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AIDS COMMUNITY RESEARCH INITIATIVE OF AMERICA

The Basics

Since the advent ten years ago of the life-extending treatments known as HAART, many of us have focused on the myriad of issues that have arisen from vast numbers of people living longer with HIV. We have been working toward the goal of making HIV disease a more manageable, long-term condition and improving people's quality of life. ACRIA in particular has worked to identify and bring to popular attention, including the attention of elected and public officials, the challenges faced by people living with HIV disease and the new physical, mental and social problems that come with getting older.

We must not forget, however, that every day people are getting diagnosed for the first time. Most of them, particularly those who are younger than the epidemic itself, are unaware of the latest developments in HIV care. They don't know about the new treatments. They don't know that there are resources available, or where to find them. They don't know what questions to ask their healthcare providers. Many of them are afraid of being stigmatized because of their HIV infection. Many of them think they are going to die.

We offer this brief guide to help those who are recently infected get the vital information they need on HIV treatment, understanding the course of their disease, selecting a primary care provider, accessing HIV-related health coverage in New York and what it means to join an clinical trial. We also offer a state-by-state key to AIDS Drug Assistance Programs across the country and a summary of new trainings offered by ACRIA via the AIDS Institute's Regional Training Centers program. We hope this is helpful and would love to know what you think of this *Update* or any of ACRIA's publications. Please email us at info@acria.org and give us your thoughts! *Daniel Tietz, Editor-in-Chief*

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winter 2006/07

An HIV Treatment Primer

by Mark Milano

Diving into the world of HIV treatment for the first time can be intimidating: dozens of meds, lab tests, medical terms and differing opinions that may make you feel like you need to go to medical school in order to make the right decisions.

You don't. Whether you've just been diagnosed with HIV, have known for a while, or are helping a friend with HIV, the good news is that you can learn enough to make informed decisions without becoming an infectious disease specialist. The trick is to take it step by step, learning enough along the way to put it all together with the help of an experienced health care provider.

Make no mistake: study after study has shown that people with HIV (or any serious illness, for that matter) do best when they are in the care of a specialist. So this guide is in no way meant to supplant the advice of a professional. But a good provider will welcome an informed patient. One thing that AIDS activism taught the health care profession is that involved consumers are to be embraced rather than feared. The goal of "health literacy" is to forge a partnership between doctor and patient – one in which decisions are made by mutual consent. This leads not only to better choices, but also to stronger buy-in from patients, leading to better long-term adherence to treatment – critical in HIV care.

One of the important concepts of health literacy is that learning needs reinforcement. When I hear a difficult medical concept the first time, it can be hard to grasp. The second time I hear it, I say, "Hmm – I've heard that before…" And the third time, I think, "Oh, I know that already!" The point is not to feel stupid if you don't grasp the information presented here on first reading. Put it down and take a second look a few days later. Or go to some of the

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ACRIA UPDATE

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ACRIAis an independent, non-profit, community-based AIDS medical research and HIVhealth literacy/treatment education organization dedicated to rapidly improving the length and quality of life for people living with HIV/AIDS. Bulk copies of *ACRIAUpdate* are available free to agencies that provide services to people living with HIV/AIDS. For more information, call 212-924-3934 ext. 129.

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ACRIA STUDIES IN PROGRESS

Lauriad for Oral Thrush
People with oral candidiasis will take either Lauriad (miconazole) tablets once a day or clotrimazole troches 5x a day for 2 weeks. Participants must be 18 or older and be on stable HAART for at least 2 months.

Transacin (NGX-4010) for Peripheral Neuropathy
People with HIV who have peripheral neuropathy will use either Transacin (capsaicin) patches or placebo patches for 30 or 60 minutes a day for 3 months. Participants must be 18 or older and have had pain in both feet for at least 2 months.

Pregabalin for Peripheral Neuropathy
People with HIV who have peripheral neuropathy will take either pregabalin (Lyrica) or a placebo (dummy pill) for 3 months. Participants must be 18 or older and have had pain in their hands or feet for at least 3 months.

IMPACT: Reyataz Resistance
People who have developed resistance to Reyataz will come in for one day of blood tests to study the I50L mutation.

For the above trials, contact Dr. Douglas Mendez at 212-924-3934 ext. 126 or Dr. Yuriy Akulov at ext. 124.

HIV Treatment Decision-Making Study
African-Americans who have not taken HIV drugs will complete a one-hour survey on a laptop computer and receive a $25 debit card. Participants must be 18 or older.
Contact Perion Smith at 212-924-3934 ext. 105.

DUET: TMC 114 & 125 for Drug-Resistant HIV (closed to enrollment)
People who are resistant to PIs and NNRTIs will take TMC125 (a new NNRTI) or a placebo (dummy) pill. Everyone will also take TMC114 (a new PI) with Norvir and other anti-HIV drugs. Participants must be 18 or older and have a viral load over 5,000.

TH9507 for Lipodystrophy (closed to enrollment)
People who have excess abdominal fat and who are taking anti-HIV drugs will take either TH9507 (an experimental growth hormone releasing factor) or a placebo for 26 weeks.

Maraviroc for Drug-Resistant HIV (closed to enrollment)
People who have taken anti-HIV drugs from three of the four classes of drugs will either take maraviroc (an experimental HIV attachment inhibitor) or placebo with an optimized regimen of anti-HIV drugs for 11 months.

Drop-In Groups
The popular groups formerly offered by Body Positive have found a new home. These peer-led drop-in support groups are held every Thursday and Friday from 6:30 to 8:00 p.m. at the LGBT Community Center, 208 West 13th St., NYC.

Editor's Notes

- All material in *ACRIA Update* is presented for educational and informational purposes only, and is not intended as medical advice. All decisions regarding one's personal treatment and therapy choices should be made in consultation with a physician.

- *ACRIAUpdate* refers to most drugs by both their commercial and scientific names upon their first reference in an article. Thereafter in the article, they will be identified with the name by which we feel they are most commonly known, either commercial or scientific.

An HIV Treatment Primer *(continued from first page)*

resources given at the end of this piece and look for similar information presented in a different way. Most people find that with repeated access these concepts are understandable.

Some people don't feel the need to be involved in all the treatment choices their health care provider recommends, at least at first. If that's you, just make sure you're seeing a provider who is well-recommended and who has a lot of experience treating people with HIV. And be sure to ask questions so you at least understand what's being recommended. You want to follow your doctor's advice because you agree with it, not just because you're told to.

A Brief History of HIV Treatment

One of the best ways to understand the current state of HIV treatment is to know how we got here. When the Human Immunodeficiency Virus (HIV) was found to be the cause of AIDS, an aggressive search began for medications that could control it. The National Cancer Institute began a massive screening effort of existing drugs to see which could limit HIV's ability to replicate ***in vitro*** (in the test tube).

One of the first drugs found was a failed cancer chemotherapy treatment known only by its chemical name, azidothymidine (AZT). When mixed with HIV-infected blood, it was very effective at preventing HIV from replicating. But many things are quite effective *in vitro*. Bleach works beautifully in the test tube, but you can't drink bleach! So the next step was to try it in people.

AZT Monotherapy

In one of the first AIDS clinical trials, people took either AZT or a placebo (dummy pill). Six months later, 19 people on placebo had died, but only one on AZT. While this was exciting, there were two problems.

First, those on AZT took it five times a day. At that high dose, many people had such severe side effects that they could not tolerate the drug. Second, we now know that when people take a single HIV drug (monotherapy), it lowers the amount of HIV in the body by about 70%. While that seems impressive, there's a problem: 30% of the HIV in the body remains, and it can change, or ***mutate***, and become ***resistant***. Once HIV becomes resistant to a drug, that drug can no longer control the virus – and when taking only one drug, this often happens within six months to a year. So, people taking AZT at this toxic dose had a lot of side effects like nausea and anemia, became resistant within a year, and sometimes died. It looked like the AZT was killing them, but in reality taking a single drug wasn't enough, no matter how much you took.

Since AZT alone wasn't working, trials began in the early 1990s in which people added a second drug like Epivir (3TC) to a lower dose of AZT (now taken only twice a day). When these two drugs were taken together, they lowered the amount of HIV in the body by 95%, with fewer side effects. This was an improvement, but the 5% of HIV that remained was still able to mutate and become resistant. It would take two to three years instead of six months, but the drugs would still stop working eventually.

HAART

The big change came in 1995, when researchers added a third drug, called Crixivan, to the mix. To their astonishment, they found that when people took three HIV drugs, they could lower the amount of HIV in their body by up to 99.99%! And, if they could get their viral levels that low and keep them there, the drugs might be able to work indefinitely. This became known as "combination therapy" or HAART (Highly Active Anti-Retroviral Therapy).

> ***"People with HIV face two major questions: Do I need to be on HIV meds, and if I do, how can I prevent my virus from becoming resistant to the drugs?"***

HAART changed everything. AIDS care now centered not on treating the many infections people got as their illness advanced, but rather on helping them take HAART correctly so the virus could not mutate and become resistant. And this is the major challenge facing people with HIV today: getting and maintaining an ***undetectable*** viral load.

A ***viral load test*** is a blood test that measures the amount of HIV in the blood. Numerous studies have found that in order to control HIV in the long run, a person usually needs to have their viral load drop below 50 copies per mm^3 (cubic millimeter – a few drops of blood). While this is called an undetectable viral load, it does not mean the virus is gone from the body – only that there is so little of it in the blood that a viral load test can't find it. (People with undetectable viral loads can still transmit HIV to others.)

Early on, researchers hoped that HAART could eradicate all the HIV from the body within two years – a cure! Well, they soon revised that estimate to four years, then to eight years, and finally to 78 years! The problem? HIV "hides" in certain cells that the drugs cannot penetrate. Since these cells live many decades, as soon as a person goes off HIV meds, the virus begins reproducing again and viral loads almost invariably shoot back up.

So, people with HIV now face two major questions: Do I need to be on HIV meds, and if I do, how can I prevent my virus from becoming resistant to the drugs? Neither question is easy to answer, unfortunately.

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An HIV Treatment Primer *(continued from previous page)*

When To Start?
As with many things about HIV and AIDS, this is a difficult question with different answers for different people. Let's start with what we know:

First, not everyone needs to be on HIV meds. Experience has taught us that the "hit hard, hit early" approach popular after HAART appeared is not the best option for most people. Long-term side effects and the possibility of resistance have led most experts to recommend waiting to start HIV meds until they're needed.

Some people find this hard to accept: If I have a virus in my body and there are drugs that can control it, why not take them as soon as possible? Well, actually, everyone lives with many viruses and other foreign microbes in their bodies and they never need drugs to control them. In fact, 90% of the cells in your body are not human – they are bacteria, parasites, and other microbes that are just "*hitching a ride*" in your gut. They don't do damage, and some even help you stay alive. Your immune system controls the ones that could do harm.

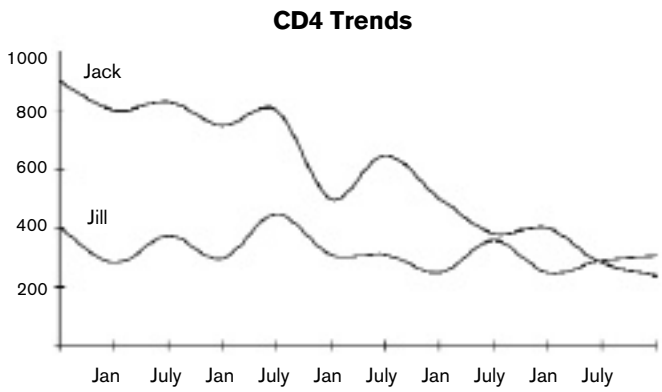
So, it's not unusual to live with a virus in your body – the trick is to keep it under control. And most people's immune system can control HIV for many years without the help of drugs. So, if you don't need 'em, why take 'em? The important thing is to know when to start.

The most commonly used test to determine when to start HIV meds is the ***CD4 count***. CD4 cells, also known as T4 cells or Helper cells, are an important part of the immune system: they tell all the other immune cells when to go to work. Without enough CD4 cells, all the other immune cells receive no instructions and can't fight off infections and cancers. A CD4 count above 500 is considered healthy, but most people who don't have HIV have a count somewhere around 1,000 (remember, that's 1,000 per mm^3 – they actually have trillions of CD4 cells.)

So most experts feel that people with HIV who have a CD4 count above 500 don't need to start HIV meds – the immune system is able to control HIV on its own. But once the CD4 count drops below 200, many studies have shown that the risk of getting a serious infection like PCP (a potentially lethal pneumonia) increases dramatically. There is strong clinical proof that if you have a CD4 count below 200 you will most likely live longer if you start HIV meds. If your CD4 count is approaching 200, you should seriously consider starting HAART, along with other drugs, like Bactrim to prevent PCP.

The trickier question is about people whose CD4 counts are between 200 and 500, which includes many people with HIV. For years, the U.S. Public Health Service recommended that anyone with a CD4 count below 500 should start HIV meds, but in 2001 those guidelines were revised. Now, it is recommended that anyone with a CD4 count below 350 or with a viral load above 100,000 start the meds, regardless of whether there are symptoms of HIV disease.

But it's not just about "magic numbers" like 350 or 100,000. Some people with high viral loads are able to maintain high CD4 counts, and some people with high CD4 counts have serious symptoms that mean it's time to start treatment. The important thing is to watch the trend of your lab tests over time. In the chart below, Jack should probably start HIV meds because his CD4 count has been dropping every year. But Jill may choose to wait even though she is below 350, since she been relatively stable over time.



In order to keep track of your trends, it's a good idea to save a copy of each lab test you get. Over time, this will give you a good indication of what's happening in your body.

Watching Your Labs
For many people, HIV is not a disease of symptoms, but of numbers on a lab report. It's quite possible to have HIV for many years with no symptoms whatsoever. Unfortunately, you can't trust what your body is telling you. Even though they feel healthy, people with a low CD4 count can get seriously ill very quickly. So, people with HIV need to get regular CD4 and viral load tests even if they feel great, and to trust the reports.

If you want to get reliable lab results, here are some tips:
- Go to the same lab every time, for consistency.
- Go at the same time of day (CD4 counts vary during the day).
- Don't go right after vigorous exercise – it can temporarily raise CD4 counts.
- Don't go if you have an infection – wait three weeks after any infection or vaccination, since they can raise your viral load temporarily.
- Get a good night's sleep before the test, and try to lower your stress level!

If you see that your CD4 count is falling each time (a drop of 100 per year is not uncommon), most experts agree it is best

to start HAART before the count hits 200. Likewise, if your viral load is rising each time, that may indicate it's time to start the meds.

What to Start With?
With 20 drugs now approved to fight HIV, it can seem like there are endless combinations from which to choose. In reality, time and research have shown that certain drugs and certain combinations work best, while others have fallen into disfavor. Zerit, for example, once a popular drug, is not commonly used as a first-line treatment anymore since it was found to cause changes in body shape more often than some other drugs. Rescriptor is similarly unpopular, since it is not as effective as other drugs and must be taken three times a day. And certain drugs don't mix well, so that narrows the choices further.

HIV drugs currently fall into four basic classes:

Nukes
(NRTIs: nucleoside reverse transcriptase inhibitors)
Emtriva, Epivir, Retrovir (AZT),
Videx, Viread, Zerit, Ziagen

Non-nukes
(NNRTIs: non-nucleoside reverse transcriptase inhibitors)
Rescriptor, Sustiva, Viramune

Protease inhibitors
Aptivus, Crixivan, Invirase, Kaletra, Lexiva,
Norvir, Prezista, Reyataz, Viracept

Fusion inhibitor
Fuzeon

Combination pills
Combivir (Epivir & Retrovir)
Epzicom (Epivir & Ziagen)
Truvada (Emtriva & Viread)
Trizivir (Epivir, Retrovir & Ziagen)
Atripla (Emtriva, Sustiva &Viread)

If you want a detailed description of how each class of drugs works, check the resource links at the end of this piece.

Current guidelines recommend that people take an "anchor drug" (a non-nuke or a PI) along with two nukes, but your doctor may recommend a different combination based on your situation. (Since Fuzeon is an injection, it is used only by people who have become resistant to the other meds.) Choosing which meds to start with depends on which side effects you're most concerned about, if you are already resistant to any of the meds, and if once-a-day or twice-a-day dosing matters to you (HIV drugs that are taken three times a day are usually not used anymore).

There are four recommended anchor drugs: three PIs (Kaletra, Lexiva and Reyataz) and one non-nuke (Sustiva). People often choose their anchor drugs based on their most common side effects, which we'll discuss below. People often choose their nukes based on their convenience. There are three pills that combine two nukes: Truvada or Epzicom (once a day) and Combivir (twice a day), but your doctor may recommend taking other nukes individually. And you can usually switch if your first choice doesn't work out. Your doctor may also have a ***genotype test*** done before you start, to see if you have drug-resistant HIV.

Some people with HIV who don't need the meds yet choose to stay away from info about the meds, in a sometimes healthy denial. But learning about the meds before you need them gives you time to make the decision that's right for you, rather than doing it hurriedly once your CD4 count gets low. And since over 99% of people with HIV will need to go on meds at some point, knowing about the drugs that may eventually save your life may make you feel more secure about your long-term health.

Before You Start
Anyone starting any new drug, HIV-related or not, should ask these questions:

What is the name of this drug?
It's good to know the names of your meds – that's the only way you're going to learn the details about that drug. And if you end up in the ER and are asked what meds you are on, answering "a blue one, a white one and a yellow one" is not going to be much help.

Why am I taking this drug?
It's important to know what each drug you take is meant to treat, and why you need to take it. If you're taking many pills, only some of them actually fight HIV — the others could do one of a number of things: control or prevent other HIV-related infections, help with side effects, treat other conditions like high blood pressure, etc. Know which drug does which job.

How do I take this drug?
Be sure you understand how many pills to take and how often. Also ask if the drug can be taken with food. Some drugs must be taken on an empty stomach, and some must be taken with food. For many drugs it doesn't matter, but taking it with food may help with side effects. Ask if you can drink alcohol while on the drug or if there are any other restrictions (like staying out of the sun, for example). Also make sure you can take the drug at the same time as other drugs. For example, some HIV drugs cannot be taken with antacids or with herbs like St. John's Wort.

Side Effects
Some people with HIV avoid all the meds because of stories they've heard about their side effects. But the most important thing you should know about the side effects of HIV meds is that *everyone is different*. Just because your friend had a certain side effect, that doesn't mean you will. The only way to know for sure which side effects, if any, you'll have is to try the meds yourself. And if you do have side effects, many are manageable.

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An HIV Treatment Primer *(continued from previous page)*

There are three important questions to ask about side effects:

*What are the **common side effects** of this drug?*
We've all seen the long list of side effects that are listed in the "package insert" that sometimes comes with a pill bottle. Most of those side effects are rare and will usually not be a problem. But some side effects are more common (like diarrhea for people on Viracept, or vivid dreams for those on Sustiva), and you should be prepared for those and know what to do if they occur.

*What are the **serious side effects** of this drug?*
Certain drugs can cause reactions that can be life-threatening if the drug is not stopped. Ask if there are side effects that should lead you to call your doctor, such as a rash from Ziagen or Bactrim. Continuing some drugs after certain side effects can be dangerous.

*What are the l**ong-term side effects** of this drug?*
Some drugs have side effects that don't show up for weeks or months, so ask if there are certain side effects you should keep an eye out for, like body shape changes or elevated liver enzymes (a sign of possible liver damage). Some drugs may require careful liver monitoring over time, so be sure to ask if you should arrange regular blood tests to check for these side effects.

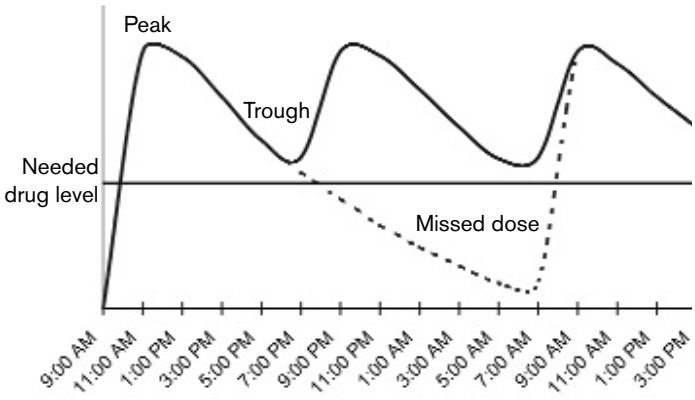
When it comes to side effects, people fall into three groups. There are those who have virtually no side effects – that isn't common, but it does happen. There are those who have persistent side effects that require them to switch their meds. But the vast majority of people will have some side effects at first, until their body adjusts to the drugs. Then the side effects usually lessen or go away completely. So it's important to give any new med you're taking a chance. For example, many people who take Sustiva have "vivid dreams" when they start the drug. If you give up after a few nights, you will miss out on a very effective HIV drug. But if you stick it out for a few weeks, most likely the dreams will stop or lessen.

When starting a new drug, ask what you can do to lessen the early side effects. People with HIV who have taken the same medication may also have tips, but remember that your experience may be different from theirs. Be sure to try any new drug for at least six weeks if you can. If you still are having unacceptable side effects, ask your doctor about stopping or switching.

Once you begin HAART, you should see your viral load drop dramatically within a few weeks – if it hasn't, that combination may not be right for you, and your doctor may recommend a different combination. In most people the CD4 count will begin to rise, but it can take months before it increases significantly, depending on how quickly the body is able to replace the missing cells.

Resistance
As mentioned earlier, HAART is most effective when it suppresses HIV levels by over 99%. Lowering it by 95% or even 98% may not be enough to avoid resistance. If the level of HIV in the body rises above 50 copies per mm^3 and stays there, the chance of resistance increases (although the drugs may still have benefit). This means people with HIV need to take nearly every dose of their HIV meds as prescribed.

Each drug has been studied to determine how much of it enters the bloodstream and how long it stays there. In the chart below, the first dose of a drug that is taken twice a day has been taken at 9 am (the solid line). Levels of the drug quickly rise to the highest level, or ***peak***, and then slowly begin falling, reaching the lowest level, or ***trough***, before the next dose is taken. But if the evening dose is missed (the dotted line), drug levels begin to fall, and the chance of developing resistance is greatly increased because there isn't enough drug in the body.



Missing one dose will not usually lead to resistance, but missing as few as three in a row or three a month can. It's best to think about ways to avoid missing doses (known as ***adherence***) before you start taking HIV meds. When you find a combination that works for you with side effects you can tolerate, you don't want to lose it. Taking every dose won't guarantee that your meds will continue to work, but it will greatly increase the chance they will.

Learning More
This primer contains the basic concepts people with HIV need to understand how their meds work, but there is much more that can be learned. ACRIA has a variety of booklets available, as do other organizations. Check out the resources below to learn more.

AIDSinfonet.org
AIDSmeds.com
TheBody.com/treatment
ProjectInform.org

Mark Milano is an HIV Health Educator at ACRIA and is an Editor of ACRIA Update.

The Course of HIV Disease

by Jack Denelsbeck

In my work as an HIV health educator, I often hear the same questions from people who are newly diagnosed with HIV:

- *What's the difference between HIV and AIDS?*
- *How long does it take to get from HIV to AIDS?*
- *How long do I have to live?*

They can be difficult to answer. But by the end of this article, you should have a better understanding of how HIV disease progresses (***pathogenesis)***. Keep these questions in mind as we look at what is known about HIV disease.

Acute Infection

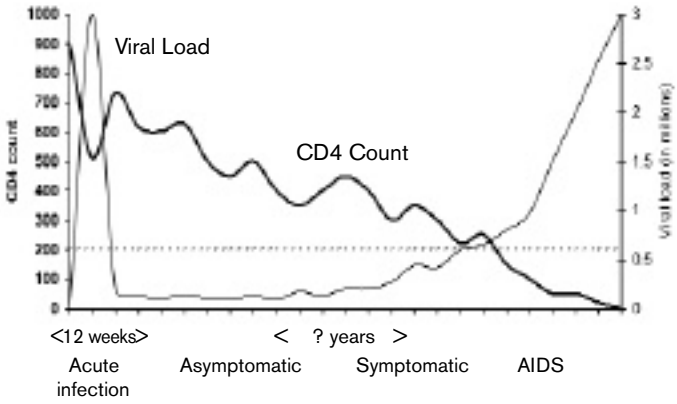
Exposure to HIV and infection with HIV are not one and the same. You can be exposed to HIV numerous times without getting infected. But once HIV is transmitted, a series of events occurs. ***Acute***, or initial infection, is the first stage after transmission. About three to four days after initial transmission of HIV, people experience a dramatic rise in their viral load (the amount of HIV in the blood). The virus multiplies very quickly and spreads into all parts of the body, including the lymph nodes, genital tract, and central nervous system.

During acute infection, people may have "flu-like" symptoms, such as rash and fever, but many people have no symptoms at all. Since their viral load is so high, anyone who engages in risky behavior with them (like having unprotected sex or sharing needles) has a high chance of being infected. During acute infection, people also experience a temporary decrease in their CD4 count, since these are some of the first cells HIV targets.

Soon after infection, the immune system mounts a response to HIV and starts producing antibodies to control the virus. This is referred to as ***seroconversion***, and can take anywhere from three weeks to three months. Until seroconversion occurs, people will test negative on a standard HIV antibody test. This is called the "window" period – the time from initial infection until the time an HIV test will come back positive. So people who think they may have been exposed to HIV should get tested no earlier than one month after the exposure. If that test is negative, another negative test at three months is needed to confirm the result.

During acute infection, the body also produces HIV-specific CD4 cells to control the virus. Unfortunately, in over 99% of people, these CD4 cells are quickly damaged and can't do their job. If they do survive (in rare cases), the immune system may be able to control HIV without medication, and the individual is known as a "long-term non-progressor." These people are being studied to find out how they are able to control HIV without treatment for 20 years or more.

After seroconversion, most people see a decrease in their viral load and a rebound in their CD4 count. The lowest point that the viral load reaches is called the ***viral setpoint***. A high setpoint can mean faster disease progression, while a low setpoint may mean slower disease progression. Another major factor of disease progression is age – people who are infected when they are older (over 50, for example) tend to progress to AIDS faster than those who get HIV when they are younger .



Asymptomatic Infection

After seroconversion, the individual moves from acute infection into a ***chronic***, or long-term infection.

The next stage in disease progression is the asymptomatic stage, meaning that people show no signs or symptoms that they are infected. They may have an ***undetectable viral load*** during this period, but an undetectable viral load doesn't mean that they can't transmit HIV – it just means that there is so little HIV in their blood the test can't see it. The asymptomatic stage can last many years and its length will not be the same for everyone.

After the asymptomatic phase, people move into the ***symptomatic*** phase. Early symptoms like thrush (a while coating of the tongue), fatigue, weight loss, etc., may begin to appear. It's not uncommon to see the CD4 count drop by 50-100 points per year.

Once the CD4 count drops below 200, the risk of developing an ***opportunistic infection***, or OI, increases dramatically. An OI is an infection that takes the opportunity of a weakened immune system to cause a serious illness. Bacteria and viruses that are normally controlled by the immune system can now lead to life-threatening conditions. When the CD4 count drops below 50, it becomes very difficult to continue living without treatment, and the risk of death is high

Time to AIDS

People often hear that people with HIV will progress to AIDS within ten years. But that's not always the case. While it's true that the ***median*** time from infection to an AIDS diagnosis is ten years, that's not the same as an ***average***. A median is the number in the middle of a range of values. That means half will be lower and half will be higher, but most will be near the middle.

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Picking a Provider

by Jerome Ernst, MD

Choosing a good health care provider, be it physician, nurse practitioner, or physician assistant, is a complicated process that can leave people unhappy and frustrated. But finding a good provider is important. Here are some observations on how you can increase your chances of finding the right clinician for you.

The first problem people encounter is that not all providers are the right match for them. If personalities clash, the same language isn't spoken, or a basic incompatibility exists, neither the patient nor the clinician will benefit from continuing the relationship. Some doctors act as if they know everything, even if they may not. For some patients this is reassuring; for others it is disturbing. Other providers are more tentative and hesitant, and their patients prefer this style. Some patients require their providers to be of the same sex, some the opposite. Some providers are biased against certain groups and are not comfortable working with them. These problems must be recognized at the beginning of the relationship and either addressed successfully or the relationship ended.

For patients with chronic diseases, especially HIV and AIDS, the course of their disease can be profoundly affected by their relationship with their provider. People who have a good relationship with their provider usually do better clinically. It's hard to discuss personal health matters with anyone, let alone a provider whom you do not trust or respect. Hiding important personal health issues from one's provider is not the best way to a healthy life. The right provider can be reassuring and supportive, even if there is not a readily available solution to the current clinical problem. This support is very important in reducing the patient's stress and by itself can improve one's health and well being.

In addition to the patient-provider relationship, there are other important factors to be aware of in choosing a good provider:

Knowledge

Smarts is important. Certainly, one wants a provider who is up to date on the latest medical knowledge. New antiretroviral drugs require clinicians to constantly refresh their knowledge of these agents. Knowing when to use newer drugs, what side effects to look out for, and what drug interactions could occur are matters that good clinicians consider when starting or changing a regimen.

Knowing the various symptoms of HIV disease is equally important. A cough may mean entirely different things depending on your CD4 count. Not every cough requires a chest X-ray or CT scan. Knowing when to act is part of the art being a good clinician. Of course, how much HIV experience your provider has is not always apparent. But if your provider is board certified in infectious diseases, s/he probably has a lot of HIV experience. Primary care physicians with large HIV practices also have lots of experience. Most providers attend refresher courses, lectures, or national or international meetings – ask what your provider does to keep up. Physician assistants and nurse practitioners have some link to physicians – ask if yours does, who the physician is, and what his or her qualifications are. PAs and NPs are not doctors but often provide care equal to the best physicians.

> ***"People who have a good relationship with their provider usually do better clinically. It's hard to discuss personal health matters with anyone, let alone a provider whom you do not trust or respect."***

Medical knowledge of illnesses other than HIV is more and more relevant for today's HIV population. As people are living longer with HIV, they are experiencing the common diseases of aging that people with HIV in the past may not have lived to worry about. HIV providers may not have a lot of experience treating the common ailments of an aging population such as high blood pressure, diabetes, arthritis, chronic lung disease, coronary artery disease, and the like. When choosing a provider, look for one who either treats both HIV-infected and uninfected patients or has experience with the common primary care ailments. Do not hesitate to ask what their experience is at your first meeting.

Communication

Smarts alone aren't enough. The clinician needs to be able to talk to the patient in a way that helps the patient understand what is happening. The patient needs to be understood and helped to feel better. To do this the clinician needs to have a good bedside manner. And not everyone does. For me, this aspect of the clinician is most important. But a good bedside manner without good clinical knowledge and skills is no good either. Being falsely reassured and comforted does not lead to good outcomes.

HIV disease can be devastating. Patient-provider encounters from the first to the last often deal with life-altering events. The provider needs to be able to impart information to the patient in ways that are understood. Frequently, this must be done repeatedly because the patient is not able to grasp the information the first, second, or even third time. So the patient needs a provider who can and will do this.

I frequently tell my patients to write down all their questions before our meeting. Then we discuss as many of them as time allows. If more time is needed and there is no one waiting, we will continue as long as we can. If there isn't enough time on this particular day, I'll schedule another visit within a couple of weeks. I find that having the patient bring a list of questions is the best way to make sure the stress of the meeting doesn't result in important issues being forgotten.

Access
The patient also needs to be assured that the clinician can always be reached in times of need. Phone calls should be returned the same day. What to do in an emergency needs to be discussed. Most providers have colleagues who cover for them on evenings and weekends. The day of the solitary family doctor who was available all the time is gone – you need to know whom you will talk to when your provider is unavailable.

Hospital Care
If you need to be hospitalized, will your provider be the one taking care of you? Ask what hospital your provider is affiliated with. Do you like that hospital? If you end up in another hospital, who will take care of you? If your provider does not follow patients if they are admitted to the hospital, who does? Are you happy with that arrangement?

In my experience, the quality of the hospital matters less than that of the physician taking care of you in that hospital. Of course, if you can have a nice clean hospital with good nurses and competent and polite staff in addition to a good doctor, you are better off. Such a magic combination, however, may be hard to find.

Office Staff
You also need to consider your provider's office arrangements. How nice and competent is the staff? Do they treat you with respect? If they call you by your first name is that okay with you? Do they telephone you the day before to remind you of your appointment? If you or your provider has to cancel, is it easy to get another appointment? Is the office clean? Is blood for lab tests drawn at the office, or are you sent across town? Does staff arrange referral appointments for you, or must you do this yourself? Do they make you feel comfortable, or do you feel as if you are disturbing them? Remember, you are the patient; they are being paid to help you.

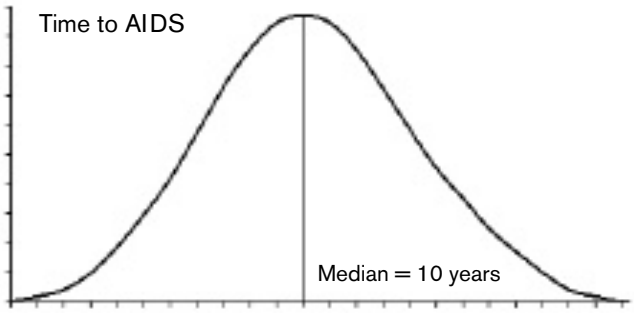
Your Role
There are several things that you need to do to ensure the success of your encounter with the medical establishment. Learn as much as you can about your disease. At a minimum, you should be familiar with basic information about HIV, how it affects the body, how one can get it, what happens if it is not treated, and what treatments exist. ACRIA and other organizations can help you with this, either on the internet or through publications and educational sessions.

Know your own medical history: when and how you were infected (if possible), what HIV drugs you have taken, what your highest and lowest CD4 counts and viral loads are and what vaccinations you have had. This information is probably best kept in a notebook with copies of lab results, hospital discharge summaries if any, lists of medications you have taken, and any side effects you may have had. You should know how to prevent your HIV from spreading to others. And this is just the HIV-specific information you need. It's also good to know your blood lipid levels, liver function tests, mammogram results if you are a woman over 40, TB test results, etc. The best way to do this is to ask for a copy of each lab test when you get it done, and to keep them all in one place. That way you have a complete record of your history even if you change providers.

All of this sounds very complicated and labor intense. Some people do all the items mentioned above, some do a few of them – it's up to you. But finding a provider who takes your life as seriously as you do and then taking the steps above will go a long way to making your life as healthy and as long as possible.

Jerome Ernst is ACRIA's Medical Director.

The Course of HIV Disease *(continued from page 7)*



The above graph shows that HIV infection takes 10 years to progress to AIDS in the largest number of people. But that doesn't apply to everyone. Some people will get an AIDS diagnosis sooner and some will take much longer. In other words, there is no way to say how long it will take for an individual to progress to AIDS. Studies that have followed people with HIV for over two decades have found that 99% of them will eventually progress to AIDS if they don't take HIV drugs at some point.

What is an AIDS diagnosis?
A person with HIV receives an AIDS diagnosis when he or she develops one or more of the 23 OIs and other conditions listed by the Centers for Disease Control, or has a CD4 count of less than 200 or a CD4% below 14. The time between asymptomatic infection and an AIDS diagnosis is called the ***incubation period***. During this time, people usually see their viral load rise and CD4 count drop. The result, if left untreated, will lead to an immune system that is ineffective at recognizing and fighting many other germs.

The good news is that treatment can usually bring even very low CD4 counts back up, to varying degrees. Many people with AIDS who have seen their CD4 go back above 200 after treatment ask, "Do I still have AIDS?" The answers is yes – the CDC currently lists AIDS as a lifelong diagnosis, though this may change as the long-term benefits of treatment are proven.

Remember those three questions I listed at the start of the article? I hope you can answer them now.

Jack Denelsbeck is an HIV Health Educator at ACRIA

Personal Perspective: **Why Me? Why Now?**

by Angelo

I am not a good person about going to the doctor. Whenever I went, they wanted to take blood to see what was wrong with me, and I didn't want that because it might come back HIV positive. I remember when I lived in California a couple of years ago, I got shingles. I was told it was due to stress and I was like, "Okay - I just lost a friend in a car accident, which I saw, so it must be that." The doctor never told me that shingles is an HIV-related illness, so I went on thinking I was okay.

I moved to New York City and started to work for an org that deals with HIV/AIDS. But last June I started coughing a lot and I was like, "Well, it has to do with the weather." I didn't think nothing of it, but at the same time I had friends coming out to me about their HIV and I started to think it was a sign from God saying, "You need to get tested." I kept on not looking at it but I saw signs. Could I be? I *was* losing weight.

I am the strong person in my group of friends, and I have lost a lot of friends to this disease. I lost my mother to AIDS. I was angry: "Why is God doing this to me? Why me and not anyone else?" I have been through a lot in this world. I had a mother who took drugs by using needles, and I was not brought up by her. I mean, I am not blaming her for my actions because I was not that innocent, either.

I just couldn't deal with it. What would my friends think? How would I look if I was sick with this? Would I die faster, like my mother? I mean, this is hard for a single person to deal with, who doesn't have no one in this world but his friends.

So I went and got a physical and when I called for my results I was told that I needed to come in and take an HIV test because my blood was not looking right. I thought, "Oh, no – has this really caught up to me? Am I now going to get sick and have my face look all sunk in?" I was worried people would look at me and say, "You are HIV positive." I felt my life was gone. How would I tell my partner? Would I have to tell everybody?

I started to hide and got very angry: "This is not going to happen to me! Now my name is going to be on some piece of paper and the whole world is going to know what is wrong with me and they are going to see that I am sick and I am going to die alone. I don't want that. I don't want this to be on a paper somewhere but now there is nothing I can do about it."

It took me a while to go to the doctor and talk to him. I was going to tell him that I was not ready for this test and that I would need some time. In the waiting room, I was shaking because I did not want to be there, number one, and number two, I was not ready. So I said to myself, "This is a mistake and this is not happening to me." I walked into his office and as he was going through my chart I was building up to telling him that I would like to wait for the HIV test because I was not ready. But as I was going to tell him, he said, "Oh, here is your result: you're HIV positive."

"This is not going to happen to me! Now my name is going to be on some piece of paper and the whole world is going to know what is wrong with me and they are going to see that I am sick and I am going to die alone."

At this point my world came down. It was finally here. I was an HIV victim. So I was like, "Okay, I am ready to leave." And he wanted to know if I should call someone or did I have someone to talk to and I said, no, I was going to be fine and I did not need no one but just wanted to leave. I took a copy of my results and left.

I wanted my world to end. I went to work but didn't talk about my problems. If my co-workers found out, how were there going to treat me? Would it be different from the way they already felt? So I said everything was fine, but I told two co-workers later on and I had the their support and they have stood behind me. I figured, "Well I have HIV now but I will not have to take meds because I have been okay without them." But my doctor had given me a prescription for something called Bactrim and I thought, Oh hell, no, I am not going on HIV meds so I can just die faster." And my roommate told me that it could cause terrible side effects.

My coworkers explained time and time again that it was just an antibiotic, like you take for pneumonia, and that the side effects didn't happen to most people. So I took it, but

then I was mad because I started to get thrush and I was like, "What is that? Now that I am taking meds, why are things happening to me? I will stop all this and forget that this is happening to me." But I didn't because my coworkers told me that I could get worse.

A month later I had to go back to the doctor but this time I was not going to the same one. I was like, "No one told you to do this test on me in the first place and I did not want to know about this." So I went and got a different doctor. They say that if you have HIV you need to feel comfortable with your doctor and I wanted to start to feel that way. If I was going to admit that I was positive I needed to really be honest. So I went to a new doctor and it was hard because I was like, "Here we go again. Will this doctor do the same thing?" But it was not so bad because when I met him we sat down and had a good talk about how I was feeling, and then I got tested for my viral load and T-cell count.

After a few days I got my results back. I had a T-cell count of 53 and that was not good. At this point I had to decide about taking meds, and I did not want to do that because I thought I would die faster. I felt like if I was going to do this I would take the best one there is but I was scared because of the side effects. My friends told me it will cause you to have nightmares and your liver would be affected and I was like, okay, Bactrim is one thing but now HIV meds? No way.

So after a few days of talking with my two co-workers, who have more experience in this, I decided to take the meds. I had to take Atripla and I want to say I have not had any side effects to this day. My T-cell count went from 53 to 268 in a month and a half, which was a good thing.

I can honestly say that this is a difficult thing to deal with but with the right support and the right knowledge you can survive. I have known about this since June and I can say I am now in acceptance of it. I am okay with saying I am HIV positive. I know that not everybody needs to know what is going on and not everybody must know. But I am glad I have done the test and I want people to understand that when you think that people are not there for you, someone is there for you. So if you feel the need to get a test, go ahead. This is my story and I hope that it helps anyone or everyone that reads this.

Should I Join a Clinical Trial?

by Dolores Holman

ACRIA was founded in 1991 to address the need for more community involvement in AIDS research. Since then, we've conducted many clinical trials of both pharmaceutical drugs and alternative treatments for HIV and its related conditions. And though research for new treatments is important, understanding the daily issues faced by people with HIV is also essential, so ACRIA has begun to do behavioral research that doesn't involve drugs.

Even though there are now 20 drugs approved to fight HIV, there is still a need for research and for community participation in that research. But joining a clinical trial can be scary because of the way research was done in the past, and because of the myths that are out there. Many people don't understand what clinical trials entail and have heard negative things about them. In my work, I speak with many people who know little about the realities of research. Here are some of the concerns I've encountered.

"I don't want to be a guinea pig."

This is the most common thing I hear when talking to people about our trials. But in clinical research we don't have guinea pigs – we have patients. People are not asked to join a trial without good reason. Clinical trials are usually done to get approval for a treatment for a specific condition. The participants in a trial are people with that condition who are looking for a treatment for it. Each person in the trial has their own reason for joining: perhaps there is presently no treatment available, or the current treatment doesn't work for them, or they are looking for a better treatment, or they want to help others in the future. There are many reasons why people choose to take part in a trial. What's important is that you make that choice that's right for you.

Let's think about research. When you have a headache, what do you take? Most people take something like Tylenol or Advil and don't even think twice about it. You simply go to the nearest drug store and buy the drug you want. But to buy that drug, it first had to be approved by the FDA (Food and Drug Administration). The FDA is a government agency that reviews data on all medications that are sold in the U.S. Without FDA approval, a drug cannot be put on the market. So, in order for Tylenol to receive FDA approval there had to be evidence showing that the drug actually did what the company claimed it did, and that it was safe to use. That evidence came from clinical trials of people (not guinea pigs) who had headaches. This is true for all over-the-counter medications and prescription medications. They all had to be tested in clinical trials in order for us to use them. Every medicine you have ever taken is available because people volunteered to be in clinical trials. If no one volunteered, we'd never know which drugs work and which ones don't.

"There are too many risks."

This is another common statement I hear when recruiting for our trials. But not all drugs in clinical trials are experimental. Some trials are done on drugs that have been already approved and are on the market. The reason for these trials could be to use the drug for another condition, or to test a new dose of the medication. Some trials compare approved drugs to see which is better.

(continued on page 16)

A Guide to Health Coverage in New York

New York State offers a number of ways for people with HIV to get coverage for their medical expenses. You don't need private health insurance to get expert medical care and access to medications. If you don't know where to begin, find someone who does: talk to a local AIDS service organization, ask your case manager, or call the numbers below.

The following is a quick reference guide to available health care coverage options in New York State. It is not a comprehensive guide to all the eligibility requirements for all programs. For example, some programs calculate your income after subtracting your payments for health-related services and basic living expenses. If you think you might be eligible for one of these programs, contact the program directly for additional eligibility and coverage information.

Medicaid 800-541-2831

Comprehensive health care coverage for people with limited assets and income who are U.S. citizens or qualified aliens. Can be working but must have a medical need. For a single person, income less than $8,304 per year and assets under $4,150.

$

SNPs 800-541-2831

Medicaid HIV Special Needs Plans

Special managed care health coverage for people with HIV/AIDS, providing enhanced coordination of quality health care through HIV specialty providers. Eligibility is the same as Medicaid. SNP's are available in the five boroughs of New York City. Some services like pharmacy benefits are covered with a regular Medicaid card when you are enrolled in a SNP.

$

Medicare 800-772-1213

Health care coverage for people over 65 or people who have been receiving Social Security disability payments for 24 months, need dialysis or have had a kidney transplant. U.S. citizens and documented immigrants only. Can work, no income or asset restrictions. (Limited home care benefit available for acute post-hospital health-related care)

$ - $$

Family Health Plus 877-934-7587

Managed care health coverage for U.S. Citizens or documented aliens ages 19-64, There are no medical requirements. Individuals can be working, with income up to $9,800 for a single person, $13,200 for a married couple, $19,800 for a single parent and families of 3 or more up to $45,300, assets (depending on family size) less than $22,950.

$ - $$

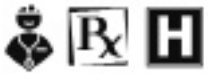
Child Health Plus 800-698-4543

Comprehensive managed care health coverage for children under 19. Must be a U.S. Citizen or qualified alien. There are no medical criteria. Household income dictates the family share of the premium cost. There are no asset limits.

$ - $$

Healthy New York 866-432-5849

Streamlined managed care health coverage for people 18-65 who do not have Medicare. Must be a U.S. citizen or qualified alien and working at least part time or episodically. Income for a single person is up to $25,125 (add $8,250 for each additional family member), no asset limit. (Limited prescription benefit available: $3,000 per person per year)



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ADAP / ADAP Plus 800-542-2437
HIV Uninsured Care Programs

Limited drug, primary care and home care coverage for New York State residents with HIV who are not eligible for Medicaid or have limited insurance coverage. Income eligibility: less than $44,000 for a single person, $59,200 for a family of two and $74,400 for a family of three or more. Assets must be less than $25,000. (Limited home care benefit - $30,000 per person per lifetime)

FREE

AHIP 518-474-9193
AIDS Health Insurance Program

Medicaid administered insurance premium payment assistance for people with AIDS or symptomatic HIV Illness. Must be U.S. citizen and can work at most part time. Income up to $18,130 for a single person. There are no asset restrictions.

FREE

APIC 800-542-2437
ADAP Insurance Continuation Program

Insurance continuation program for people with HIV who need help paying for their insurance premiums. Eligibility criteria are the same as the ADAP / ADAP Plus HIV Uninsured Care Programs.

FREE

EPIC 800-332-3742
Elderly Pharmaceutical Insurance Coverage

Prescription drug coverage for people over 65. Undocumented individuals are eligible. No medical eligibility criteria, income under $35,000 if single and $50,000 if married, there are no asset restrictions. Cost of coverage depends on income.

$ - $$$

Prenatal Care Assistance Program 800-522-5006

Comprehensive Health Care for pregnant women during their pregnancy and for two months after giving birth. Undocumented women are eligible; women can be working, net income up to $26,400 per year, no asset limit.

$

Private Insurance
State Insurance Department 800-342-3736

Comprehensive private insurance coverage can be purchased by anyone with HIV (or any other medical condition) living in New York, regardless of their disease status (how sick they are) at the same price as anyone else. For people who have not had other insurance coverage in the 12 months before they buy the policy, the company can impose a "pre-existing condition" clause for up to twelve months – this means that if you have HIV and buy a policy the insurance company does not have to cover any of your HIV care for up to 12 months. After that, the company must pay for all of your health care needs. If you are eligible and decide to buy a policy, APIC may be able to help pay the premiums.

$$$$

Symbol Key

Primary Care Services

Prescription Drug Coverage

Inpatient Care

Home Health Care

Medical Transportation

$$$$ Over $200 per month
$$$ $100 – 200 per month
$$ Less than $100 per month
$ Less than $50/month, co-payments of $1-$3

ADAP: State-by-State

The AIDS Drug Assistance Program (ADAP) is a national program that was started by the U.S. government in 1987 to provide free or low-cost drugs to people with HIV who have limited financial resources. Generally, these are people who have an income that is too high for Medicaid, but who don't have private health insurance because their employer doesn't offer it or because they can't afford it.

ADAPs vary from state to state in terms of what drugs are available, what the income requirements are, and what measures each state has taken to support the program. Most states add money to the funding they receive from the federal government, but some do not. As a result, most states offer drugs to anyone who qualifies, while some have waiting lists. ADAPs act as the payer of last resort, a "safety net" that catches people with HIV who fall through the cracks in the U.S. health care system. With more than 134,000 enrollees, ADAP reaches about a quarter of all people with HIV who are currently in care. Almost 2/3 of ADAP clients are people of color, and half have incomes at or below the Federal Poverty Level ($9,800 a year for an individual).

The steps taken by some states to control the costs of ADAPs include waiting lists, limiting the number of drugs available (formularies) and lowering the income eligibility criteria. As of November 15, 2006, 340 people were on waiting lists. 12 states had some kind of waiting list at some point during 2006, and several others had limited access in other ways.

For more detailed info, visit NASTAD.org or ATDN.org/access.

	Contact Number	Maximum Individual Income	Number of drugs as of Oct. 2005	Clients in June 2005	Cost-cutting steps in 2006
Alabama	800-228-0469	$24,500	38	915	Waiting list, Fuzeon waiting list
Alaska	907-269-8058	$29,400	72	37	Waiting list
Arizona	602-364-3610	$29,400	91	918	
Arkansas	800-342-2437	$29,400	53	272	Waiting list
California	916-449-5900	$50,000	153	18,275	
Colorado	303-372-1713	$29,400	48	1,045	
Connecticut	860-424-5206	$39,200	191	1,205	
Delaware	302-739-3032	$49,000	238	249	
District of Columbia	202-332-2437	$39,200	78	726	
Florida	850-245-4335	$34,300	71	8,682	
Georgia	404-657-3127	$29,400	56	162	
Guam	671-735-7137	$19,600 (co-payment if over)	19	5	
Hawaii	808-732-0315	$39,200	56	162	
Idaho	208-334-5943	$19,600	35	161	Waiting list
Illinois	217-524-5983	$39,200	86	3,459	
Indiana	317-233-7450	$29,400	97	62	Waiting list
Iowa	515-242-5316	$19,600	35	161	
Kansas	785-296-8701	$29,400	54	315	
Kentucky	505-564-6539	$29,400	48	401	Waiting list
Louisiana	504-568-5489	$19,600	26	1,704	Fuzeon waiting list

	Contact Number	Maximum Individual Income	Number of drugs as of Oct. 2005	Clients in June 2005	Cost-cutting steps in 2006
Maine	207-287-2437	$29,400	39	43	
Maryland	410-767-2549	$49,000	114	2,301	
Massachusetts	617-624-5762	$50,000	open formulary	2,368	
Michigan	888-826-6565	$43,065	194	1,337	
Minnesota	651-582-1980	$29,400	130	726	
Mississippi	601-576-7723	$39,200	52	772	Medical restrictions
Missouri	573-751-6439	$29,400	238	1,200	Reduced formulary, income restrictions
Montana	406-444-4744	$32,340	144	49	Waiting list
Nebraska	402-471-0362	$19,600	104	265	Waiting list
Nevada	800-842-2437	$39,200	69	704	
New Hampshire	603-271-4939	$29,400	open formulary	137	Reduced formulary, medical restrictions
New Jersey	609-984-6328	$49,000	open formulary	3,964	
New Mexico	505-827-2363	$29,400	69	Not reported	
New York	800-542-2437	$44,000	480	12,686	
North Carolina	919-715-3111	$12,250	59	1,887	
North Dakota	701-328-4555	$39,200	94	33	
Ohio	614-752-2427	$49,000	86	1,371	
Oklahoma	405-271-9444	$19,600	53	611	Annual limit per person
Oregon	503-731-4029	$19,600	63	1,028	
Pennsylvania	717-772-6341	$30,000	76	3,186	
Puerto Rico	787-274-5582	$19,600	124	3,750	
Rhode Island	401-222-7548	$39,200	67	Not reported	
South Carolina	803-896-3834	$29,400 or sliding scale	54	1,793	Waiting list, reduced formulary
South Dakota	605-773-3737	$29,400	44	59	Annual limit per person
Tennessee	615-741-8903	$29,400	91	346	Reduced formulary
Texas	512-490-2510	$19,600	41	8,802	Fuzeon waiting list
Utah	801-538-6131	$39,200	37	225	Reduced formulary, cost sharing
Vermont	802-863-7253	$19,600	92	136	
Virgin Islands	340-772-0260	$19,600	38	57	
Virginia	804-864-8019	$32,340	68	1,781	
Washington	360-236-3477	$29,400	179	1,194	
West Virginia	304-242-9443	$24,500	33	183	Waiting list
Wisconsin	608-267-6875	$29,400	69	477	
Wyoming	307-777-5800	$19,600	80	47	

Source: NASTAD *National ADAP Monitoring Project Annual Report,* March 2006

Should I Join A Clinical Trial? *(continued from page 11)*

Of course, with an experimental drug, the risks are greater. With everything we do in life there are risks. Some of us take those risks, which is an individual choice. The same decision applies to clinical trials. Making the choice to join a trial though there may be risks is something you should do only after talking to your doctor. There are times when the risks outweigh the benefits. In that case, joining the trial would not be a good choice. However, there are times when the benefits outweigh the risks. The only way to know is to ask the people running the trial a lot of questions and to make the decision that's right for you.

"Why join a trial if there may be side effects?"
The answer to this question goes back to the reason why trials are done. Trials are done to not only to prove that the drug works but also to prove that it's safe. So if you participate in a trial you will be closely monitored by the research staff. This is necessary because we don't know how each participant will react to the treatment – different people can have different reactions.

An important part of this monitoring involves you reporting any changes in your health, whether major or minor. This includes changes in the condition being studied and changes not connected to the condition. Basically, anything that happens to you needs to be reported. For example, if you sprained your ankle while in the trial, you would report when it happened, whether you took anything for it, whether you had to go the hospital for it, etc. All this information is available to the FDA to help them determine if the drug is safe. If the researchers feel that your safety may be in jeopardy you could be asked to leave the trial. And if there is a risk to other people in the trial, the FDA could shut it down completely.

Of course, the changes that happen to people in trials aren't always negative. You would need to report good changes as well. For example, if you were always tired and had little energy, but since starting the medication you have more energy, we'd want to know that and so would the FDA. The other sites involved in the trial are made aware of any serious changes, and this information is shared among all research staff so they can look for similar changes in their patients.

You will eventually learn about all of the side effects of your medications. The FDA requires drug companies to release this information, but you may not be aware that you have it. Every prescription drug comes with a "package insert" – a paper folded inside with small print and a lot of information. This information is gathered from the clinical trials and lists the side effects of the medication based on the results of its trials. Since the insert lists every side effect reported in the trials – no matter how rare – it can be intimidating. Ask your doctor which side effects are most common, and what you can do about them, before you start the drug.

"Will I know what drug I'm taking?"
This is an important question to ask before you join a trial. In some trials – ***open label*** trials – everyone knows what drug they're taking. But in many trials, neither the doctor nor the patient knows who is taking what drug until the trial is over. This is called a ***blinded*** trial, and is done to prevent the researchers or participants from influencing the outcome of the trial. So, if you join a blinded trial, you will be taking drug A or drug B and won't know which one for perhaps six months or longer. Are you okay with that? If you're taking drug A and it doesn't work for you, can you switch to drug B? Knowing what will happen in the trial before you start is important when deciding whether or not to join.

Key things to remember if you decide to join a trial:

You are a Volunteer
Make sure it's your decision to join – don't let anyone pressure you. And remember, you can leave the trial at any time if you or your doctor feel that's best for you.

You have Rights
As a participant in a trial you have the right to be informed about the trial. This is where ***informed consent*** comes into play. The informed consent form is a document that gives you much information about the study. It tells you who is doing the trial, the purpose of the trial, its length, the number of visits, the risks, the benefits, other alternatives available, etc. But there may be something not mentioned that you have a question about. You have a right to have those questions answered, so ask the research staff. Keep in mind that we may not always know the answer, but we will make sure to find out. When you sign the consent form you agree to join the trial, but remember: you're a volunteer, so you can always change your mind.

You are not Alone
Some people decide to participate in a trial without consulting with their doctor. This is not a good idea, since your doctor knows you better than the research staff. S/he can offer advice on whether or not the trial may help you. At ACRIA, we always encourage people to talk the trial over with their doctor, and we keep your doctor involved while you are in the trial.

Be sure to ask a lot of questions before you make your decision:

- How long is the trial? How often do I have to visit the study site and how long will each visit take?
- What else do I have to do while in the study?
- What is known about the immediate and long-term side effects of this drug?
- Are there other treatments available for my condition?
- Will the lab tests cost me anything? Will I get the results of these tests?
- Will I get any money for participating in the trial?
- Will I get the study drug once the trial is over?
- Who do I contact if I have a problem with how I am treated while in the trial?

Participating in research can be a scary thing. But the more you know about it, the less scary it will be. Looking beyond the myths of research and learning about the reality of clinical trials will help you to make the best decision for you. Because in the end, it's your decision.

Dolores Holman is ACRIA's Clinical Trials Manager.

ACRIA Expanding Clinical Trials

When ACRIA was formed in December 1991, it was as a direct response to the snaillike progress of anti-HIV medical research. Under the leadership of prominent AIDS physicians and researchers, a group of doctors, activists, and people with HIV brought an activist approach to the study of new treatments for AIDS and HIV.

In the 15 years that followed, we have been involved in clinical trials of all the classes of drugs now used to treat HIV. We have been directly involved in the testing of ten drugs that now have FDA approval and are saving tens of thousands of lives. We are currently involved in nine clinical trials, some for drugs used to treat HIV and some for treatment of side effects, such as peripheral neuropathy and diarrhea, of HIV meds. (See page 2 for details.)

We believe we have the experience and the expertise to do more. To that end, we have hired a Clinical Trials Manager, Dolores Holman, to increase the number of trails we participate in and the number of people with HIV who participate and benefit from new drugs. In addition, we are about to hire a Research Enrollment Coordinator, who will act as a recruiter, marketing our trials directly to potential participants and to providers. Our goal is to double the size of our clinical trials efforts in the coming year.

ACRIA International

"ACRIA" stands for AIDS Community Research Initiative of America, but we are working on becoming a research initiative of *the Americas*, and beyond. Almost since we started publishing, *ACRIA Update* and our topic-specific educational booklets have crossed our borders, and we regularly send copies to agencies in Canada, Cuba, Denmark, Dominican Republic, France, Germany, Ghana, Greece, Iceland, India, Indonesia, Italy Kenya, Mexico, Nigeria, South Africa, Sweden, Switzerland, Uganda, Ukraine, United Kingdom, Zambia, and Zimbabwe.

Our growing participation in international conferences, such as the XVI International Conference on AIDS in Toronto last summer and the North American Treatment Action Form annual meeting in Oaxaca, Mexico, last year, have gained us recognition as an international service organization by the federal Office of Personnel Management and the Combined Federal Campaign, a workplace-giving program for federal employees.

We're now looking to partner with other AIDS organizations to expand our international work. Plans are already in the works to collaborate with another group to expand our work in the Caribbean and Latin America, and perhaps to set up a clinical trials site there.

Regional Training Center News

ACRIA has completed our first cycle as an AIDS Institute Regional Training Center. We would like to thank individuals from each of the agencies that offered their space and support: Kevin Huang-Cruz, Michelle Catuncan, and Melissa Nibungco at APICHA, Audria Russell at Women in Need, David Nimmons and James Learned at The Family Center, and Sharon Toney, Joseph Lunievicz, Diana Padilla, and Mary Arias-McCarthy at NDRI. Also thanks to Tony Jimenez at Cicatelli and Debra Brown and Ilvan Arroyo at Stony Brook for invaluable information. Our consultants, Karin Timour and Kim-Monique Johnson, brought their experience and wisdom to this first cycle.

In 2007 we are taking most of our trainings outside of Manhattan, thanks to the support of Jacobi Medical Center (Bridgett Binder and Miguelina "Millie" Luna), Bronx United Parents (Carrie Taft), Steinway Child and Family Services, Inc in Queens (Brendan Collins), and Women in Need, in Brooklyn.

Serving Older Adults

As we've reported earlier, ACRIA's Research on Older Adults with HIV (ROAH) report has attracted a lot of attention, and helped put the special needs of this growing population on the map. And finally, some action is being taken.

ACRIA has agreed to work with GMHC on a program for older adults at GMHC, similar to its Women's Institute. ACRIA will provide educational booklets and other printed materials to the project. Other organizations working with older adults with HIV that will participate in this partnership are Services and Advocacy for GLBT Seniors (SAGE) and Griot Circle.

New Workshop Support

Since the reprioritization of Ryan White Title I funds, ACRIA has been working diligently to find new revenue streams to support the vital services that used to operate with Ryan White money. Of particular urgency has been seeking funding for our well-attended and well-received client workshops, which have been paid for out of ACRIA's unrestricted funds since our Title I contracts ended last February. We're happy to report that we have just received word that the Elton John AIDS Foundation has awarded us $25,000 a year for the next three years to support these workshops and other HHLP services.

EJAF was founded in 1992 by Elton John, and since then has raised over $100 million to support AIDS groups in 55 countries around the world. Thank you, Sir Elton!

Policy Making

Daniel Tietz and Dr. Stephen Karpiak have been appointed to a task force of the NYC Council charged with developing policy and Council involvement in programming for HIV-positive New Yorkers over age 50.

The task force is a joint effort of the Council Committees on Aging and on Health. Tietz and Karpiak will be joined on the task force by members of the Council, representatives of the NYC Department of Health and Mental Hygiene, senior services providers, HIV experts, and activists, including people with HIV. The formation of the task force is in part another outgrowth of the new attention to this population sparked by our ROAH study. In fact, several members of the ROAH Advisory Committee are represented on the task force.

generous contributions

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