported to us by other practitioners in Chicago. Besides the obvious toll on one's health, STD's are associated with a greater risk of HIV transmission to uninfected partners. We can not believe the carelessness and lack of responsibility that is becoming more rampant in the community. This is a sad commentary of our times.

Antiretroviral drug holidays

is booming of increased interest to HIV clinicians and researchers. Presently we believe this approach may also have relevance to patients currently overtly failing their regimens, so to encourage the re-domination of susceptible wild-type virus among selected patients. However this approach is also being investigated among stable patients with undetectable viral loads. But data to support the approach is small and very preliminary at

best. This tactic may provide more drug free periods which decrease toxicity, improve adherence and decrease cost of treatment. It is refreshing to see the old conservative researchers becoming more creative while also stretching their necks out, once in a while.

Merck and Co, Inc has been investigating a novel protease inhibitor,

MK-944 (formerly L-756,423) to be used with Crixivan in a single capsul. However, a recent Phase II study was suspended due to unexpected renal (kidney) toxicity with rats. Although this was not seen previously in a study with dogs or other pre-clinical studies, the study was suspended and further development with this agent was placed on hold. We hope that Merck remain committed to understanding this problem and perhaps continuing in their previous efforts to develop further treatment options for HIV infected patients.

Hydroxyurea's role

in HIV treatment is still unclear. A recent study published from researchers from Johns Hopkins reported higher incidence rates of peripheral neuropathy among patients on hydroxyurea combined with d4T + ddI as compared with ddI/d4T alone. These finding add to the other accumulating toxicity of this drug which also include pancreatitis and not uncommonly seen - hematologic adverse events.

Delavirdine (Rescriptor) may have finally found a niche in HIV therapeutics.

Reported in a small study at the XIII International Conference on AIDS in Durban, South Africa, delavirdine, a non-nucleoside reverse transcriptase inhibitor appeared to enhance HIV protease inhibitor blood levels. When used in combinations with protease inhibitors, combination treatment with delavirdine appeared to result in reducing HIV load and increasing CD4 T cell count.