the National Association of People with AIDS

MEDICAL ALERT

this issue sponsored by
Philip Morris Companies Inc. and
Ross Products Division of Abbott Laboratories

ISSUE ONE 1998

Standards Set for the Treatment of HIV in Children

Guidelines for the treatment of HIV infection in children were recently released by the U.S. Department of Health and Human Services. The guidelines were developed by the *Working Group on Antiretroviral Therapy and Medical Management of HIV-infected Children* convened by the National Pediatric and Family HIV Resource Center and sponsored by the Health Resources and Services Administration. These guidelines are intended to be general recommendations to physicians caring for HIV-infected infants, children and adolescents and serve as a companion to the Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents that were released in November 1997 (See November/December issue of *Medical Alert*).

The following is a brief summary of the guidelines. Copies of the complete guidelines are available from the National AIDS Clearinghouse (800-458-5231)

Important concepts influencing these antiretroviral guidelines include:

1. Identification of HIV infected women before or during pregnancy is critical to providing optimal therapy for both infected women and their children and preventing perinatal transmission.

2. Determination of HIV RNA copy number and CD4 + lymphocyte levels are essential for monitoring and modifying antiretroviral treatment in infected children and adolescents as they are valuable prognostic markers. (see tables 1 and 2)

3. Viral replication is continuous and maximal viral suppression, preferably to undetectable levels, is the optimal goal of antiretroviral therapy.

4. The choice of antiretroviral regimens for children and adolescents should take into consideration factors influencing adherence to therapy, including: a) availability and palatability of pediatric formulations; b) impact of the medication schedule on quality of life, including number of medications, and need to take with or without food; c) ability of the child's caregiver or the adolescent to administer complex drug regimens and availability of resources might be effective in facilitating adherence; d) the potential for drug interactions; and e) the potential for the development of antiretroviral resistance.

continued on page 14

Table 1
1994 Revised Pediatric HIV Classification System: Immunologic Categories Based on Age-Specific CD4+ Lymphocyte Count and Percentage

Age of Child Immune Category	under 12 mos number/µL (%)	1-5 yrs number/µL (%)	6-12 yrs number/µL (%)
Category 1: No suppression	≥ 1,500 (≥ 25%)	≥ 1,000 (≥ 25%)	≥ 500(≥25%)
Category 2: Moderate suppression	750-1,499 (15-24%)	500-999 (15-24%)	200-499 (15-24%)
Category 3: Severe suppression	< 750(<15%)	< 500 (<15%)	< 200 (<15%)

Modified from Centers for Disease Control. 1994 Revised Classification System for Human Immunodeficiency Virus Infection in Children Less than 13 Years of Age. MMWR 1994;43 (No. RR-12): 1-10

Managing Pain in HIV Disease

An Update from the 16th Annual Scientific Meeting of the American Pain Society

by A. Cornelius Baker

For some it can be a raging headache that comes from nowhere and goes in a snap, for others the constant tingling sensation in the feet or fingers caused by peripheral neuropathy and for still others it can be a severe burning in a throat coated with thrush. Each of these experiences of pain commonly occur in people with advanced HIV disease, or AIDS. Studies suggest that 40% to 60% of people with AIDS are likely to be in pain and that this condition also effects about one third of people with early stage HIV disease.

Pain in people with HIV is similar to, and occasionally stronger than, pain in people with cancer. Clinicians should follow the same core principles for the management and treatment of pain in both groups. The World Health Organization (WHO) guidelines for management of cancer pain have been endorsed by the U.S. Public Health Service (PHS)'s Agency for Health Care Policy and Research (AHCPR) and by clinical experts in AIDS care. Treatment should be based on WHO's analgesic ladder, and the selection of analgesics (pain relievers) should be based on the severity and mechanism of pain. Opioid analgesics are the most powerful and effective pain relievers for treating severe pain. The most common side effects of pain medication are constipation, nausea, vomiting, drowsiness and slowed breathing. Counter-measures can be taken to prevent or treat these side effects in order to ease unnecessary pain in people with HIV/AIDS.

The American Pain Society 16th Annual Scientific Meeting held in New Orleans, October 23 - 26, 1997 offered participants current information about the diagnosis, treatment, and management of acute pain, chronic cancer and noncancer pain, and recurrent pain.

Pain is Undertreated in Most People with HIV

According to William Breithart, MD of Memorial Sloan-Kettering Cancer Center in New York (212.639.2000) pain in AIDS is much less adequately

continued on page 3

A Letter to our Readers...

To the Reader:

NAPWA was founded 15 years ago with the belief that people with AIDS would survive this epidemic by equipping themselves with information about the virus and sharing it with others. We still hold this to be true.

Since 1992, *Medical Alert* has been one of the tools NAPWA has used to provide you and others with life saving information. From reader responses and the number of request we get daily from new people wanting to join the mailing list we know its value to you. AIDS, or HIV disease, has changed dramatically over the last year and it has evolved into an even more complex health condition. Because of this, our strategies are changing to meet new challenges.

Beginning with this issue, *Medical Alert* will be published four times a year on a quarterly basis. We believe this publication schedule better reflects the flow of new scientific information and medical advances. Our focus will also expand slightly to provide more information on health care access and quality of care, including working with your physician, AIDS service organization, and managed care provider to advocate for your needs. Our Education staff will continue to assist you in finding up-to-date information and linking you to other national and local organizations meeting your special needs.

NAPWA also takes this opportunity to welcome Charles Nelson, our new Associate Director for Health Education. Charles, a graduate in biology from Morehouse College, is an African-American gay man living with HIV who has long been involved in treatment education and advocacy. He has also been a member of the National Task Force on AIDS Drug Development, convened by the U.S. Department of Health and Human Services and the Working Group on Guidelines for the Prevention of AIDS related Opportunistic Infections, convened by CDC, NIH and the Infectious Disease Society of America. We look forward to his leadership as editor of this publication.

Thank you for your continued support. Together, we will continue to learn and do what we must to survive.

A. Cornelius Baker
Executive Director

ON the PULSE...

NIH Study on Mouth Sores

The National Institute of Dental Research and the Clinical Center at NIH are looking for patients age 18 and older to take part in a study of a promising new treatment for mouth sores associated with HIV and AIDS. Those who qualify receive care by some of the nation's leading experts in the field. The study medication, a gel applied directly to the sores, is provided at no cost. Participants can stay on their regular course of medical treatment for HIV or AIDS while participating in this study. People or their doctors can contact NIH's Patient recruitment and Referral Center for more information: (Interested deaf or hard-of-hearing callers should use their state relay services to contact these telephone numbers) at 800.411.1222 or E-Mail: prrc@nih.gov. Patients living outside the Washington, DC metropolitan area should ask about compensation for travel expenses.

New Cytovene Capsule on the Market

Hoffmann-La Roche has introduced a new 500 mg capsule of CYTOVENE (ganciclovir) for maintenance treatment of CMV retinitis, the most common manifestation of CMV disease. The company has also received approval from the FDA to market the new capsule for use in the prevention of CMV disease in people with advanced HIV (AIDS). The new Cytovene capsule will reduce a person's daily pill count of ganciclovir in half–from 12 capsules to six per day.

Drug to Treat Crypto on Fast Track

The FDA has granted priority review status to Unimed Pharmaceuticals, Inc. new drug application (NDA) to market NTZ (nitazoxanide) for the treatment of cyrptosporidial diarrhea in people with HIV disease. This NDA is the first application for treatment of the diarrhea associated with cyrptosporidiosis. In immunocompromised patients, crypto is a serious medical condition that can be fatal without effective treatment. An FDA priority review ensures that a NDA will be completely reviewed and acted upon within six month of receipt. Unimed holds an exclusive license to develop and market oral dosage forms of NTZ for human use in the U.S.

Regain Strength and Restore Energy–Anabolic Treatment for Anemia

In a recently published study by the CDC's National Center for HIV, STD, and TB Prevention, anemia, or a low number of red blood cells, is indicated as a frequent complication of HIV infection. According to the study, people who developed anemia but never recovered had a 170% greater risk of death than people who developed anemia but later recovered. Chronically ill patients now have an additional tool to help combat the debilitating effects of anemia. Anadrol®-50 (oxymetholone) -- 50 mg tablets -- is the only oral anabolic-androgenic hormone indicated for the treatment of anemia. Anadrol®-50 helps people suffering from anemia by stimulating red blood cell production by enhancing the release of the body's own erythropoietin, as well as directly signaling the stem cells within the bone marrow to produce red blood cells. Unimed Pharmaceuticals, Inc. has established a Patient Assistance Program and Reimbursement Hotline: 1-800-256-8918.

Drug Shown to Reduce Shedding of Herpes Virus in People Living with HIV

The University of Minnesota recently released results from a study led by Dr. Timothy Schaker showing that Famciclovir (Famvir¨, SmithKline Beecham Consumer Healthcare) when taken daily significantly reduces asymptomatic shedding, the time when the herpes virus is contagious but there are no signs or symptoms, in HIV-infected patients with genital herpes. Herpes simplex virus infection is one of the most common infections among people living with HIV. This study is important because genital herpes outbreaks in people living with HIV occur more frequently; are especially severe; and can lead to life-threatening complications. For more information, contact Dr. Timothy Schacker, Assistant Professor of Medicine at the University of Minnesota, at 1-612-624-9955, or call Clara Morris at 1-212-598-2807.

Crixivan® Receives Full Approval by the FDA

The U.S. Food and Drug Administration (FDA) recently granted traditional approval to Crixivan¨, Merck & Company's HIV protease inhibitor, based on the results from two studies that confirm the clinical benefits of combination therapy with Crixivan reduces AIDS-defining illnesses or death and produces prolonged suppression of HIV/RNA. Merck has developed, with the American Dietetic Association, a list of foods, light meals or snacks that can be taken with Crixivan. For more information visit Merck's new website www.crixivan.com.

NAPWA is committed to your survival. For 24 hour confidential toll-free information on CMV call the

National CMV HOTLINE

800-838-9990

continued from page 1

treated than cancer pain. Recent studies cited by Dr. Breithart, during his keynote address, suggest that "only 6% of AIDS patients with severe pain are prescribed a strong opioid like morphine, despite the fact that the WHO Analgesic Ladder suggests that clinicians consider using strong opioids in all patients with severe pain." Using the Pain Management Index as a measure of adequacy of analgesic therapy, only 15% of AIDS patients with pain receive adequate analgesic therapy, compared to almost 60% of cancer pain patients. Dr. Breithart has also found that women with AIDS-related pain are twice as likely to be undertreated than men. People with less formal education and those who contracted HIV through injection drug use are also more undertreated for pain.

The following chart provides information on opioid analgesics:

Opioid Analgesics

Drug	Length of Effectiveness	Other Information
Morphine	Intravenous or intramuscular–2 to 3 hours By mouth—3 to 4 hours Sustained release—8 to 12 hours	Starts to work quickly. Oral form can be very effective for cancer pain
Codeine	By mouth—3 to 4 hours	Less potent than morphine. Sometimes taken with aspirin or acetaminophen
Meperidine	Intravenous or intramuscular—3 hours By mouth—not very effective	Can cause seizures, tremors, and muscle spasms
Methadone	By mouth—4 to 6 hours, sometimes longer	Also used to treating heroin withdrawal
Propoxyphene	By mouth—3 to 4 hours	Generally taken with aspirin or acetaminophen to treat mild pain
Levorphanol	Intravenous or intramuscular—4 hours By mouth—about 4 hours	Oral form is strong. Can be used instead of morphine
Hydromorphone	Intravenous or intramuscular—2 to 4 hours By mouth—2 to 4 hours Rectal suppository—4 hours	Begins wto work quickly. Can be used instead of morphine. Helpful for cancer pain
Oxymorphone	Intravenous or intramuscular—3 to 4 hours Rectal suppository—4 hours	Starts to work quickly
Oxycodone	By mouth—3 to 4 hours	Usually combined with aspirin or acetaminophen
Pentazocine	By mouth—up to 4 hours	Can block painkilling action of other opioids. About as strong as codeine. Can cause confusion and anxiety, especially for the elderly.

Source: The Merck Manual of Medical Information Home Edition, Merck Research Laboratories, 1997

The Women, Suffer...

April Hazard Vallerand, Ph.D., R.N., University of Pennsylvania School of Nursing in Philadelphia (732.780.6224) reported the findings of a pilot study to assess the relationship of pain to functional status and quality of life in women with HIV/AIDS. A sample of 25 women with HIV infection or AIDS with pain complaints in a primary care clinic dedicated to the care of people with HIV were asked to complete several assessment tools including the Brief Pain Inventory (BPI), the Inventory of Functional Status - Chronic Pain (IFS-CP), the Functional Assessment of HIV Infection (FAHI) quality of life instrument, and a demographic data sheet. The majority of participants had severe pain in the past week. Adequacy of analgesic therapy was assessed using the Pain Management Index and the type and frequency of analgesics prescribed for pain. Based on the PMI, 79% of the women reporting severe pain were receiving inadequate pain relief therapy. Of the 12 participants reporting severe pain, 7 were receiving no analgesic therapy, while only 2 were prescribed a strong opioid. The women with pain were found to have decreased functional status. Lower quality of life scores were also found in those women with lower functional status.

Dr. Vallerand acknowledges in her conclusion a need for more information on the effects of pain and its relationship to function status in women. But given previous data on the lack of effective pain medication being offered to women, improving the management of pain in women should be a priority for clinicians.

...While Drug Users Struggle

In a poster session Dr. Gayle Newshan, Ph.D., NP, St. Vincent's Hospital in New York City (212.604.7465) reported on her study designed to increase understanding of the lived experience of pain in hospitalized people with AIDS using a qualitative perspective (Is Anybody Listening? A Phenomenological Study of Pain in Hospitalized Persons with AIDS). For this study, data was gathered from audiotape, open-ended interviews with eleven hospitalized people, film, literature, first-person accounts and clinical observations. The evaluative criteria of trustworthiness was applied to assure rigor. The participants interviewed were a mixed group: 8 men and 3 women, ages 28-44. Of these 7 were white, 2 black, and 2 Latino. Eight individuals had a history of chemical dependence (either alcohol and/or cocaine and/or heroin).

From the interviews and other data five themes were identified, four of which were common among all participants: knowing pain, battling pain, pain's influence and having AIDS. The fifth theme, being a drug user, was found only among the chemically dependent.

Theme 1 ("Knowing Pain") is focused on the difficult task of describing pain and its impact on the body. According to the study, participants often described pain using metaphors, such as "It feels like someone poking you with needles." Theme 2 (Battling Pain) centers on the strategies adopted by individuals for addressing pain and the barriers to pain relief. Barriers include nurses, family members, friends and patients themselves who do not take episodes of pain seriously, especially among those with histories drug addiction. Interestingly, Dr. Newshan reports that participants both fought for and feared 'the big guns,' or strong opiates. One participant described the experience of opiates for pain management as "It's like pulling teeth to get them" while another said the morphine caused him/her "to feel like a zombie -- it was scary." Under theme 3 (Pain's Influence) all of the participants described the limitations placed on their lives due to pain and, often, the greater spirituality they gained.

Theme 4 (Having AIDS) related pain to the "uckky" experience of having AIDS. And theme 5 (Being a drug User) captures the very real experience of people living with AIDS who have histories of drug use. For these individuals pain management is made especially hard because of the high tolerance to the effects of opiates that their bodies have developed and the bias of many healthcare providers in prescribing pain medication to current or former drug users.

The participants of the study who all experience multiple sources of pain which influences all of their lives, and often feel unheard recommended the following for clinicians:

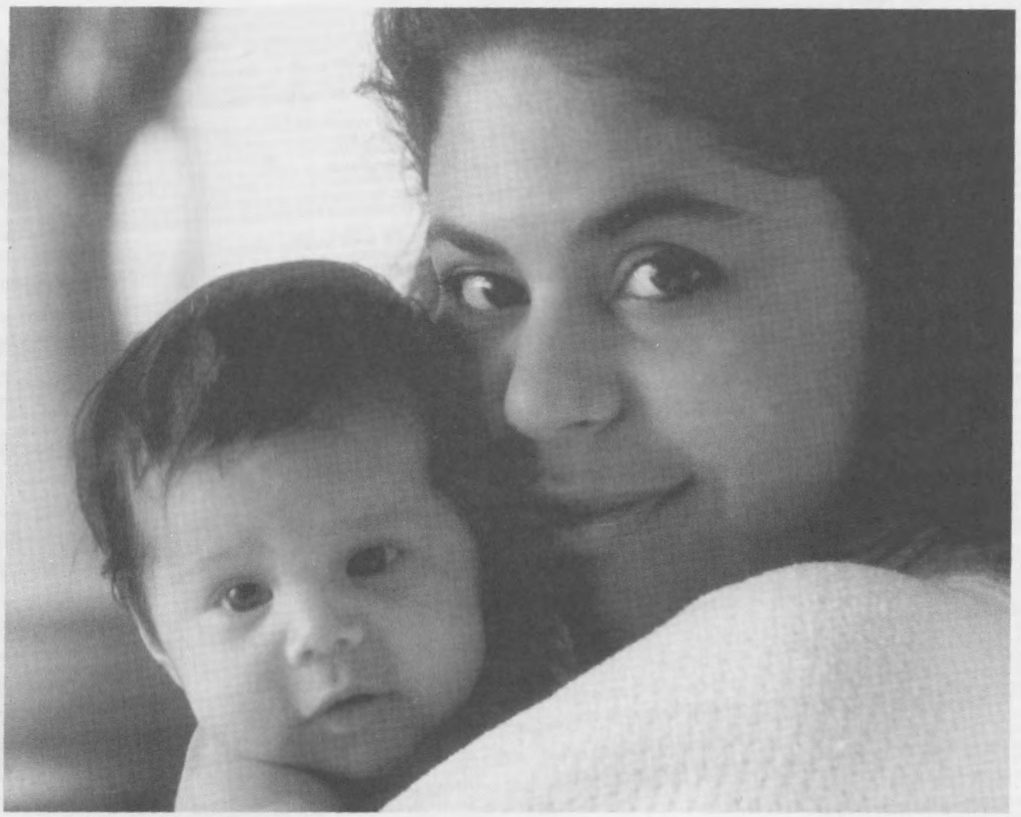
1. Listen to me.
2. Do not abandon me.
3. Keep trying.
4. Keep me informed.
5. Do not judge me.

Dr. Newshan concludes, "as healthcare givers, we must ask [ourselves], 'Am I listening?'"

Duragesic: Another Route to Pain Relief

In another study conducted by Dr. Newshan with Matthew Lefkowitz, MD, State University of New York, Health Science Center at Brooklyn, New York

continued on page 11



VIRACEPT®
nelfinavir mesylate

Information for Patients About VIRACEPT® (VI-ra-cept)
Generic Name: nelfinavir (nel-FIN-na-veer) mesylate

For the Treatment of Human Immunodeficiency Virus (HIV) Infection

Please read this information carefully before taking VIRACEPT. Also, please read this leaflet each time you renew the prescription, just in case anything has changed. This is a summary and not a replacement for a careful discussion with your doctor. You and your doctor should discuss VIRACEPT when you start taking this medication and at regular checkups. You should remain under a doctor's care when taking VIRACEPT and should not change or stop treatment without first talking with your doctor.

WHAT IS VIRACEPT AND HOW DOES IT WORK?

VIRACEPT is used in the treatment of people with human immunodeficiency virus (HIV) infection. Infection with HIV leads to the destruction of CD4 T cells, which are important to the immune system. After a large number of CD4 cells have been destroyed, the infected person develops acquired immune deficiency syndrome (AIDS).

VIRACEPT works by blocking HIV protease (a protein-cutting enzyme), which is required for HIV to multiply. VIRACEPT has been shown to significantly reduce the amount of HIV in the blood. You should be aware, however, that the effect of VIRACEPT on HIV in the blood has not been correlated with long-term health benefits. Patients who took VIRACEPT also had significant increases in their CD4 cell count.

VIRACEPT is usually taken together with other antiretroviral drugs such as Retrovir® (zidovudine, AZT), Epivir® (lamivudine, 3TC), or Zerit® (stavudine, d4T). Taking VIRACEPT in combination with other antiretroviral drugs reduces the amount of HIV in the body (viral load) and raises CD4 counts.

VIRACEPT may be taken by adults, adolescents, and children 2 years of age or older. Studies in infants younger than 2 years of age are now taking place.

DOES VIRACEPT CURE HIV OR AIDS?

VIRACEPT is not a cure for HIV infection or AIDS. The long-term effects of VIRACEPT are not known at this time. People taking VIRACEPT may still develop opportunistic infections or other conditions associated with HIV infection. Some of these conditions are pneumonia, herpes virus infections, *Mycobacterium avium* complex (MAC) infections, and Kaposi's sarcoma.

It is not known whether VIRACEPT will help you live longer or reduce the number of infections or other illnesses that may occur. .

There is no proof that VIRACEPT can reduce the risk of transmitting HIV to others through sexual contact or blood contamination.

WHO SHOULD OR SHOULD NOT TAKE VIRACEPT?

Together with your doctor, you need to decide whether VIRACEPT is appropriate for you. In making your decision, the following should be considered:

Allergies: If you have had a serious allergic reaction to VIRACEPT, you must not take VIRACEPT. You should also inform your doctor, nurse, or pharmacist of any known allergies to substances such as other medicines, foods, preservatives, or dyes.

If you are pregnant: The effects of VIRACEPT on pregnant women or their unborn babies are not known. If you are pregnant or plan to become pregnant, you should tell your doctor before taking VIRACEPT.

If you are breast-feeding: You should discuss with your doctor the best way to feed your baby. You should be aware that if your baby does not already have HIV, there is a chance that it can be transmitted through breast-feeding. **Women should not breast-feed if they have HIV.**

Children: VIRACEPT is available for the treatment of children 2 through 13 years of age with HIV. There is a powder form of VIRACEPT that can be mixed with milk, baby formula, or foods like pudding. Instructions on how to take VIRACEPT powder can be found in a later section that discusses how VIRACEPT Oral Powder should be prepared.

If you have liver disease: VIRACEPT has not been studied in people with liver disease. If you have liver disease, you should tell your doctor before taking VIRACEPT.

Other medical problems: Certain medical problems may affect the use of VIRACEPT. Be sure to tell your doctor if you have hemophilia types A and B, diabetes mellitus, or an increase in thirst and/or frequent urination.

CAN VIRACEPT BE TAKEN WITH OTHER MEDICATIONS?

VIRACEPT may interact with other drugs, including those you take without a prescription. You must discuss with your doctor any drugs that you are taking or are planning to take before you take VIRACEPT.

Drugs you should <u>not</u> take with VIRACEPT:

- Seldane® (terfenadine, for allergies)
- Hismanal® (astemizole, for allergies)
- Propulsid® (cisapride, for heartburn)
- Cordarone® (amiodarone, for irregular heartbeat)
- Quinidine (for irregular heartbeat), also known as Quinaglute®, Cardioquin®, Quinidex®, and others
- Ergot derivatives (Cafergot® and others, for migraine headache)
- Halcion® (triazolam)
- Versed® (midazolam)

Taking the above drugs with VIRACEPT may cause serious and/or life-threatening adverse events.

- Rifampin (for tuberculosis), also known as Rimactane®, Rifadin®, Rifater®, or Rifamate®

This drug reduces blood levels of VIRACEPT.

Dose reduction required if you take VIRACEPT with:

Mycobutin® (rifabutin, for MAC); you will need to take a lower dose of Mycobutin.

A change of therapy should be considered if you are taking VIRACEPT with:

- Phenobarbital
- Phenytoin (Dilantin® and others)
- Carbamazepine (Tegretol® and others)

These agents may reduce the amount of VIRACEPT in your blood and make it less effective.

- Oral contraceptives ("the pill")

If you are taking the pill to prevent pregnancy, you should use a different type of contraception since VIRACEPT may reduce the effectiveness of oral contraceptives.

HOW SHOULD VIRACEPT BE TAKEN WITH OTHER ANTI-HIV DRUGS?

Taking VIRACEPT together with other anti-HIV drugs increases their ability to fight the virus. It also reduces the opportunity for resistant viruses to grow. Based on your history of taking other anti-HIV medicine, your doctor will direct you on how to take VIRACEPT and other anti-HIV medicines. These drugs should be taken in a certain order or at specific times. This will depend on how many times a day each medicine should be taken. It will also depend on whether it should be taken with or without food.

Nucleoside analogues: No drug interaction problems were seen when VIRACEPT was given with:

- Retrovir (zidovudine, AZT)
- Epivir (lamivudine, 3TC)
- Zerit (stavudine, d4T)
- Videx® (didanosine, ddI)

If you are taking both Videx (ddI) and VIRACEPT: Videx should be taken without food, on an empty stomach. Therefore, you should take VIRACEPT with food one hour after or more than two hours before you take Videx.

Nonnucleoside reverse transcriptase inhibitors (NNRTIs):

When VIRACEPT is taken together with:

- Viramune® (nevirapine)

The amount of VIRACEPT in your blood may be reduced. Studies are now taking place to learn about the safety of combining VIRACEPT with Viramune.

- Other NNRTIs

VIRACEPT has not been studied with other NNRTIs.

Other protease inhibitors:

When VIRACEPT is taken together with:

- Crixivan® (indinavir)

The amount of both drugs in your blood may be increased. Currently, there are no safety and efficacy data available from the use of this combination.

- Norvir™ (ritonavir)

The amount of VIRACEPT in your blood may be increased. Currently, there are no safety and efficacy data available from the use of this combination.

- Invirase® (saquinavir)

The amount of saquinavir in your blood may be increased. If used in combination with saquinavir hard gelatin capsules at 600 mg three times daily, no dose adjustments are needed. Currently, there are no safety and efficacy data available from the use of this combination.

WHAT ARE THE SIDE EFFECTS OF VIRACEPT?

Like all medicines, VIRACEPT can cause side effects. Most of the side effects experienced with VIRACEPT have been mild to moderate. Diarrhea is the most common side effect in people taking VIRACEPT, and most adult patients had at least mild diarrhea at some point during treatment. In clinical studies, about 20% of patients receiving VIRACEPT 750 mg (three tablets) three times daily had four or more loose stools a day. In most cases, diarrhea can be controlled using antidiarrheal medicines, such as Imodium® A-D (loperamide) and others, which are available without a prescription.

Other side effects that occurred in 2% or more of patients receiving VIRACEPT include abdominal pain, asthenia, nausea, flatulence, and rash.

There were other side effects noted in clinical studies that occurred in less than 2% of patients receiving VIRACEPT. However, these side effects may have been due to other drugs that patients were taking or to the illness itself. Except for diarrhea, there were not many differences in side effects in patients who took VIRACEPT along with other drugs compared with those who took only the other drugs. For a complete list of side effects, ask your doctor, nurse, or pharmacist.

HOW SHOULD I TAKE VIRACEPT?

VIRACEPT is available only with your doctor's prescription. The light blue VIRACEPT Tablets should be taken three times a day. VIRACEPT should always be taken with a meal or a light snack. You do **not** have to take VIRACEPT exactly every 8 hours. Instead, you can take it at normal times when you are eating.

Take VIRACEPT exactly as directed by your doctor. Do not increase or decrease any dose or the number of doses per day. Also, take this medicine for the exact period of time that your doctor has instructed. **Do not stop taking VIRACEPT without first consulting with your doctor, even if you are feeling better.**

Only take medicine that has been prescribed specifically for you. Do not give VIRACEPT to others or take medicine prescribed for someone else.

The dosing of VIRACEPT may be different for you than for other patients. **Follow the directions from your doctor, exactly as written on the label.** The amount of VIRACEPT in the blood should remain somewhat consistent over time. Missing doses will cause the concentration of VIRACEPT to decrease; therefore, **you should not miss any doses.** However, if you miss a dose, you should take the dose as soon as possible and then take your next scheduled dose and future doses as originally scheduled.

Dosing in adults (including children 14 years of age and older)

The recommended adult dose of VIRACEPT is 750 mg (three tablets) taken three times a day. Each dose should be taken with a meal or light snack.

Dosing in children 2 through 13 years of age

The VIRACEPT dose in children depends on their weight. The recommended dose is 20 to 30 mg/kg (or 9 to 14 mg/pound) per dose, taken three times daily with a meal or light snack. This can be administered either in tablet form or, in children unable to take tablets, as VIRACEPT Oral Powder.

Dose instructions will be provided by the child's doctor. The dose will be given three times daily using the measuring scoop provided, a measuring teaspoon, or one or more tablets depending on the weight and age of the child. The amount of oral powder or tablets to be given to a child is described in the chart below.

Pediatric Dose to Be Administered Three Times Daily

Body Weight Kg	Body Weight Lb	Number of Level Scoops*	Number of Level Teaspoons†	Number of Tablets
7 to < 8.5	15.5 to <18.5	4	1	-
8.5 to <10.5	18.5 to <23	5	1¼	-
10.5 to <12	23 to <26.5	6	1½	-
12 to <14	26.5 to <31	7	1¾	-
14 to <16	31 to <35	8	2	-
16 to <18	35 to <39.5	9	2¼	-
18 to <23	39.5 to <50.5	10	2½	2
≥23	≥50.5	15	3¾	3

In measuring oral powder, the scoop or teaspoon should be level.

* 1 level scoop contains 50 mg of VIRACEPT. Use only the scoop provided with your VIRACEPT bottle.

† 1 level teaspoon contains 200 mg of VIRACEPT. Note: **A measuring teaspoon used for dispensing medication** should be used for measuring VIRACEPT Oral Powder. Ask your pharmacist to make sure you have a medication dispensing teaspoon.

How should VIRACEPT Oral Powder be prepared?

The oral powder may be mixed with a small amount of water, milk, formula, soy formula, soy milk, dietary supplements, or dairy foods such as pudding or ice cream. Once mixed, the entire amount must be taken to obtain the full dose.

Do **not** mix the powder with any acidic food or juice, such as orange or grapefruit juice, apple juice, or apple sauce, because this may create a bitter taste.

Once the powder is mixed, it may be stored at room temperature or refrigerated for up to 6 hours. Do **not** heat the mixed dose once it has been prepared.

Do **not** add water to bottles of oral powder.

VIRACEPT powder is supplied with a scoop for measuring. For help in determining the exact dose of powder for your child, please ask your doctor, nurse, or pharmacist.

VIRACEPT Oral Powder contains aspartame, a low-calorie sweetener, and therefore should not be taken by children with phenylketonuria (PKU).

HOW SHOULD VIRACEPT BE STORED?

Keep VIRACEPT and all other medicines out of the reach of children. Keep bottle closed and store at room temperature (between 59°F and 86°F) away from sources of moisture such as a sink or other damp place. Heat and moisture may reduce the effectiveness of VIRACEPT.

Do not keep medicine that is out of date or that you no longer need. Be sure that if you throw any medicine away, it is out of the reach of children.

Discuss all questions about your health with your doctor. If you have questions about VIRACEPT or any other medication you are taking, ask your doctor, nurse, or pharmacist. You can also call 1.888.VIRACEPT (1.888.847.2237) toll free.

Issued 10/7/97

CALL 1.888.VIRACEPT

Agouron Pharmaceuticals, Inc.
La Jolla, California, 92037, USA

Getting What You Need: Annual Health Care Access Guide

Produced with support from the U.S. Health Resources and Services Administration (HRSA)

Today, most people are aware of new treatment strategies that work well for slowing or stopping progression of illness in many people living with HIV. Unfortunately, too many people living with HIV have not been able to take advantage of these treatments because they do not have reliable access to health care. As we learn more about HIV, we know that getting into a coordinated system of care can be critical to your survival.

While barriers to care remain, there are many programs available to serve people living with HIV and AIDS. Wherever you live, we urge you to explore your health care options. The following Health Care Access Guide is a starting point for people living with HIV throughout the nation. We urge you to use this guide to learn more about programs that may be able to serve you. The Guide provides basic information on federal health care programs for which you may qualify. We also list contact numbers to learn more about specific program requirements. Most of these programs are operated by state health departments, and some states have additional programs that are not listed here.

If you have questions after reading this guide, we invite you to call NAPWA's Health Education Department for more information. Tina Perkins-Gibson or Patrick Aiken will either answer your questions or refer you to someone in your own state or community who knows about specific programs available in your area. An additional strategy for learning about your health care options involves contacting organizations in your community that provide services for people living with HIV and AIDS.

Studies have shown that persons diagnosed with HIV infection and address their health care needs early, are more likely to live healthier, and more productive and fulfilling lives. To learn more about currently recommended treatment strategies, contact I & R Services for a copy of "Do You Know Your Options?", a guide to antiretroviral therapy produced by NAPWA to help you advocate for the best care. Following are the programs that provide health treatment access to people with HIV/AIDS.

Medicaid

Medicaid is a program operated by each state, where the federal government pays at least half of the costs. Approximately seventy percent of federal money spent on health care for people living with HIV comes through Medicaid. If you qualify, Medicaid, either alone or with other programs listed here, is probably your best option for getting into a coordinated system of care. While the federal government provides oversight and matching funds, each state's Medicaid program differs from others.

Medicaid provides mandatory services all states must provide, and additional services that each state may elect to provide. Services covered by all Medicaid program include: hospital care, whether it is inpatient (overnight stay) or outpatient (you return home the same day you get health care services), doctor visits, laboratory tests, x-rays, and nursing home and home health services. Optional services may include prescription drug benefits, clinic services, case management services, and a range of other services.

In most cases, to qualify for Medicaid, adults with HIV must be classified as disabled under the Social Security Administration's definition. This generally requires a person to have an AIDS diagnosis (advocates are trying to expand Medicaid to cover people living with HIV who do not have AIDS, but this has not yet happened). Persons who meet the Social Security criteria for disability and have an income too high to qualify for Medicaid, may qualify as "medically needy"--a special eligibility category available in many states for persons who meet the Medicaid income requirements after subtracting their incurred medical expenses. Children living with HIV and some mothers of children with HIV can qualify for Medicaid if the family income is below a certain level.

To determine if you qualify for Medicaid benefits, contact the Medicaid program in your own state, at the number listed below.

Medicare

Medicare is a national health insurance program that provides health care security to America's seniors and working people who have become disabled. Medicare, unlike Medicaid, is administered solely through the federal government.

Medicare has consisted of two parts. Part A provides for hospital visits, and is financed through employee and employer taxes. Part B provides supplementary medical insurance, including doctor visits. This part is funded through premiums paid by the individual and general revenues. While Part B is voluntary, most Part A enrollees participate in Part B. In the Balanced Budget Act of 1997, Congress created a Part C called Medicare Plus Choice, which creates more opportunities to enroll in managed care. For people living with HIV, a major shortcoming of Medicare is that it does not cover prescription drugs. Many people with HIV in Medicare, however, are also eligible for Medicaid, which they can use to receive their drug benefits. Persons who are in both Medicaid and Medicare are called dual-eligibles.

There are also two programs to help low-income people cover costs of the Medicare program. The Quality Medicare Beneficiary (QMB) and the Specified Low-Income Medicare Beneficiary (SLMB) programs enable Medicaid to pay cost-sharing expenses and premiums for extremely low-income Medicare recipients.

Medicare requires working age enrollees (under age 65) who become disabled (under the same disability criteria as Medicaid) to have 40 quarters of employment credit and be classified as disabled for two years before they can receive benefits. To determine if you are eligible for Medicare benefits, including the QMB and SLMB Programs contact your state representative listed below.

Ryan White CARE Act

The Ryan White CARE (Comprehensive AIDS Resources Emergency) Act was enacted in 1990 and reauthorized in 1996 to supplement Medicaid and Medicare as our nation's response to the HIV epidemic. Additionally, the CARE Act was intended to provide assistance to cities that shouldered a disproportionate number of AIDS cases, and to states to build their infrastructures for responding to the HIV epidemic. Named for the Indiana teenager who was a hemophiliac with AIDS, the CARE Act is the largest comprehensive program specifically for people living with HIV. The CARE Act provides health care services for low income, uninsured and underinsured Americans who are either not currently eligible for Medicaid or who do not have private insurance.

The CARE Act charges the Federal government with forming partnerships with state and local governments, and community based programs and AIDS service organizations, in order to provide care and services to HIV infected persons. The CARE Act is comprised of five Titles, each addressing a specific component of HIV health care services.

Title I

Title I supports cities and metropolitan areas most heavily impacted by HIV and AIDS. This title provides emergency assistance for the delivery of comprehensive HIV and AIDS medical care and support services. Currently, nearly 49 metropolitan areas receive Title I funding and support. Those cities are listed in the state resource charts below.

Title II

Title II authorizes funds to every state, the District of Columbia, Puerto Rico and other territories, to ensure comprehensive and uniform services throughout the nation. The services covered under this title include prescription drugs, primary AIDS care services, health care insurance continuation, and home health care for persons living with HIV. These programs are administered in urban, suburban and rural communities.

Title II includes the AIDS Drug Assistance Program (ADAP). Many HIV infected people receive HIV drug therapies through their state's ADAP program. Use the number listed for your state for more information.

Title IIIB

Title IIIB provides funding for community-base clinics and public health providers to develop and deliver early and ongoing comprehensive HIV/AIDS services on an outpatient basis. Financial assistance through this title services rural and underserved urban areas, and particularly among women, adolescents and people of color.

Title IV

Title IV supports HIV services and clinical research programs targeting populations for which the growth rate of new infections is increasing rapidly, children, youth, women and families. The majority of the funds provide direct primary medical care. Contact your state HIV/AIDS office for information on services offered in your area.

Title V

Financial support from Title V funds are for the AIDS Education and Training Centers (AETCs) and the HIV/AIDS dental reimbursement programs. Also, the Special Projects of National Significance (SPNS) program is funded through this title. The AETC program helps educate health care providers on advances in HIV disease, to improve the delivery of clinical care. The Dental program helps train dentists to care for patients with HIV, and reimburses dental schools who attend to the oral and dental needs of indigent HIV infected patients.

Veterans Benefits

Eligible veterans with HIV infection or AIDS may receive a full range of services, ranging from testing and counseling to acute and long-term care. Eligibility for most VA benefits is based upon discharge from active military service under other than dishonorable conditions. The U.S. Department of Veterans Affairs operates a system of health care facilities throughout the United States. These facilities include 172 medical centers, outpatient clinics, Veterans Centers, nursing homes, domiciliaries and or extended care programs such as hospice care. To obtain a referral in your area call the Veterans Benefits Number at 1-800-827-1000.

Other Resources

In addition to the federal health care programs listed above, people infected with HIV may access approved and experimental medications or medical services through two other programs: Pharmaceutical Company Drug Assistance Programs, and AIDS Clinical Trials.

Drug Assistance Programs of Pharmaceutical Companies

Many pharmaceutical companies have drug assistance programs for people living with HIV who are not able to afford medications. Each company has eligibility criteria for their respective drug treatments for antiretrovirals and most opportunistic infections. For more information of the programs, and to determine if you are eligible, contact the pharmaceutical companies listed below, or call MedExpress at 1-800-808-8060 for assistance.

AIDS Clinical Trials

AIDS clinical trails are studies conducted to help find effective drug and other therapies for people living with HIV. The treatments include experimental antiretroviral and opportunistic infection drugs, and alternative therapies. Clinical trials provide vital information on new treatments. Participating in a clinical trials is another way of taking positive action. All drugs currently used have been studied through clinical trials.

Individuals living with HIV and health care providers can find out more information on federally or privately sponsored AIDS clinical trials by contacting the Information Service listed below. Eligibility requirements are different for each clinical trial. Strict guidelines are used to protect patient privacy and safety.

AIDS Clinical Trials Information Service:
1-800-TRIALS-A (1-800-874-2572)

KEY CONTACTS FOR MORE INFORMATION

Alabama	AIDS Office	(334) 206-5364
	Medicaid	1-800-362-1504
	Medicare	1-800-243-5463
	Title II/ADAP	(334) 206-5364
Alaska	AIDS Office	(907) 269-8000
	Medicaid	(907) 465-3355
	Medicare	1-800-478-6065
	Title II/ADAP	(907) 269-8058
American Samoa	Medicaid	(648) 633-4590
	Medicare	1-800-444-4606
Arizona	AIDS Office	(602) 230-5819
	Medicaid	1-800-962-6690
	Medicare	1-800-432-4040
Title I	Phoenix	(602) 277-7526
	Title II/ADAP	(602) 230-5819
Arkansas	AIDS Office	(501) 661-2135
	Medicaid	(501) 682-6728
	Medicare	1-800-852-5494
	Title II/ADAP	(501) 661-2292
California	AIDS Office	(916) 323-7415
	Medicaid	(916) 445-0174
	Medicare	1-800-434-0222
Title I	Los Angeles	(213) 931-9828
	Oakland / Alameda Co.	(510) 548-6511
	Orange Co.	(714) 824-7758
	Riverside / San Bernadino	(909) 387-6653
	Sacramento	(916) 537-5353
	San Diego	(619) 699-2514
	San Francisco	(415) 554-9125
	San Jose	(408) 258-2480
	Santa Rosa / Petaluma	(707) 869-2849
	Title II/ADAP	(916) 327-6784

KEY CONTACTS FOR MORE INFORMATION

Colorado	AIDS Office	(303) 692-2719
	Medicaid	(303) 866-2993
	Medicare	1-800-544-9181
Title I	Denver	(303) 757-7227
	Title II/ADAP	(303) 866-2445
Connecticut	AIDS Office	(860) 509-7832
	Medicaid	(860) 424-5371
	Medicare	1-800--994-9422
Title I	Hartford	(860) 527-0856
	New Haven	(203) 392-6567
	Title II/ADAP	1-800-233-2503
Delaware	AIDS Office	(302) 739-3032
	Medicaid	(302) 577-4900
	Medicare	1-800-336-9500
	Title II/ADAP	(302) 739-3032
District of Columbia	AIDS Office	(202) 727-2500
	Medicaid	(202) 727-2500
	Medicare	(202) 676-3900
	Title I	(202) 371-9100
	Title II/ADAP	(202) 727-2500
Florida	AIDS Office	(904) 487-3684
	Medicaid	1-850-488-3560
	Medicare	1-800-963-5337
Title I	Ft.Lauderdale / Broward Co.	(954) 522-4749
	Jacksonville	(904) 630-1650
	Miami / Dade Co.	(305) 573-6010
	Orlando	(407) 862-4676
	Tampa / Saint Petersburg	(813) 272-5040
	West Palm Beach	(561) 833-2862
	Title II/ADAP	(904) 413-0735
Georgia	AIDS Office	(404) 657-3100
	Medicaid	(404) 657-3590 or 1-800-869-1150
	Medicare	1-800-669-8387
Title I	Atlanta/Fulton Co.	(404) 522-0400
	Title II/ADAP	(404) 657-3127
Guam	AIDS Office	(671) 734-7298
	Medicaid	(671) 734-7269
	Medicare	1-800-444-4606
	Title II/ADAP	(671) 734-7142
Hawaii	AIDS Office	(808) 733-9010
	Medicaid	(808) 587-3521
	Oahu	(808) 587-3875
	Other Islands	800-518-8887
	Medicare	(808) 586-0100
	Title II/ADAP	(808) 732-0026
Idaho	AIDS Office	(208) 334--6526
	Medicaid	(208) 334-5747 or (208) 334-5815
	Medicare	1-800-247-4422
	Title II/ADAP	(208) 334-6526
Illinois	AIDS Office	(312) 814-4846
	Medicaid	1- 800-252-8635
	Medicare	1-800-548-9034
Title I	Chicago	(773) 784-7297
	Title II/ADAP	1-800-825-3518
Indiana	AIDS/Office	(317) 383-6867
	Medicaid	(317) 232-4966
	Medicare	1-800-452-4800
	Title II/ADAP	(317) 920-3190
Iowa	AIDS Office	(515) 242-5838
	Medicaid	1-800-972-2017
	Medicare	1-800-351-4664
	Title II/ADAP	(515) 242-5838

continued on next page

KEY CONTACTS FOR MORE INFORMATION

Kansas	AIDS Office	(913) 296-6173
	Medicaid	(913) 296-3349
	Medicare	1-800-860-5260
	Title II/ADAP	(913) 296-6036
Kentucky	AIDS Office	(502) 564-6539
	Medicaid	1-800-635-2570
	Medicare	(502) 564-6539
	Title II/ADAP	(502) 564-6539
Louisiana	AIDS Office	(504) 586-7474
	Medicaid	(504) 342-9240
	Medicare	1-800-259-5301
Title I	New Orleans	(504) 945-3229
	Title II/ADAP	(504) 568-7474
Maine	AIDS Office	(207) 287-5551
	Medicaid	(207) 287-3094
	Medicare	1-800-750-5353
	Title II/ADAP	(207) 287-5060
Maryland	AIDS Office	(410) 767-5013
	Medicaid	(410) 767-1432
	Medicare	1-800-243-3425
Title I	Baltimore	(410) 715-0895
	Title II/ADAP	(410) 767-5087
Massachusetts	AIDS Office	(617) 624-5300
	Medicaid	1-800-841-2900
	Medicare	1-800-882-2003
Title I	Boston	(617) 498-1472
	Title II/ADAP	(617) 566-8358
Michigan	AIDS Office	(517) 335-8468
	Medicaid	1-800-642-3195
	Medicare	1-800-803-7174
Title I	Detroit	(313) 864-8081
	Title II/ADAP	(517) 335-9333
Minnesota	AIDS Office	(612) 623-5143
	Medicaid	(612) 296-7675
	Medicare	1-800-333-2433
Title I	Minneapolis / St. Paul	(612) 870-1723
	Title II/ADAP	(612) 297-3344
Mississippi	AIDS Office	(601) 960-7711
	Medicaid	(601) 987-3944
	Medicare	1-800-948-3090
	Title II/ADAP	(601) 960-7723
Missouri	AIDS Office	(573) 751-6141
	Medicaid	1-800-392-1261
	Medicare	1-800-390-3330
Title I	Kansas City	(816) 756-1304
	St. Louis	(573) 658-1044
	Title II/ADAP	(573) 751-6439
Montana	AIDS Office	(406) 444-9028
	Medicaid	(406) 444-4540
	Medicare	1-800-322-2272
	Title II/ADAP	(406) 444-4744
Nebraska	AIDS Office	(308) 535-8134
	Medicaid	(402) 471-9147
	Medicare	(402) 471-2201
	Title II/ADAP	(402) 559-4673
Nevada	AIDS Office	(702) 687-4800
	Medicaid	(702) 687-4776
	Medicare	1-800-307-4444
	Title II/ADAP	(702) 687-4800
New Hampshire	AIDS Office	(603) 271-4576
	Medicaid	1-800-852-3345 (x.4346 or 4344)
	Medicare	1-800-852-3388
	Title II/ADAP	1-800-852-3345 (x.4483)
New Jersey	AIDS Office	(609) 984-5874
	Medicaid	(609) 588-2600
	Medicare	1-800-792-8820
Title I	Bergen / Passaic	(201) 523-8316
	Hudson Co. / Jersey City	(201) 795-4555x.26
	Middlesex / Somerset / Hunterdon	(908) 826-9160
	Newark	(201) 483-4250
	Vineland / Millville / Bridgeton	(609) 825-6810
	Title II/ADAP	(609) 984-6125
New Mexico	AIDS Office	(505) 476-8451
	Medicaid	(505) 827-3100
	Medicare	1-800-432-2080
	Title II/ADAP	(505) 476-8470
New York	AIDS Office	(518) 473-7542
	Medicaid	(518) 486-9057
	Medicare	1-800-333-4114
	New York City	(212) 869-3850
Title I	Dutchess Co.	(914) 471-9185
	Nassau / Suffolk	(516) 968-3001
	New York	(212) 788-2762
	Title II/ADAP	(518) 459-1641
North Carolina	AIDS Office	(919) 715-3118
	Medicaid	1-800-662-7030
	Medicare	1-800-443-9354
	Title II/ADAP	(919) 715-3118
North Dakota	AIDS Office	(701) 328-2378
	Medicaid	(701) 328-2321
	Medicare	1-800-247-0560
	Title II/ADAP	(701) 328-2378
Northern Mariana Islands		
	AIDS Office	(670) 234-8950
	Medicaid	(670-234-8950 x.2905
	Medicare	1-800-444-4606
Ohio	AIDS Office	(614) 644-8026
	Medicaid	(614) 466-6650
	Medicare	1-800-686-1578
Title I	Cleveland / Lorain / Elyria	(216) 664-4370
	Title II/ADAP	(614) 466-6669
Oklahoma	AIDS Office	(405) 271-4636
	Medicaid	(405) 521-3679
	Medicare	1-800-763-2828
	Title II/ADAP	(405) 271-4636
Oregon	AIDS Office	(503) 731-4029
	Medicaid.	1-800-273-0557 or 1-800-359-9517
	Medicare	1-800-722-4134
Title I	Portland	(503) 248-5429
	Title II/ADAP	(503) 731-4029
Pennsylvania	AIDS Office	(717) 783-0479
	Medicaid	1-800-692-7462 or (717) 787-3119
	Medicare	1-800-783-7067
Title I	Philadelphia	(215) 546-0300
	Title II/ADAP	1-800-922-9384
Puerto Rico	AIDS Office	(787) 274-5502
	Medicaid	(809) 765-1230
	Medicare	(809) 721-8590
Title I	Caguas	(787) 745-0340
	Ponce	(787) 840-7510
	San Juan	(787) 763-6560
	Title II/ADAP	(787) 763-4575
Rhode Island	AIDS Office	(401)277-2320
	Medicaid	(401) 464-3361
	Medicare	1-800-322-2880
	Title II/ADAP	(401) 222-2320 (x.107)
South Carolina	AIDS Office	(803) 737-4110
	Medicaid	(803) 737-5900
	Medicare	1-800-868-9095
	Title II/ADAP	(803) 734-6033
South Dakota	AIDS Office	(605) 773-3737
	Medicaid	(605) 773-3495 or (605) 945-5006
	Medicare	1-800-822-8804
	Title II/ADAP	(605) 773-3737
Tennessee	AIDS Office	(615) 741-7500
	Medicaid.	1-800-523-2863 or 1-800-669-1851
	Medicare	1-800-525-2816
	Title II/ADAP	(615) 741-8903
Texas	AIDS Office	(512) 490-2515
	Medicaid.	1-800-252-8263 or 1-800-252-9330
	Medicare	1-800-252-9240
Title I	Austin	(512) 450-1272
	Dallas	(214) 368-0348
	Fort Worth / Arlington	(817) 921-7830
	Houston	(713) 526-8798
	San Antonio	(210) 692-8831
	Title II/ADAP	(512) 490-2510
Utah	AIDS Office	(801) 538-6096
	Medicaid	1-800-662-9651
	Medicare	1-800-439-3805
	Title II/ADAP	(801) 538-6096
Vermont	AIDS Office	(802) 651-1533
	Medicaid	1-800-529-4060
	Medicare	1-800-642-5119
	Title II/ADAP	(802) 863-7245
Virginia	AIDS Office	(804) 786-6267
	Medicaid	1-804-692-1720
	Medicare	1-800-552-3402
	Title II/ADAP	(804) 225-4844
Virgin Islands	AIDS Office	(809) 774-3168
	Medicaid	(809) 774-4624
	Medicare	(809) 774-2991
	Title II/ADAP	(809) 774-3168
Washington State	AIDS Office	(360) 586-8344
	Medicaid	1-800-562-3022
	Medicare	1-800-397-4422
Title I	Seattle	(206) 720-4377
	Title II/ADAP	(360) 586-7388
West Virginia	AIDS Office	(304) 558-5358
	Medicaid	(304) 558-4098
	Medicare	1-800-642-9004
	Title II/ADAP	(304) 926-1758
Wisconsin	AIDS Office	(608) 267-5287
	Medicaid	1-800-362-3002
	Medicare	1-800-242-1060
	Title II/ADAP	(608) 267-6875
Wyoming	AIDS Office	(307) 777-5932
	Medicaid	(307) 777-7531
	Medicare	1-800-856-4398
	Title II/ADAP	(307) 777-5800

Drug Assistance Programs of Pharmaceutical Companies

Acyclovir, Zovirax
Glaxo Wellcome Co. 1-800-722-9294
Alpha Interferon-2A, Roferon-A
Hoffmann-La Roche, Inc. 1-800-443-6676
Alpha Interferon-2B, Intron-A
Schering-Plough Corp. 1-800-521-7157
Amitriptyline
Roche Laboratories 1-800-285-4484
Astemizole, Hismanal
Janssen Pharmaceutica 1-800-544-2987
Atovaquone, Meprone
Glaxo Wellcome Co. 1-800-722-9294
Azithromycin, Zithromax
Pfizer, Inc. 1-800-646-4455
AZT, Zidovudine Retrovir
Glaxo Wellcome Co. 1-800-722-9294
Bleomycin, Blenoxane
Britol-Myers Squibb 1-800-272-4878
Cefitaxime, Claforan
Hoechst-Roussel 1-800-422-4779
Ceftriaxone, Rocephin
Roche Laboratories 1-800-285-4484
Cefuroxime, Ceftin
Eli Lilly and Company 1-800-545-6962
Glaxo Wellcome 1-800-722-9294
Cimetidine, Tagamet
SmithKline Beecham 1-800-546-0420
Ciproflaxacin, Cipro
Miles Pharmaceuticals 1-800-998-9180
Clarithomycin, Biaxin
Abbott Laboratories 1-800-688-9118
Clindamycin, Cleocine
Upjohn Company 1-800-242-7014
Clofazimine, Lamprene
Ciba Pharmaceuticals 1-800-257-3273
Clonazepam, Klonopin
Roche Laboratories 1-800-285-4484
Clotrimazole, Mycelex,Lotrimin
Miles Inc. 1-800-998-9180
Schering Laboratories 1-800-656-9485
Cyclophosphamide, Cytoxan
Bristol-Myers Squibb 1-800-272-4878
Cyclosporine, Sandimmune
Sandoz Pharmaceuticals 1-800-631-8184
Daunorubicin, Lipsomal, DaunoXome
NeXstar Pharmaceuticals 1-800-226-2056
ddC, Zalcitbane HIVID
Hoffmann-La Roche, Inc. 1-800-285-4484
Dexamethasone, Dacadron
Merck & Co. 1-800-994-2111
Didanosine, ddI, Videx
Bristol-Myers Squibb 1-800-272-4878
Dronabinol, Marinol
Roxane Laboratories. 1-800-274-8651
Doxcycline, Vibramycin
Pfizer Inc. 1-800-646-4455
Doxorubicin, liposomal, Doxil
Sequus Pharmaceuticals 1-800-375-1658
Erythropoietin, EPO, Procrit, Epogen
Ortho Biotech 1-800-553-3851
Amgen 1-800-272-9376
Ethambutol, Myambutol
Wyeth-Ayerst 1-800-568-9938
Etoposide, VP16, Vepesid
Bristol-Myers Squibb 1-800-272-4878
Erythromcyin
Wyeth-Ayerst 1-800-568-9938
Famciclovir, Famvir
SmithKline Beecham 1-800-546-0420
Famotidine, Pepcid
Merck & Co. 1-800-994-2111
Fentanyl, Duragesic
Janssen Pharmaceutica 1-800-544-2987
Fluconazole, Diflucan
Pfizer, Inc. 1-800-869-9979
Flucytosine, Ancobon
Roche Laboratories 1-800-285-4484
Flucinonide, Lidex
Roche Laboratories 1-800-285-4484
Fluoxetine hydrochloride, Prozac
Eli Lilly and Company 1-800-545-6962
Foscarnet, Foscavir
Astra Pharmaceutical Products, Inc. . . . 1-800-488-3247
Ganciclovir, Cytovene
Roche Laboratories 1-800-285-4484
Ganciclovir, Intraocular, Vitrasert
Chiron Vision 1-800-843-1137
G-CSF, Neupogen
Amgen 1-800-272-9376
GM-CSF, Leukine
Immunex Corporation 1-800-466-8639
Granisetron, Kytril
SmithKline Beecham 1-800-866-6273
Hydrocortisone, Hydrocortone, Cortef
Merck & Co. 1-800-994-2111
Upjohn Co. 1-800-242-7014
Hydroxyzine, hydrochloride
Pfizer, Inc. 1-800-646-4455
Hydroxyzine pamoate,Vistaril
Pfizer, Inc. 1-800-646-4455
Immune globulin, IV, WinRho SD
Univax 1-800-789-2099
Indinavir, Crixivan
Merck & Co. 1-800-927-8888
Itraconazole, Sporanox
Janssen Pharmaceutica 1-800-544-2987
Ketoconazole, Nizoral
Janssen Pharmaceutica 1-800-544-2987
Lamivudine, 3TC, Epivir
Glaxo Wellcome Co. 1-800-722-9294
Loperamide, Imodium
Janssen Pharmaceutica 1-800-544-2987
Laratadine, Claratin
Schering Laboratories 1-800-656-9485
Megestrol Acetate, Megace
Bristol-Myers Squibb 1-800-272-4878
Methotrexate, Rheumatrex
Wyeth Ayerst 1-800-568-9938
Methylprednisolone, Medrol
Upjohn Co. 1-800-242-7014
Mexiletine, Mexitil
Boehringer Ingelheim 1-800-556-8317
Morphine sulfate, Roxanol
Roxane Laboratories. 1-800-274-8651
Nizatidine, Axid
Eli Lilly and Co. 1-800-545-6962
Nystatin, Mycostatin
Bristol-Myers Squibb 1-800-272-4878
Octreotide acetate, Sandostatin
Sandoz Pharmaceuticals. 1-800-631-8184
Oxandrolone, Oxandrin
Bio-Technology General Corp. 1-800-741-2698
Paclitaxel, Taxol
Bristol-Myers Squibb 1-800-272-4878
Paramomycin, Humatin
Parke-Davis 1-800-755-0120
Pentamidine aerosolized, NebuPent
Fujisawa Pharmaceuticals 1-800-366-6323
Pentoxifulline, Trental
Hoechst Roussel Pharmaceuticals 1-800-422-4779
Phenytoin, Dilantin
Parke-Davis 1-800-755-0120
Prednisone
Schering Laboratories 1-800-656-9485
Prochlorperazine, Compazine
SmithKline Beecham 1-800-546-0420
Pyrazinamide, P.USP
Wyeth-Ayerst 1-800-568-9938
Pyrimethamine, Daraprim, Fansidar
Glaxo Wellcome Co. 1-800-722-9294
Roche Laboratories 1-800-285-4484
Ranitidine, Zantac
Glaxo Wellcome 1-800-722-9294
Rifabutin, Mycobutin
Pharmacia 1-800-366-5570
Rifampin, Rimactane
Ciba Pharmaceuticals 1-800-257-3273
Ritonavir, Norvir
Abbott Laboratories 1-800-659-9050
Saquinavir, Invirase
Roche Laboratories 1-800-282-7780
Sertraline hydrochloride, Zoloft
Phizer, Inc. 1-800-646-4455
Stavudine, d4T
Bristol-Myers Squibb 1-800-272-4878
Strptomycin, S.USP
Pfizer, Inc. 1-800-254-4445
Sucralfate, Carafate
Marion Merrell Dow 1-800-552-3656
Terfenadine, Seldane
Marion Merrell Dow 1-800-552-3656
Testosterone, Transdermal patch
Alza Pharmaceuticals 1-800-634-8977
Trimethroprim sulfamethoxazole TMP/SMX,
Septra, Bactrim
Glaxo Wellcome Co. 1-800-722-9294
Hoffmann-La Roche 1-800-285-4484
Trimetrexate, NeuTrexin
US Bioscience 1-800-285-4484
Valacyclovir, Valtrex
Glaxo Wellcome 1-800-722-9294
Vinblastine, Velban
Eli Lilly and Company 1-800-545-6962
Vincristine, Oncovin
Eli Lilly and Company 1-800-545-6962

continued from page 3

(718.625.4244) the authors compared the analgesic efficacy of at least 15 days of a stable dose of oral opoids with the analgesic efficacy of at least 15 consecutive days of therapy with fentanyl transdermal system (Duragesic) in patients with AIDS related chronic pain. Side effects, quality of life, and patient satisfaction were also evaluated.

Fentanyl transdermal system (FTS) is delivered by a noninvasive transdermal system (a skin patch) which allows continuous delivery of a potent opioid providing pain relief for up to 72 hours. While the FTS is approved for the treatment of chronic pain in people requiring opioid analgesia and research has shown its effectiveness for treating cancer, the product had not been evaluated for its effectiveness in treating chronic pain in people with AIDS.

The study, supported by Janssen Research Foundation, was an open-label, pre-treatment vs. Post-treatment trial of outpatients at one site in the United States. All patients had experienced at least moderate pain control with a stable daily dose of a potent oral opioid for the 3 days preceding enrollment. On enrollment (visit 1), patients completed a pain questionnaire and underwent a history and physical examination. For 15 days, participants remained on a stable dose of the oral opioid analgesic that had been prescribed previously. At The end of 15 days (visit 2) patients' medication was titrated to a stable dose of FTS according to the package insert instructions. After the participants had received a stable dose of FTS for a least 15 consecutive days, the end of study (visit 3) assessments were made. The assessments included the Brief Pain Inventory before (visit 2) and after (visit 3) 15 days of treatment with FTS.

Among the exclusion criteria were use of ritonavir (Norvir) during the trial, life expectancy of less than 3 months, active substance abuse, and the inability to speak, read or understand English.

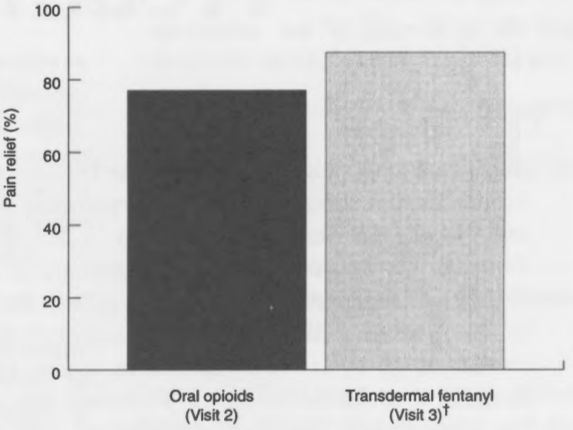
A total of 35 individuals were enrolled in the study. Of the group 74% were men, 26% were women; 37% were Latino, 34% were black, 23% were white and 6% were of unknown racial origin. Nearly 70% of the participants had completed high school, including 17% who had also completed college. The participants were divided among those who were former intravenous drug users (43%), those who had never used intravenous drugs (49%) and those who were enrolled in a methadone treatment program (8%). At study start, most patients were taking more than one medication for chronic pain: 71% were taking strong oral opioids and 45.7% were taking nonsteroidal anti-inflammatory drugs, such as aspirin or ibuprofen. Of those taking a strong opioid, the majority (63%) were taking oxycodone plus acetaminophen (Percocet) before beginning treatment with the FTS.

The participants reported that the major impediments to pain management were the difficulty of assessing pain (74.3%), the belief that pain was part of their condition (62.9%), and the fear of becoming addicted to pain medication (54.3%).

The participants received therapy with FTS for a mean of 22.5±1.9 days, and the mean dose administered was 50±4.6mcg. During the FTS period, 32.4% of participants reported adverse events. The most frequently reported side effects were headache, somnolence, and bronchitis, reported by 2 persons each. Additionally, one participant died during the oral opioid phase and one withdrew because of excessive somnolence during the FTS phase.

The investigators report their study shows Duragesic effectively alleviates chronic pain in patients with AIDS. On a scale of 0% to 100% relief, the mean pain relief score increased from 77.1% with oral opioids to 87.5% with FTS (figure1). The Fentanyl transdermal system provided an overall improvement in general activity, mood, walking ability, normal work, relationships, and enjoyment of life over oral opioids (figure 2). There was no difference in adherence to therapy or frequency of side effects in the two groups (figure 3).

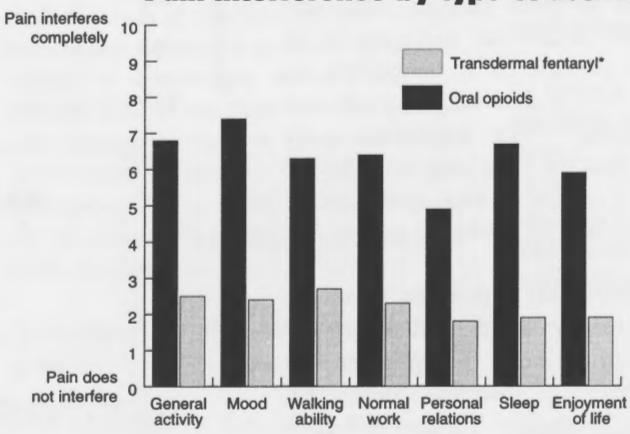
Figure 1
Change in percent of pain relief by visit*



* A mean increase in score from visit 2 to visit 3 (visit 3 - visit 2 > 0) indicates improvement. Item was scored as follows: 0%=no relief, to 100%=complete relief.

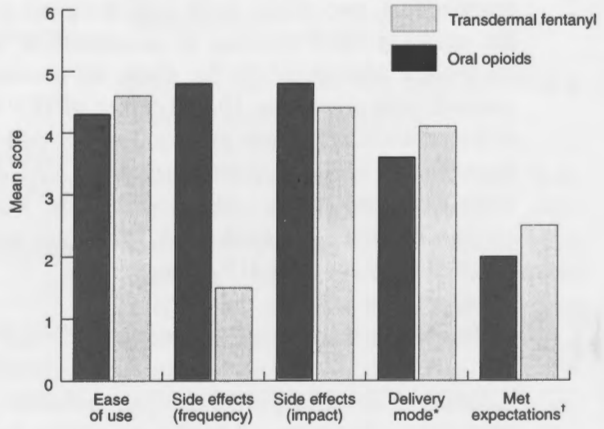
† P<0.001 (Wilcoxon's signed rand test).

Figure 2
Pain interference by type of activity*



* P < 0.001 (Wilcoxn's signed rank test).

Figure 3
Satisfaction with pain medication



* P=0.03

† P=0.001 (Wilcoxon's signed rand test).

An informational brochure on pain in HIV/AIDS is available on NAPWAFax (Document No.1901) at 202-789-2222. For additional information contact Cancer Care at 212-221-3300 or www.cancercareinc.org.

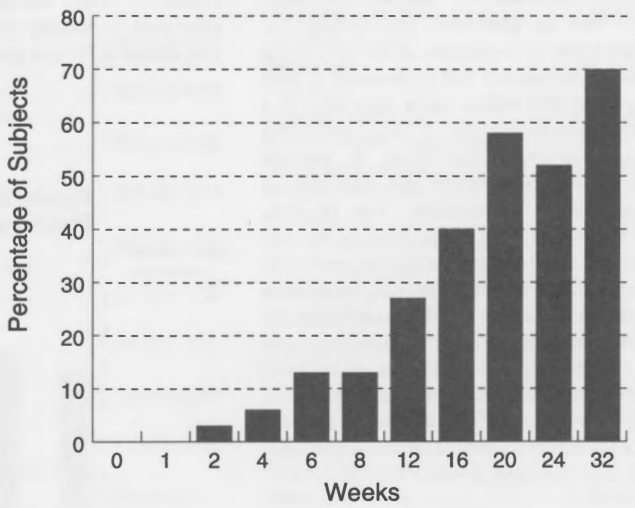
FORTOVASE Added to Treatment Guidelines

The Panel on Clinical Practices in the Treatment of HIV Infections, convened by the U.S. Department of Health and Human Services and the Henry J. Kaiser Family Foundation, has amended its guidelines to include Fortovase (saquinavir), the new soft gelatin formulation of the protease inhibitor Invirase (saquinavir mesylate) manufactured by Hoffman-La Roche, among the list of drugs in its preferred strategies. Fortovase was approved for marketing by the FDA in November 1997 based in part on data from study NV15355 which showed a significantly greater proportion of patients, who received Fortovase plus two nucleoside analogues, achieved viral load reductions to below the limit of detection (400 copies/mL), as compared to those patients who have received Invirase plus two nucleoside analogues at 16 weeks. Other studies considered in amending its guidelines included NV15107, a dose ranging study, and NV15182, a safety study. The guidelines were formalized in November also and have been amended for the first time following a review of data on the use of Fortovase in clinical trials over 24 weeks.

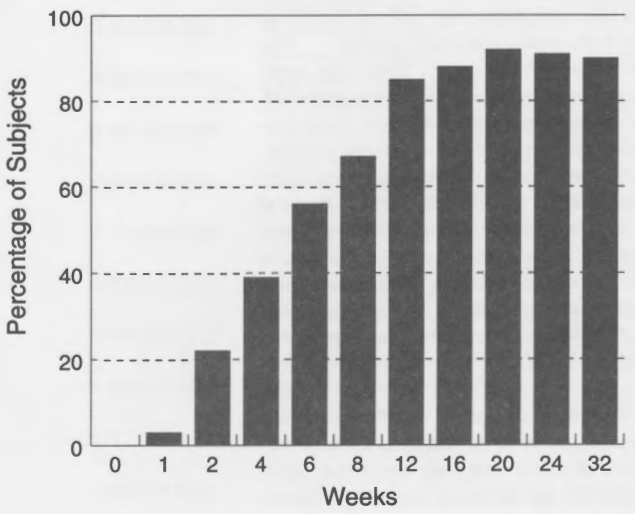
Given at 1200 mg three times daily with meals, Fortovase has been shown to provide increased level of drug to attack HIV compared with Invirase. The primary side effects are nausea, vomiting, diarrhea, flatulence, abdominal discomfort and headaches. Tables 1 & 2 show the percentage of people whose viral load levels were below 400 copies/mL and 20 copies/mL after 6 months of treatment in the Sun Study (M61005), an open label, non-comparative, two center study trial designed to evaluate the efficacy of Fortovase in combination with two nucleoside analogues. In the study, 42 treatment-naive patients with more than 10,000 copies of HIV-RNA/mL of blood and CD4 counts greater than 100 cells received Fortovase at 1200 mg three times daily, AZT at 300 mg twice daily, and 3TC at 150 mg twice daily. Patients had a mean baseline viral load of 65,757 copies and a mean baseline CD4 count of 419 cells.

Hoffman-La Roche will continue to make Invirase available to patients currently on the drug through early summer. Following this period, patients who are currently on Invirase will be able to receive the original product under a limited distribution program. As always, patients should discuss their future treatment options with a knowledgeable physician.

SUN Study
FORTOVASE™ (SQV) SGC+AZT+3TC
% of Pts. with HIV-1 RNA < 20 COPIES/ml



SUN Study
FORTOVASE™ (SQV) SGC+AZT+3TC
% of Pts. with HIV-1 RNA < 400 COPIES/ml



Nutrition Nibbles

Body Composition Analysis is an Important Tool

by Marcy Fenton, M.S., R.D. and Stephanie Correnti, R.D.

Weight fluctuations measured on a scale may not always be the truest indicator of changes in lean body mass.

Bioelectric Impedance Analysis (BIA) is an important tool to determine body composition. Used in HIV-related wasting studies, BIA tests are quick, accurate and relatively inexpensive compared to some other body composition tests. Along with viral load and CD4 count, some physicians believe that BIA should be a standard test for any HIV-infected person.

Body composition analysis provides early detection of conditions so that changes can be made at a time when they can be more effective and less costly. These changes could involve food, fluid, exercise or medications. It is a powerful way to take control of your health.

Causes for weight loss and wasting

Usually, there are multiple reasons contributing to the underlying mechanisms that cause weight loss and wasting. The four main areas are:

- **Lack of intake of calories and nutrients**–reduced intake due to a decrease or loss of appetite (anorexia), depression, illness, lack of food, fatigue, nausea, vomiting, diarrhea.
- **Malabsorption**–vomiting, diarrhea, inability to digest fats, lactose (the sugar that is found in milk) or gluten (a protein found in wheat flour).
- **Metabolic changes**–increased demand and use of energy and protein. Hypogonadism, which may originate as a result of weight loss, is a decrease in the growth or functional activity of the sexual organs, the testes or ovaries, which then contributes to further lean body mass losses.
- **Reduction in use of muscle**–from factors such as illness, being fatigued, change in lifestyle and depression.

Why test for body composition?

The BIA test should be performed soon after an HIV diagnosis in order to establish a baseline. Each person's result and progress is individual, and each person acts as his/her own control. The BIA test should be repeated at least two to four times a year, and more depending on the results of the previous tests, or changes in nutritional or medical status.

Changes in body composition, specifically changes in functioning tissue, should be detected by performing a BIA test. Functioning tissue–called body cell mass (BCM) and often referred to as lean body mass (LBM)–is the protein and active part of the cells found in muscle and organs. BIA also identifies the amounts of water in and outside the body cell mass. Analysis of this fluid and fluid changes can indicate an increase in muscle or wasting, edema or dehydration. Most importantly, changes in BCM and fluid can reflect positive and negative changes in nutritional intake, metabolism, response to disease and effectiveness of treatment, so that outcomes can be seen and interventions modified to be made more effective.

To prepare for the BIA test, the following guidelines should be observed:

- Do not exercise or use a sauna, steambath or Jacuzzi eight hours or less prior to the test.
- Do not drink alcohol for 12 hours prior to the test.
- Do not be tested while perspiring or feverish."
- Do not skip any meals.
- Limit or eliminate caffeine-containing beverages and food. Caffeine (found in coffee, chocolate, colas, teas) is a dehydrating agent that may affect the results of the test.
- Although a specific amount of water intake is not specified for the test, the usual recommendation is to drink 10-12 cups of fluid daily.
- Do not use diuretics, antihistamines or steroids. Continue taking prescribed medication, but be prepared to tell w drugs you are taking at the time of the te
- An accurate weight and height is done at time of testing.
- Prior to the test, remove jewelry on the side of your body.

BIA Testing procedure:

The entire BIA test takes only five minu to perform.

First, you will be asked to lay quietly with motion flat on your back with arms and l separated away from the body so no parts touching or touching a wall. Using spec adhesive pads, electrodes are attached on yo right foot on the ankle and just below t middle toes, and on your right hand on the wr and first joint of the middle finger.

To assure a better contact, areas of electro placement will first be cleansed with rubbi alcohol. (If you are sensitive to rubbi alcohol, let it be known to the pers administering the test.) The strength of t electrical signal is very low. Most people do n feel anything.

After the electrodes are removed, a qualifi health care professional should provide opportunity to discuss the procedure with yo either immediately following the test or at follow-up appointment. Although the raw da from the BIA test is available immediate complete analysis must be processed usi special software.

When the test results have been processed, copy will be sent to your physician.

If your doctor does not provide bo composition testing, BIA tests are oft available at your local AIDS Services Provid For more information, or for a referral to agency that provides BIA Testing, conta NAPWA's Health Education Department.

Reprinted with permission from Positive Livi Newsletter, December 1997. Marcy Fenton, M. R.D. is the HIV nutrition advocate at AIDS Proj Los Angeles. Stephanie Correnti R.D., is t registered dietitian at Project Angel Food.

continued from page 1

5. Monitoring growth and development is important for the care of HIV-infected children. Nutritional support is a therapeutic intervention that affects immune function, quality of life and bioactivity of antiretroviral drugs.

6. Information regarding the efficacy of antiretroviral drugs for children can be extrapolated from clinical trials in adults. The absence of pediatric-specific clinical trials does not preclude the use of any approved antiretroviral drug in children.

7. Management of infants, children, and adolescents with HIV/AIDS is rapidly evolving and increasingly complex, therefore, wherever possible, management of HIV-infected children and adolescents should be directed by a specialist in the treatment of pediatric and adolescent HIV infection. If this is not possible, then it is important to consult with such experts regularly.

8. Adult guidelines for antiretroviral therapy are appropriate for adolescents.

Background information on HIV viral load:

The HIV RNA pattern among perinatal-infected infants differs from that seen in infected adults. In one large prospective study, HIV RNA levels were generally low at birth (<10,000 copies/ml), rose to extremely high values within the first 2 months of life (most infants had values > 100,000 copies/ml), and then fell very slowly; the mean HIV RNA level during the first year of life was 185,000 copies/ml. These very high levels only slowly decline over the next few years of life to the set point value.

High RNA levels (above 100,000 copies/ml) in infants have been shown to be associated with high risk for disease progression and mortality, particularly if the CD4+ lymphocyte percentage is under 15%. In preliminary data from pediatric clinical trial, PACTG 152 correlating baseline virologic data with risk of disease progression or death, there was a 54% reduction in the relative risk of progression for each log 1(10) decrease in baseline HIV RNA level. Disease progression was documented in 11% of children 30 months old or less at entry (mean age, 1.1 years) with baseline RNA in the lowest quartile (undetectable to 150,000 copies/ml) compared to 52% of those with baseline RNA in the highest quartile (>1,700,000 copies/ml). Among children over 30 months old at entry (mean age, 7.3 years), none of those with baseline RNA in the lowest quartile (undetectable to 15,000 copies/ml) compared to 34% of those in the highest quartile (>150,000 copies/ml) had progression.

Key Recommendations

1. When to Initiate Antiretroviral Therapy:

Antiretroviral therapy is recommended for all HIV infected infants and children with clinical symptoms of HIV infection (CDC Clinical Category A, B or C) or evidence of immune suppression (CDC Immune Category 2 or 3), regardless of viral load.

The Working Group recommendations for initiating antiretroviral therapy in asymptomatic infants and children with normal immune function are as follows:

Most Working Group participants would initiate antiretroviral therapy in all HIV-infected infants under 12 months of age as soon as a confirmed diagnosis is established regardless of clinical status, immunologic status or viral load. HIV-infected infants under the age of twelve months are considered at particularly high risk for disease progression and the predictive value of immunologic and virologic parameters to identify those who will have rapid progression is less than at older ages.

Most Working Group members also favored the approach of initiating therapy in all HIV infected children older than 12 months regardless of age or symptom status in order to treat infected children as early as possible in the course of disease and intervene prior to immunologic deterioration.

Alternatively, some Working Group members would defer treatment in asymptomatic children and would carefully monitor clinical, immunologic and virologic status. In such cases, factors that should be considered in deciding to initiate therapy include: development of clinical symptoms; rapidly declining CD + lymphocyte number or percentage to values approaching the moderate immune suppression threshold; and high or increasing HIV RNA levels. Although the level of RNA considered indicative of increased risk for disease progression is not well defined in young children less than 30 months of age, the Working groups concluded that RNA level >100,000 copies/ml is clearly indicative of a high risk for mortality. For those children over 30 months of age, most Working Group members would also initiate treatment at lower HIV RNA levels (e.g. greater than 15,000 to 20,000), more consistent with the adult guidelines.

2. Choice of Antiretroviral Therapy:

Combination therapy is recommended for all infants, children and adolescents who are treated with antiretroviral agents. When compared to monotherapy, combination therapy: 1) slows disease progression and improves survival, 2) results in a greater and more sustained virologic response, and 3) delays development of resistant mutations.

Most Working Group participants recommend aggressive antiretroviral therapy for primary prenatal infection with 3 drugs, believing that this approach provides the best opportunity to delay progression and possibly to eradicate HIV infection. Based on clinical trials in infected adults, the preferred regimen to accomplish this is combination therapy with two nucleoside analog reverse transcriptase inhibitors (NRTIs) and one protease inhibitor (see table 3).

continued on next page

Table 2
1994 Revised HIV Pediatric Classification System: Clinical Categories

CATEGORY N: NOT SYMPTOMATIC
Children who have no signs or symptoms considered to be the result of HIV infection or who have only ONE of the conditions listed in Category A.

CATEGORY A: MILDLY SYMPTOMATIC
Children with TWO or more of the conditions listed below but none of the conditions listed in categories B and C.
- Lymphadenopathy (>0.5 cm at more than two sites; bilateral = one site)
- Hepatomegaly
- Splenomegaly
- Dermatitis
- Parotitis
- Recurrent or persistent upper respiratory infection, sinusitis or otitis media

CATEGORY B: MODERATELY SYMPTOMATIC
Children who have symptomatic conditions other than those listed for Category A or C that are attributed to HIV infection. Examples of conditions in clinical category B include but are not limited to:
- Anemia (<8 gm/dL), neutropenia (<1,000/mm_), or thrombocytopenia (<100,000/mm_) persisting ® 30 days
- Bacterial meningitis, pneumonia, or sepsis (single episode)
- Candidiasis, oropharyngeal (thrush) persisting (> 2 months) in children > 6 months of age
- Cardiomyopathy
- Cytomegalovirus infection, with onset before 1 month of age
- Diarrhea, recurrent or chronic
- Hepatitis
- Herpes simplex virus (HSV) stomatitis, recurrent (more than two episodes within 1 year)
- HSV bronchitis, pneumonitis, or esophagitis with onset before one month of age
- Herpes zoster (shingles) involving at least two distinct episodes or more than one dermatome
- Leiomyosarcoma
- Lymphoid interstitial pneumonia (LIP) or pulmonary lymphoid hyperplasia complex
- Nephropathy
- Nocardiosis
- Persistent fever (lasting > 1 month)
- Toxoplasmosis, onset before 1 month of age
- Varicella, disseminated (complicated chickenpox)

CATEGORY C: SEVERELY SYMPTOMATIC
Children who have any condition listed in the 1987 surveillance case definition for acquired immunodeficiency syndrome, with exception of LIP (which is category B condition)

Modified from: Centers for Disease Control. 1994 Revised Classification System for Human Immunodeficiency Virus in Children Less than 13 Years of Age. MMWR 1994;43 (No. RR-12): 1-10

Table 3
Recommended Antiretroviral Options for Initial Therapy of Pediatric HIV Infection

Preferred Regimen: Evidence of clinical benefit and sustained suppression of HIV RNA in clinical trials in infected adults; studies in pediatric patients are ongoing.

One highly active protease inhibitor plus 2 NRTIs

- **Protease inhibitor: ***
  Preferred protease inhibitor for young children:
  Nelfinavir

  Alternatives
  Ritonavir
  Indinavir (for children who can swallow pills)

- **Recommended dual NRTI combinations:**

Most data in children:	ZDV + ddI
	ZDV + 3TC†
More limited data in children:	d4T + ddI
	D4T + 3TC†
	ZDV + ddC††

Alternative Regimens: Less likely to produce sustained HIV RNA suppression in infected adults; combination nevirapine, ZDV and ddI produced dramatic and sustained viral suppression in two of six infants first treated at < 4 months of age in small preliminary pediatric study. (Luzuriaga 97)

Nevirapine + 2 NRTIs (as above)
or
3 NRTIs: d4T + ddI + 3TC

Secondary Alternative Regimen: Clinical benefit demonstrated in clinical trials in infected adults and/or children, but initial viral suppression may not be sustained.

2 NRTIs (one of the recommended dual NRTI combinations listed above)

Not Recommended: Evidence against use due to overlapping toxicity and/or virologically undesirable

Any monotherapy
d4T + ZDV
ddC + ddI
ddC + d4T
ddC + 3TC

Please see the guidelines for important notes on these therapeutic options.

While Working Group participants favor an initial approach to therapy with two NRTIs and a protease inhibitor, it is recognized that some may favor a more conservative approach and would initiate therapy with 2 NRTIs, particularly if there were concerns by the caregiver regarding the feasibility of carrying out a complex three-drug regimen or the patient and family preferred a 2-drug regimen. Alternative regimens have shown clinical benefit in adult and pediatric patients, although these regimens may not suppress viral load to below detectable levels as does combination therapy with 2 NRTIs and a protease inhibitor. Such alternative regimens include combination regimens of two NRTIs alone or combination therapy of two NRTIs with a non-nucleoside reverse transcriptase inhibitor, substituted for the protease inhibitor.

3. When to Consider Changing Antiretroviral Therapy:

There are 3 main reasons for considering changing antiretroviral therapy:

Failure of the current regimen with evidence of disease progression based on either clinical, virologic or immunologic parameters; 2) toxicity or intolerance to the current regimen; 3) new data demonstrating that a drug or regimen is superior to the current regimen.

Clinical disease progression includes: 1) progressive neurodevelopmental deterioration; 2) growth failure defined as persistent decline in weight growth velocity despite adequate nutritional support and without further explanation; 3) disease progression, as defined by advancement from one CDC Clinical category to another.

Immunologic disease progression includes: 1) progression from one CDC Immune Category to another; 2) a persistent decline of 5 percentiles or more in those with < 15% CD4 + lymphocytes; and 3) rapid and extensive decrease within a given CDC immunologic category.

Special Issues with Adherence for HIV Infected Children & Adolescents

Lack of adherence to prescribed regimens and subtherapeutic levels of antiretroviral medications may enhance the development of drug resistance, particularly to protease inhibitors. Therefore, education of the child or adolescent and/or his/her caregivers regarding the importance of compliance with the prescribed drug regimen is necessary at the time of initiation of therapy, with continued reinforcement at subsequent visits.

Infants and young children are dependent upon others for administration of medication; thus, assessment of the capacity for adherence to a complex multi-drug regimen requires evaluation of the caregiver and his or her environment as well as the ability and willingness of the child to take the drug. Liquid formulations or formulations suitable for mixing with formula or food are necessary for administration of oral drugs to young children. Lack of palatability of such formulations may be problematic if the child is to accept and retain the medication.

For adolescents, treatment regimens must balance the goal of prescribing a maximally potent antiretroviral regimen with realistic assessment of existing and potential supports to facilitate adherence. In order to meet the multiple needs of HIV infected adolescents, who are frequently unexperienced with health care systems, comprehensive systems of care are required to serve both medical and psychosocial needs.

Coordinated, comprehensive, family-centered systems of care can often address many of the day-to-day problems facing children, adolescents, and families that may affect their adherence to complex medical regimens. Case managers, mental health counselors, peer educators, outreach workers and other members of the multidisciplinary team may often be able to address specific barriers to adherence.

NAPWA wishes to thank the National Pediatric and Family HIV Resource Center and the New Jersey AIDS Education and Training Center (S. Grubman, MD, J. Oleske, MD, G. Scott, MD, L. Mofenson, MD, and C. Burr, RN, MS) for their assistance.

1413 K Street, NW
Washington, DC 20005-3442

Medical Alert is a free, health education newsletter. To ensure you receive each issue, please complete and return this coupon.

Free subscriptions are made possible through the generous support of our Friends. Please help us continue our health education work by making a tax-deductible contribution of $25 or more to support **Medical Alert** and NAPWA's important work.

Name

Organization (if applicable)

Street Address

City / State / Zip

Phone

FAX

Email

How can we better serve you?

❍ I want to support the important health education and advocacy work of NAPWA. Enclosed is my tax-deductible gift to NAPWA's Circle of Friends.

Mail, FAX or Email to:
NAPWA, 1413 K Street NW,
Washington DC 20005-3442
FAX: 202-898-0435 , Email: medical_alert@napwa.org

Editor
Charles Nelson

Managing Editor
Matthew Doerpinghaus

Contributors
Patrick Aiken
C. Burr, RN, MS
Stephanie Correnti, R.D.
Jeffrey S. Crowley, M.P.H.
Anthony Farmer, M.B.A.
Marcy Fenton, M.S., R.D.
S. Grubman, MD
L. Mofenson, MD
J. Oleske, MD
G. Scott, MD

Executive Director
A. Cornelius Baker

world wide web
www.napwa.org