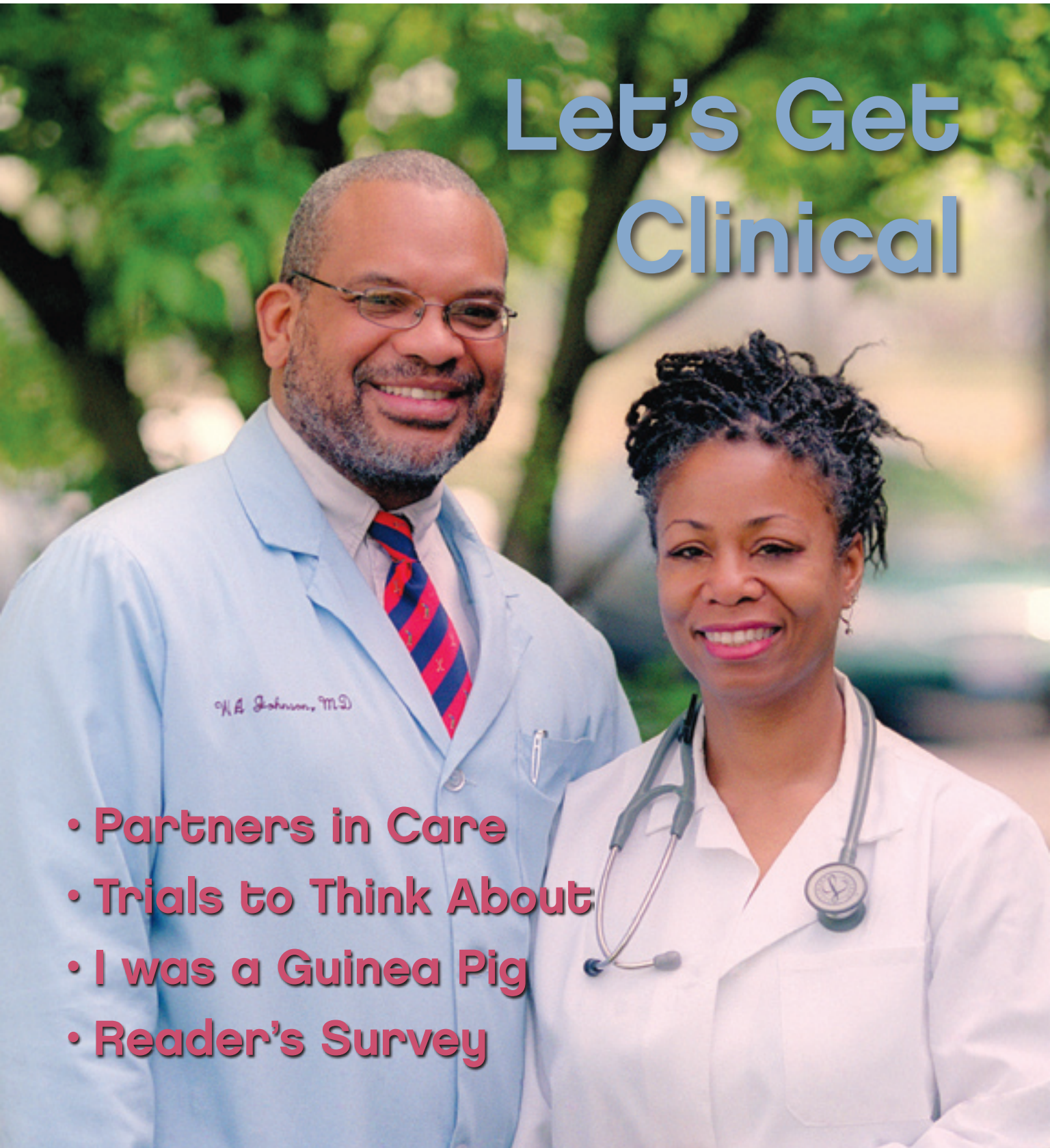
July / August 2004

Positively Aware

The Journal of Test Positive Aware Network



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Let's Get Clinical

Last year I had the chance to go behind the scenes in the making of a clinical trial.

My editor asked me to think about applying to the Community Constituency Group (CCG) of the Adult AIDS Clinical Trials Group (AACTG). We thought it would be a good experience to see how the studies I report on are actually put together.

But when I was accepted and got to the CCG, I felt that I had one overriding concern: recruiting women and people of color into clinical trials.

I strongly believe that people of color working in HIV must lead the way in advocating for study enrollment from our communities.

We should teach our communities how to access care and be on the inside track of so many benefits out there. We must speak up and help people to get over our fears.

I don't have HIV, but if I did, I would not be expecting some Dr. Frankenstein to be taking me down.

But then, I sit at the table with HIV researchers and see that they're not monsters. If anything, I believe HIV doctors, more than any other doctors, are trying to save lives with all of their heart and soul.

As a Puerto Rican woman, I'm not without suspicion. I know that U.S. doctors conducted unethical research on the island as well as a mass sterilization campaign without letting women know they were being sterilized. I would always watch my step—no doubt!

But for the most part, that was then and this is now. We have a lot of safeguards that were put in place after the abuses of the past.

It hurts me to see so many doctors, nurses, pharmacists and other medical providers with hearts of gold—people of all races and ethnic groups—struggling to serve underrepresented communities, and sometimes to enroll them in clinical trials. They work in such good faith, and we still struggle to have representation in all our trials across the country. We're letting them down and making their job difficult—the job of finding a cure.

Having met and talked with nurse practitioner Bethsheba Johnson and her husband Dr. William Johnson, it's inconceivable to me that anyone would think they would use some kind of poisonous concoction on their fellow African Americans. They're trying desperately to save lives in their communities, as are African American providers across the country (and providers in both poor and wealthier communities whatever the racial and ethnic makeup).

Sometimes the Johnsons are waging a battle against the powers that be. They're trying to secure resources that are not available in the poorest neighborhoods. They need the support of the community.

Dr. Kimberly Smith of Rush University Medical Center, near Chicago's downtown, is struggling to establish the Johnsons' clinic as an outpost of the ACTG, in keeping with the ACTG movement to spread their efforts out of huge white institutions and into smaller clinics out in the community. Will people enroll?

When I mentioned to Bethsheba Johnson that I had never had the privilege of meeting her mentor and how impressed I was with her clinic, tears welled up in her eyes. "Sherry Luck was a wonderful doctor," she told me in her soft, lyrical voice, "and we hope we can continue her legacy to serve this community."

I hope we do what we can to help the Johnsons run their clinic with the best the world has to offer.

In this special issue of PA, we do not have all the answers for how to bring our communities up from under. As CCG leader Wil Strain notes in his essay here—among other things—lack of study involvement goes hand in hand with lack of access to care overall. As new columnist Keith Green says—among other things—we're dealing with stigma that is killing us. These are complicated issues. Many thanks to Edd Lee, Eva Powell, Matt Sharp and Wil Strain for their "clinical" contributions and, of course, to Charles, for loaning me his column.

I hope this edition serves one simple purpose—to let you know that we believe in clinical trials, and that we encourage you to believe in them too. I know for sure that as you reach out to support groups, educational forums and clinical trials, you will learn about all kinds of things you can benefit from.

Get access.

Enid Vázquez

Clinical Trials Editor

Send comments and reactions to enid@tpan.com

Photo © Russell McGonagle

Readers Forum

Positively Aware will treat all communications (letters, faxes, e-mail, etc.) as letters to the editor unless otherwise instructed. We reserve the right to edit for length, style or clarity. Please advise if we can use your name and city.

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Drug guide correction

A statement on peripheral neuropathy was put on the Emtriva (FTC) drug page. However, peripheral neuropathy has not been reported with Emtriva. Rather, it is a potential side effect of the class of drugs of which Emtriva is one. *Positively Aware* apologizes for the misconception the drug class warning may have created. Emtriva and its sister drug, Epivir (3TC), are two HIV drugs with the least amount of side effects associated with them.

Corrections on transplants

Positively Aware unintentionally dropped an important point made by Dr. Michelle Roland, lead researcher on a study of transplants in people with HIV (May/June 2004), cautioning that transplants are difficult and not expected to be a perfect solution. She said, "You're trading one set of problems for another."

Also, we dropped an Internet address for the latest medical information on transplants in people with HIV: www.thebody.com/confs/retro2004/helfand1.html.

Women and lipodystrophy

Well done. That was a great article and I really enjoyed reading it ("Lipodystrophy and Women: A Beach Ball on Sticks," May/June 2004). As I have recently published a book on HIV/AIDS and how it affects women, I found this article interesting and well written. Just thought I'd let you know.

Marjorie Manduli Bolz,
via the Internet.

Editor's note: This was the first article written for Positively Aware by TPAN's new Treatment Education Coordinator, Barbara Marcotte. Thank you for the compliments.

Affordable gyms

There are still a lot of people who are HIV-positive who are on disability or a limited income. It would be great if there was some way for some of these people to be able to afford to go to a gym where they can get help with exercises that can help strengthen their hearts ("Managing Metabolic Syndrome," May/June 2004). I for one can't afford the gym and the YMCA is of no help either, they want a fee that I simply cannot afford. Even at a reduced rate, I don't qualify for free membership to the YMCA, though I make only $550 a month from disability. And I'm not that motivated to do the exercises at home, since I'm not 100% sure of what I'm doing.

It would definitely be nice if these expensive gyms could lower their payments so that everyone can afford to go and we'd have people going to help improve their health. I've been HIV-positive for 16 years that I know of and currently am not on any medications. My T-cell count is 265 and my viral load is 2,000. It's been that way for many years.

Name withheld,
via the Internet.

Editor's note: You make a valid point. Until things change, if you can't afford a gym membership or YMCA fees, then you really need to motivate yourself and work out at home or go for long walks. Also, check out www.medibolics.com.

Great issue

The other day I received in the mail the most recent copy of *Positively Aware* (May/June 2004). I want to compliment you and your staff at TPAN on an excellent issue. I have to say this is one of the best issues I have read in a while.

Your Editor's Note is right on target. Our healthcare system is very much broken. The costs for healthcare are out of control, to say the least. Plus, the delivery system needs to be overhauled. It appears our healthcare system has forgotten the old saying, "An ounce of prevention is worth a pound of cure." Not only private health care but also public health care in the areas of Medicare, Medicaid and ADAP are all in need of being updated.

In addition, the articles about Managing Metabolic Syndrome and Organ Transplants are very timely. I also feel the article about Surviving Anal Cancer was not only timely but a long overdue topic that needed to be discussed openly.

Again, great work on your behalf as well as all of those on your staff!

Jack R. Kelly,
Chicago

Edd Lee is Director of Education & Outreach for the AIDS Vaccine Advocacy Coalition (AVAC), in New York City. He grew up in the Twin Cities area in Minnesota, where he was involved with groups like the American Cancer Society, The Queer Street Patrol, the Dim Sum Club and other various health and human rights organizations. Most recently, Edd was Associate Director of Prevention Services for the Asian & Pacific Islander Wellness Center in San Francisco. Visit www.avac.org.

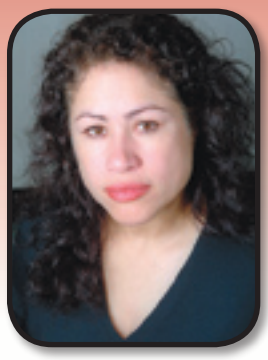
In *"Children's Research—A Mom's Perspective,"* **Eva Janzen** advocates for the freedom and power of parents to ask questions and talk about their own and their children's care decisions so that they all have as much control as possible in living with HIV. Janzen was the co-chair of the Pediatric Community Advisory Board (CAB) at Children's Memorial Hospital in Chicago from 1996, when the CAB was formed, until August 2003, and remains active. In July 2000 she began a four-year term as a member of the Pediatric Community Constituency Group (PCCG), a national committee of the Pediatric AIDS Clinical Trials Group (PACTG). She was part of the PACTG South Africa Site Preparation Team in January 2003. In connection with her work on the PCCG and CAB, Eva has participated in a Community Training on Ethics in Research. Eva is also currently a member of the Board of Trustees of the AIDS Foundation of Chicago. She has a B.A. with an emphasis in criminal justice and served 10 years as a paralegal before her HIV diagnosis. She enjoys drawing and painting and most recently, she had the pleasure of seeing her son graduate from high school.

Matt Sharp, Director of Treatment Education for TPAN, writes about a few of his many clinical trial experiences in "Going to Extremes to Stay Alive." He has a 10-year history of writing about AIDS for publications such as the Bay Area Reporter, American Foundation for AIDS Research Global Link, the newsletter of the AIDS Community Research Initiative of America, and Positively Aware, including the activist voice of the Annual HIV Drug Guide. He became involved in AIDS activism volunteering with ACT UP Golden Gate and served on five local community advisory boards for AIDS clinical research. He worked at Healing Alternatives Foundation (San Francisco's AIDS buyers club), first as a volunteer and later becoming the director. He then helped to coordinate one of the first peer-based HIV treatment training programs funded through the Ryan White Care Act, at the Asian and Pacific Islander Wellness Center in that city. At TPAN, he oversees all education, support, treatment and prevention programs, including the Treatment Education Advocacy Management (TEAM) programs and client services such as support groups, the Positive Buddy program, medical clinic and needle exchange. In 2001 he moved to Chicago to be with his partner.

William Strain discusses many of the reasons African Americans and Latinos do not join clinical trials or access care in "Who Are We Hurting?" William works as Health Policy Analyst for the Los Angeles County Office of AIDS Programs and Policy. He began working in HIV as a treatment advocate at AIDS Project Los Angeles. Over the last 10 years, he has been involved with the AIDS Clinical Trials Group (ACTG), the Black AIDS Institute, the National Minority AIDS Council and the Forum for Collaborative HIV Research to promote HIV prevention education, testing, care and treatment issues and research advocacy. He is currently one of two representatives of the ACTG's Community Constituency Group (CCG) on the network's Executive Committee.

Charles Clifton has been associated with TPAN since 1996 when he first moved to Chicago to pursue graduate studies at the University of Chicago. He has served as Editor of PA for the past four years and as Executive Director of Test Positive Aware Network since 2002. In Chicago, he serves as co-chair of the Public Policy Committee with the Service Providers Council of the AIDS Foundation of Chicago, a member of the Chicago HIV Prevention and Planning Group (HPPG), and a founding member of MOCHA (Men of Color HIV/AIDS) Collaboration. On a national level, Clifton is serving a one-year term as Treasurer on the Steering Committee of the AIDS Treatment Activists Coalition, on the community program committee for the Conference on Retroviruses and Opportunistic Infections and conference co-chair of the North American AIDS Treatment Action Forum (NATAF). Charles has an undergraduate degree from San Francisco State University (1993) and Masters Degrees from Dartmouth College (1995) and the University of Chicago (2002).

News Briefs



by Enid Vázquez

Viracept at 625 mg

Pfizer announced in May that the 625 mg formulation of Viracept (nelfinavir) protease inhibitor is finally available. Now people can take two tablets instead of five 250 mg tablets (both dosages taken twice a day). Call 1-888-VIRACEPT for more information.

Two drugs, one pill

The U.S. Food and Drug Administration (FDA) is set to look at approving two new HIV pill combinations this summer or early fall.

Viread (tenofovir disoproxil fumerate) and Emtriva, both from Gilead Sciences, are up for approval as one pill, once a day.

Also up for approval is a once-a-day combination of the nucleosides Ziagen (abacavir sulfate) and Epivir from GlaxoSmithKline (GSK).

Ziagen recently received full ("traditional") FDA approval. All HIV drugs have been granted accelerated approval to bring them to market faster. Continued study of a drug can later lead to full approval.

Drug interaction

The combination of the protease inhibitor (PI) Invirase with a small dose of the PI Norvir is not affected by the drug Viread, according to a study conducted by the manufacturer of Invirase (Roche). The company examined a twice-daily combination of 1,000 mg Invirase with 100 mg Norvir. Viread has been shown to interact with other HIV drugs. The Roche study with 18 people was presented in a poster at the Fifth International Workshop on Clinical Pharmacology of HIV Therapy, held in Rome in April.

Women with advanced HIV benefit from treatment

Good news from the Women's Interagency HIV Study (WIHS). Doctors found that women with advanced disease still benefited from HIV therapy. They reported that women were able to raise their T-cells to more than 200 and lower their viral load below 10,000. WIHS doctors said this six-year study should encourage women with advanced disease who've never taken HIV therapy to step up and benefit from medications. They noted, however, that not all of the women were able to go back to more than 200 T-cells. WIHS is a cohort, wherein medical results in a group of people with similar attributes are followed. This analysis looked at 1,132 women. It was recently published in the *Annals of Internal Medicine*.

George Martinez receives liver transplant

May/June 2004 *Positively Aware* cover boy George Martinez received his liver transplant on May 15. In the two days before his transplant, two livers became available. One would not work for him and the other was "a perfect match. The doctors found that my liver had turned cancerous, so they got it in the nick of time. It was meant to be," George said. He did not expect his transplant to come this soon. Two weeks post-transplant he felt sore and weak, but much better. "It's going to be a long battle towards healing." Congratulations and best wishes can be sent to his e-mail address, Aztec5545@aol.com.

Gonorrhea med changes

The U.S. Centers for Disease Control and Prevention (CDC) no longer recommends the use of fluoroquinolones as first-line therapy for gonorrhea in men who have sex with men (MSM) in the U.S., due to a high rate of drug resistance to that class of drugs seen in this group (up to eight times higher than seen in heterosexual men). This is unfortunate because these are the only oral drugs currently available for gonorrhea and are inexpensive.

The new CDC-recommended treatment options for MSM with gonorrhea include the injectable antibiotics ceftriaxone at a dose 125 mg intramuscularly (for anorectal, urogenital and pharyngeal/throat cases) or alternatively spectinomycin, 2 g intramuscularly (not for pharyngeal cases). The CDC urged public health departments to spread the word among clinicians in their communities. Healthcare providers should report treatment failures or resistant gonococcal isolates to the CDC at (404) 639-2059.

Brief IL-2

National Institutes of Health (NIH) scientists reported that brief, widely-spaced courses of the experimental immune-boosting drug interleukin-2 (IL-2) allowed people with HIV to maintain near normal levels of T- cells for long periods. The group injected themselves subcutaneously with IL-2 twice daily in 5-day-long cycles. Cycles were initiated as often as necessary to maintain T-cells at predetermined, individually tailored amounts. Of the original 77 volunteers, 61 achieved and maintained normal or near normal levels of T-cells for periods ranging from two to 91 months between IL-2 cycles. During the most recent period of study, the average time between cycles was more than three years. (Of the 16 people no longer participating, six experienced CD4+ T cell count declines that did not respond to IL-2 therapy.) The findings were published in the May 1 issue of *Blood*.

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Partners in Care

Dr. William Johnson and Bethsheba Johnson continue the vision of Dr. Sherry Luck

by Charles E. Clifton

Photographs by Russell McGonagle

People with HIV/AIDS have unique problems that go beyond the medical aspects of the disease. The social stigma that is associated with HIV/AIDS frequently results in loss of emotional and physical support from family and friends. Even when this support exists, the enormous demands of the disease can create burdens beyond the patient's and family's ability to handle.

Sherry L. Luck, M.D. founded the Roseland Community Hospital HIV/AIDS clinic in 1994. As a board certified Internal Medicine Specialist, Dr. Luck had a vision of providing care for HIV-positive patients and their families in an underserved area of Chicago.

Dr. Luck realized early on that when a person is living with HIV or AIDS that the entire community is impacted. Her commitment to HIV/AIDS was a response to the dire need in the African American community. Prior to the establishment of the clinic, a comprehensive program to address the needs of people infected with and impacted by HIV did not exist on the far South Side of Chicago.

At the age of 44, Dr. Luck died in her sleep in May 1999. Through diligence and preservation, Dr. Luck's vision was continued. The Luck Care Center was dedicated in honor of Dr. Luck's memory and Dr. William Johnson and his wife Bethsheba Johnson continue her vision.

It was Dr. Luck who persuaded Bethsheba, a nurse practitioner, to join her in 1997. Although the work is all consuming and the hours long, Bethsheba energetically proclaims, "I can't think of doing anything else."

Dr. William A. Johnson, a board certified Internal Medicine Specialist, is now the Medical Director of the Luck Care Center, an appointment he has held for five years. He completed his residency at Rush Hospital in the HIV/AIDS unit during the early 1990s.

> Providing a caring, professional staff makes it more likely that the client will keep appointments, improve adherence and reduce and eliminate high-risk behaviors.

Until March of 2003, the clinic was under the umbrella of Roseland Community Hospital. Today, Luck Care Center is under the not-for-profit umbrella of the Southside Health Association, of which Dr. Johnson serves as President.

The passion that Dr. Johnson and Bethsheba Johnson have for their patients and the community is immediately apparent. The clinic provides a place for individuals to come for HIV specialty care in their neighborhood. With so many institutionalized barriers to care, "this is a change for the better," states Bethsheba.

Prior to the opening of the clinic, patients had to travel to other parts of the city and faced several unnecessary barriers to care, including the "South Side vs. West Side" division, inadequate transportation, and childcare problems. Or in other instances, patients received care via the public health clinics, which in Chicago fortunately are staffed by competent HIV physicians, however patients had to contend with the additional stigma of going to a public health clinic for care.

In the mid-1990s, Bethsheba remembers that so many of her patients would come into the hospital at "death's door" with PCP or other AIDS-related opportunistic infections (OI). She is grateful that several of these same individuals are "working and productive" again. But still she is "surprised that so many people today still don't know about treatment and come into care presenting an OI."

Today the client base at Luck Care Center is approaching 200. While the majority of the patients are African American men who have sex with men, Bethsheba states they are seeing more African American women—younger, married and with children—who are being infected with HIV via unprotected heterosexual sex.

A history of mental health, substance abuse and illiteracy often compound treating the clients Dr. Johnson serves at Luck Care Center. Because of these multiple issues, Dr. Johnson believes clients have a more difficult time accessing care, understanding HIV disease, and adhering to antivirals. "Developing a treatment plan that encompasses the current and past life experience of the patient is even more important" in this regard states Dr. Johnson.

Providing a caring, professional staff dedicated to excellence in the community and engaging the client as a partner in the management of HIV disease makes it more likely that the client will keep appointments, improve adherence and reduce and eliminate high-risk behaviors.

Clinical Trials

Prior to joining Dr. Luck, Bethsheba worked for seven years at the Northwestern Memorial Hospital as a pulmonary clinical nurse, working primarily with clinical trials. "There has always been a disparity in gender and people of color in clinical trials," she states. Dr. Johnson adds, "in the clinic I've observed the differences in how HIV disease progresses in people of color and women, as well as how these groups process antivirals and cope with their side effects." Both agree that there is a need to recruit more people of color and women into clinical trials in order to gain a better perspective on disease management.

In this regard, both Dr. Johnson and Bethsheba Johnson have been working closely with Dr. Kimberly Smith, of Rush University Medical Centers and a lead researcher of the ACTG (AIDS Clinical Trials Group), to expand access and participation in clinical trials. The ultimate goal is to have Luck Care Center become a satellite office for the ACTG in Chicago. Dr. Johnson states that, "the education of the clients is key to success in recruitment." Bethsheba and Dr. Smith have spent a great deal of time speaking with clients and service providers across the South Side of the city to increase awareness and encourage participation.

Several of their patients have clinical trial experience and were more than willing to share their knowledge.

Howard Spiller

Howard Spiller is a 39 year-old African American man who was diagnosed with HIV in 1986.

In 1996, he suffered a devastating stroke that has partially affected his mobility, but not his willpower. A few years ago following extensive rehabilitation and initiating HAART, Spiller entered a Procrit trial studying the impact of anemia on HIV-positive individuals.

The best part of the study, as Spiller remembers, was the level of care. "Every month I was having my labs done," he recounts. "Having this information explained on a regular basis really informed me about my HIV and taught me to advocate for myself."

The experience inspired Spiller to become involved with the Ryan White Care Council and the HIV Prevention Planning Group in Chicago. However before entering any clinical trial, Spiller

One-on-one with Gregory Braxton

by Charles Clifton

Gregory Braxton, 48, is an AIDS treatment and clinical trial advocate. He is currently a member of the HIV Prevention Planning Group, a community-planning group working in collaboration with the HIV/AIDS/STD Division of the Chicago Department of Public Health to stem the rising tide of HIV and STD infections in the Chicago area.

He is living with AIDS and would be considered a salvage patient when it comes to his experience with antivirals. He was diagnosed with AIDS in 1994, with a T-cell count of 60.

Braxton has participated in multiple clinical trials, including Viracept, Kaletra and most recently the T-20 (Fuzeon) Phase III trial and is enrolled in the Phase II TMC 125 trial. "I got paid for a trial many years ago, but blew all the money on drugs and didn't take the meds as I should. I lied to the doctor."

Braxton, like many individuals with long-term addiction problems, "blew" his first, second, and third regimens because of a history of drug use. By the time he entered the T-20 study he "had no other choice." Now he says, "I've learned the hard way how important adherence can be." He remained on T-20 for about 6 to 8 months before stopping because it didn't lower his viral load.

It was at a community update presented at TPAN on clinical data presented at the 2002 International AIDS Conference (Barcelona) that Braxton first heard about T-20. He then went and talked with his primary care physician about T-20 and expressed his interest in joining the trial. "With my substance abuse history, using needles to inject T-20 was not a problem for me," Braxton jokes.

Earlier this year, he entered the Tibotec trial for the experimental protease inhibitor TMC 125. When he entered the trial his viral load was at 250,000 on a failing regimen. However within 2 months of adding TMC 125 to his regimen and (restarting) T-20 his viral load declined to 13,000.

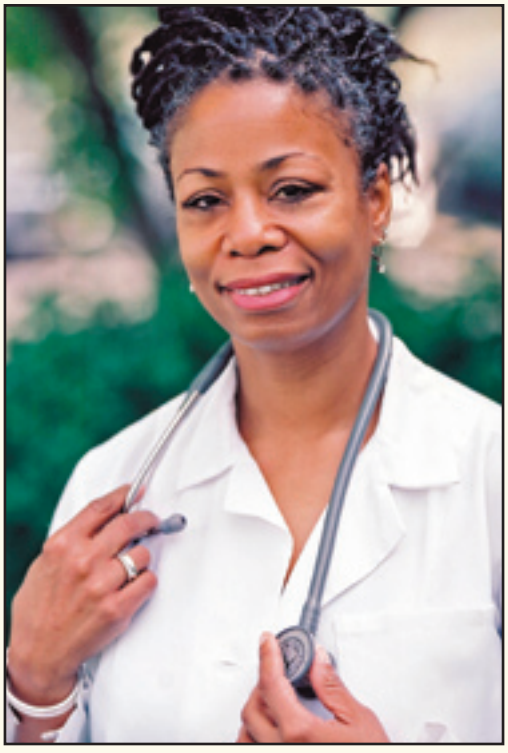
Clinical trials vary greatly. Braxton cautions individuals considering joining a trial to review the study protocol carefully and if they can't understand the "jargon" to make certain everything is explained carefully by the practitioner. "Listen and ask questions," he says. His current trial is covering the cost of Braxton's monthly doctor appointments and lab work to monitor his progress on TMC 125. However, it only covers the study drug (TMC 125), not all of the drugs in his current regimen. Braxton says he doesn't feel like a guinea pig, because as he states, "I believe I'm receiving state-of-the-art care." However, he cautions individuals to monitor themselves closely for side effects. "Being altruistic is great, but you have to look out for yourself."

suggests that "individuals interview physicians involved with trials, ask clarifying questions, find out the benefits and risks for your health and whether the results of the trial benefit others, especially African Americans living with HIV."

One Women's Story

Another patient of Dr. Johnson is a young African American mother of three small children, who asked that her name be withheld from the story. Myrna [not her actual name] was diagnosed with HIV nearly four years ago and lost her husband to AIDS in 2001. She has spent the last few years caring for her children, who are HIV negative, and learning as much as she can about this disease that causes AIDS. "I'm infected, but that doesn't mean I'm going to die."

She enrolled in a clinical trial combining Viracept and Combivir several years ago because as she states, "I wanted the best chance to survive and see my children grow up. So many people I encounter are not informed on how to live with this virus. We need to change how we live in order to survive."



Myrna admits that she was a nervous wreck when she first entered care and the clinical trial. However, her hesitation has all subsided, replaced by a strong desire to share her experience and help others living with HIV. She volunteers in the clinic as a peer advocate. "God has restored my health," she proclaims. "I feel as if I have a calling to help other women, like myself, who have struggled." She credits much of her treatment success to the care she has received from her providers at Luck Care Center.

Challenges Ahead

While the expansion of clinical trials is paramount to the long term

One-on-one with Paula Turner

by Charles Clifton

Paula Turner is an outreach case manager at the AIDS Research Alliance Chicago (ARAC). She herself has participated in many clinical trials.

Turner recounts that she once got more than $2,500 for one study at Evanston Hospital, in 1995 or '96. "I spent two weeks in the hospital with an IV drip, with 69 other people. We played video games and ordered pizzas. We had a blood draw every four to six hours around the clock. They would wake us up. We went through a rigorous screening, and we got paid for that too. The drug didn't even make it to first base.

"I was given the best of care. I did see other people get sick, but I never did. In that one study, I went in with about 275 T-cells and came out with 140 or 170. That scared the dickens out of me. That's why I got on medications. They immediately went up, to more than 300. But I got an AIDS diagnosis when they dropped and it's still there in my file."

In her current job she helps to keep people engaged in the clinical trial process. "People lose interest in making appointments. A lot of people don't like going to the doctor. But if we don't get consistent data, the study might be a wash."

Over the years, Turner has found that people enter trials for multiple reasons, but definitely not in the numbers she would like to see. Initially Turner herself would use a study to get labs results, "because I wanted to know my numbers," she states. "With all the resources there are in Chicago, there's not that many people accessing them, and I've never understood that. People in Africa wish they could get that."

The majority of the people Turner encounters are encouraged by what they're offered, "be it a coupon, a hundred dollars or 20 dollars. People are definitely not doing it for the good of humanity. I give them a food voucher or a bus or movie pass, something to let them know I'm sincere. I'm not paying them. I'm encouraging them. This is for you to do for you. I don't want them to be reliant on seeing me coming and seeing dollar signs. I'm pretty good at getting my point across."

However, it is very difficult engaging and keeping the clients she works with involved with the clinical trial process. "Mostly it's the hardships people are experiencing that are holding them back. Housing is a major problem. Some lack refrigeration for meds or are hiding their medications from other people." Others, she states, need some form of mental health care. "This was on the burner before HIV came on board. And now it's compounded. The reasons are valid and the services are shallow."

Outreach is also important. "The more people see something, the more their curiosity is raised. Most of the high-end doctors don't get out to the community. Maybe the clinical trial people—community members and doctors—could do more to keep studies in people's minds. They need to let people know these trials are available." Turner believes, "All of them are half-stepping.

"They also need to get some good trials. We know this medicine is chemotherapy in a pill."

In Turner's opinion the key to surviving long term with HIV is attitude. "Attitude is everything. In the back of my mind, I was really hoping and praying that I was in something that was going to work."

survivability of women and people of color living with HIV, the amount of administrative follow-up and paperwork is a huge barrier to recruitment and participation in trials for smaller clinics such as Luck Care Center.

The center, like many HIV specialty centers across the U.S. not affiliated with a major research institution, is limited by available resources. "The process of case reporting and recruitment is time consuming" states Bethsheba. Dr. Johnson adds "it is important to have someone on staff dedicated to recruitment and paperwork," in order for the clinical trial process to be successful at a smaller specialty center.

Myrna admits that she was a nervous wreck when she first entered care and the clinical trial.

It is also important for the Center to be knowledgeable and understand its responsibility in the clinical trial process. "You need to know whether blood work and certain tests are covered by the trials. These can get to be expensive over time," states Dr. Johnson. Luck Care Center has experienced its own growing pains in this regard, but is learning how to negotiate with companies sponsoring trials in order to ensure that administrative overhead and as many tests (e.g. PCR) as possible are covered.

Dr. Johnson and Bethsheba Johnson are true partners in care. Together they carry on Dr. Luck's vision while seeking to guide the growth of the clinic in local, national and international arenas. While the work is daunting and there never seems to be enough funding, Dr. Johnson concludes that it is their "faith and belief in God that keeps us [he and his wife] and this clinic together."

WHO ARE WE HURTING?

THE HESITATION BY PEOPLE OF COLOR

BY WILLIAM STRAIN

I've been thinking a lot about the importance of participation in clinical trials by people of color. I hear about the need for this inclusion almost every day. The cries seem to be somewhat endless. In fact, I hear it coming out of my own mouth.

There has traditionally been relatively little proportional involvement of people of color in clinical trials research for HIV disease. Is this lack of involvement the result of exclusion or merely just a lack of interest? The majority of volunteers have always been gay White men. That's pretty much just how it's always been. But its not like we haven't been asked to participate. The invitation may not have been immediate. But who needs an invitation to save their life?

Even still, we live in a time where there are 21 FDA approved HIV antiretrovirals—even with the relatively small numbers of Blacks or Latinos involved in HIV research. So is it a bad thing that so few of us have been involved? Thus far, all of the approved antiretrovirals seem to be pretty effective and relatively safe in people of color—again, despite the lack of overwhelming numbers of Black and Latino volunteers who helped make the safety data possible. I don't hear too many stories these days about AZT killing Black folks.

So why then is it so important that people of color participate in HIV clinical trials research? Especially when, without any real effort on their part, Black and Brown people with HIV and AIDS reap the clinical and life-saving benefits of ARV therapy?

But are they really reaping these benefits? I wonder. Lately, I have seen a few reports that despite the advent and widespread use of powerful agents to control viral load and increase CD4 cells, low income, disenfranchised people of color are less likely to receive HAART (highly active antiretroviral therapy) than their White counterparts. Why is this?

I know times are tough and ADAPs (AIDS Drug Assistance Programs) are strapped, but this seems a bit one-sided. This must be a totally different situation than in the real world where African Americans and Latinos receive the same level of care

as Whites across the board, right? Aren't African Americans and Latinos with cancer, diabetes and heart disease offered the same cutting-edge procedures and new medications that save the lives of White people every day? Of course they aren't.

At the same time, African Americans and Latinos are less trustful of the medical establishment and more likely to rely on already over-burdened and under-funded public health systems for little more than acute care. The legacy of Tuskegee is all too real for many of us. Many African Americans and Latinos have deep and sincere cultural reliances on non-traditional therapies, including faith, and in some cases, deep denial.

AFRICAN AMERICANS AND LATINOS ARE LESS TRUSTFUL OF THE MEDICAL ESTABLISHMENT

But how and in what world is any of this okay? The CDC (Centers for Disease Control and Prevention) estimate that African Americans accounted for over half of all AIDS cases diagnosed in 2002. Isn't this a public health emergency? If it isn't, I wonder what it would take to qualify. Given these numbers, how can it be that people of color are not offered the same treatments that Whites receive everyday, which we know will extend and improve their life? Given these numbers, why aren't African Americans and Latinos breaking down the doors of their local HIV clinic or rioting in the streets demanding those regimens? If memory serves, gay White men did that in the eighties. It resulted in the first of many treatments for HIV—twenty one at last count.

Visit http://aactg.org for the new website of the Adult AIDS Clinical Trials Group, listing studies available, in easy-to-understand language.

But clinical trials research for HIV long ago stopped being a selfish endeavor and we already have 21 approved antiretrovirals. Isn't that enough?

Few clinical trials these days offer access to unapproved medications for the very ill in the way that was the norm just five years ago.

As is the case in most other diseases FDA approval takes ten years and volunteers for clinical trials are altruists, contributing to the health and benefit of those to come. Here, too, we have a problem, because as we know, there are few people of color participating in HIV clinical trials. Aren't African Americans and Latinos invested in the welfare of others? Their own?

Even the United States government seems to be very concerned right now with the threat that HIV poses to people of color—but only on other continents. Even Oprah has taken a very keen interest in the horrific tragedy of AIDS orphans in South Africa (I love Oprah). So why are there so few people of color volunteering to make a difference in the lives of other people of color? I'm haunted by the line from The Matrix: "It's the sound of inevitability."

I believe there are so few people of color involved in clinical trials research for the same reason people of color remain at higher risk for HIV infection, which is the same reason why we aren't knocking down the doors of our local HIV clinic and rioting in the streets. The issues of racism, sexism, discrimination, poverty and self-hatred are pervasive, overwhelming and ultimately lethal.

Within a few years, there will be more Blacks in Africa participating in HIV clinical trials than the number of American Blacks who have ever participated in HIV clinical trials. This is astounding, except when you consider that their continued existence is dependent on enrollment into clinical trials that provide otherwise unavailable and cost-prohibitive treatments.

But the CDC says that in 2000, HIV/AIDS was among the top three causes of death for African American men ages 25–54 and African American women ages 35–44. Doesn't that somewhat suggest the continued existence of African Americans may be similarly dependent? Oh, that's right. We already have those 21 drugs. It's a good thing we don't need any more or an HIV vaccine.

It seems kind of a shame that the VaxGen trial, while not designed or powered properly to rely on the results, did suggest that there was a benefit for African Americans that was not observed for Whites or Latinos. But we don't really want a vaccine that works only in African Americans anyway, right? So we don't need to join the trials.

Aside from the realities that we need more than 20 antiretrovirals and that African Americans and Latinos care about others and their own, I don't have any real answers. Everything I've said has been said before and met with silence and inactivity. I don't think there is a simple answer. That would be far too easy. There may not be an easy answer. But I'm sure there is one. We just need to think harder and do more to find it.

Vaccines—A Community Role for HIV

The time to get involved is now

by Edd Lee

While the reality of having an effective vaccine to prevent HIV infections is probably still many years away, the effort to find one is growing even as you read this article. More experimental vaccines are entering into clinical trials today, with many more products coming down the pipeline.

As exciting as it is to have a variety of different experimental AIDS vaccines in development, one of the greatest challenges still to overcome has to do with people just like you. Without the involvement of ordinary, everyday people, HIV vaccine research doesn't stand a chance. This is because the only way we will be able to discover what will protect a person from HIV is to test experimental vaccines in people.

So what are the obstacles to getting people into clinical trials? A recent study by the National Institutes of Health found that one out of five persons surveyed believed that an HIV vaccine already exists, but is being kept secret. About half of those surveyed had not heard anything about HIV vaccine research over the past year.

What does all this mean? That few people are aware of the current effort to develop an HIV vaccine, which would help to explain the challenge of finding people who are willing to volunteer to be in clinical trials. After all, how can people volunteer for something they don't even know is going on?

Ironically, a vaccine trial needs to enroll thousands of people and for more than three years, thousands more people (and more years) than is needed to bring an HIV drug to market!

Clinical trials around the world

More than 60 AIDS vaccines are in development right now (visit www.avac.org). More than 25 are entering or about to enter Phase I and II trials. Currently vaccine clinical trials are being conducted (or will soon be conducted) all over the world.

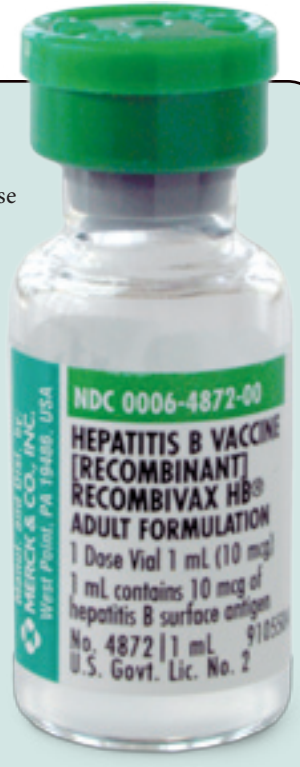
In the continental U.S., HIV vaccine clinical trials sites include Providence, Rhode Island; Rochester and New York City; Boston; Chicago; Baltimore; Birmingham, Alabama; Nashville; San Francisco; Seattle; and St. Louis, Missouri.

Around the world, vaccine clinical trial sites include Canada, Haiti, the Dominican Republic, Puerto Rico, Trinidad and Tobago, Peru, Brazil, Finland, the United Kingdom, the Netherlands, Belgium, Germany, France, Switzerland, Italy, Cameroon, Rwanda, Uganda, Kenya, Tanzania, Malawi, Zambia, Botswana, South Africa, Russia, India, Thailand, China and Australia.

Challenges

Current research efforts have raised issues that must be addressed today. Understanding these issues and preparing for them proactively will speed up the development of an AIDS vaccine. Here are a few issues that the public needs to be aware of.

Vaccine-induced seropositivity: HIV vaccines that teach the body to make antibodies to



How vaccines work

Basically, vaccines stimulate an immune response that can either

- prevent infection or
- create resistance to an infection

Vaccines are an incredibly useful public health tool, as they've greatly reduced the number of cases of diseases like smallpox and polio. Yet due to issues of access and affordability, every year three million people in the world die of vaccine preventable diseases.

Most people are familiar with whole killed or live attenuated vaccines.

Whole killed vaccines use the pathogen or disease-causing agent (such as bacteria or virus), kill it and then present it to the immune system. These include vaccines for flu, rabies, hepatitis A, and the Salk polio vaccine.

Rather than killing the pathogen, live attenuated vaccines weaken it so it cannot cause disease. These include vaccines for measles, mumps, rubella, and the Sabin polio vaccine. However, neither of these vaccine approaches are considered safe for HIV.

Instead scientists are developing recombinant vaccines, vaccines that are made of genetically engineered components in order to avoid using HIV itself, thus making it impossible to become infected from the vaccine. Recombinant vaccines, of any kind, are not yet on the market.—Edd Lee

the virus could cause someone to test positive on an HIV test. That's because HIV tests do not actually detect HIV. Instead, they detect antibodies to HIV. (Antibodies are proteins made by a person's immune system to fight off infection.) While it is possible to tell the difference between someone who has antibodies from a vaccine versus a person who is HIV infected, most HIV testing staff have not been trained to do so. It is important that our system for HIV testing be improved to overcome this challenge.

Partially effective vaccines: It is likely that the first HIV vaccines will be less effective than treatment that is normally licensed in the U.S. (70–95% effective). Though a partially effective vaccine is not the ideal vaccine, it could be beneficial in parts of the world with high infections rates. Mathematicians estimate that a 30% effective AIDS vaccine could curb the number of new infections when used in a region of the world with a high infection rate, like southern Africa or Southeast Asia. But when the mathematicians accounted for people abandoning safe sex and needle use behaviors, they found the pandemic would actually worsen. This means any AIDS vaccine, particularly partially effective vaccines, must be provided with HIV prevention interventions in order to ensure people understand all the ways to keep themselves negative.

Two types of AIDS vaccines

AIDS vaccines fall into one of two categories, preventative or therapeutic.

Preventative vaccines are made for people who do not have HIV. The goal is to

- prevent HIV infection,
- slow or prevent disease if the person becomes infected, and/or
- make it harder to transmit HIV to someone else

Preventative AIDS vaccines focus on two parts of the immune system, the humoral and cellular.

- The humoral arm of the immune system makes antibodies, proteins that are designed to attach to a specific virus, in this case HIV. Antibodies can keep a virus from infecting cells in the body and activate the rest of the immune system.
- The cellular arm of the immune system controls cytotoxic T lymphocytes (CTL), or white blood cells. White blood cells fight HIV by finding cells in the body that are infected and killing them before HIV can replicate itself.

Therapeutic vaccines are made for people who are living with HIV and are designed to help teach their immune system to control the HIV in their body. It is hoped, for example, that a vaccine can stop someone from progressing to AIDS.—Edd Lee

Disease Modulation: A preventative AIDS vaccine might not prevent infection, but instead keep an infected person from becoming sick. If this is the case, then new standards will have to be developed for treatment plans.

Accelerating vaccine development: Ever since the events of September 11, the U.S. government has accelerated the development of vaccines for anthrax and smallpox. Incentives such as guaranteed purchasing and liability insurance have helped to spark private investment in these types of vaccines. Such incentives have not been put in place for HIV/AIDS vaccines, even though 40 million people in the world live with HIV while there are zero cases of smallpox. The politics of AIDS continue to challenge efforts to end the pandemic and requires the public to overcome it. It is true the nature of vaccine research is time consuming, but we are not doing all we can to speed this process up.

Community participation and trial participant protections: Again, community participation in AIDS vaccine clinical trials is essential. Unless people are willing to participate in clinical trials, development of an effective AIDS vaccine is impossible.

But the community first requires education about clinical research and participant protections. The public must be informed about the potential of an AIDS vaccine, as well as the risks and benefits of participating in clinical research. Also, trial participants and their loved ones must be assured that their rights and health are being championed throughout this process.

Past abuses in biomedical research, such as the Tuskegee experiments, remain fresh in the memory of many people. Furthermore, examples like Tuskegee also illustrate some of the reasons certain communities have greater distrust of biomedical research than others.

After Tuskegee, several safeguards were put into place to ensure that such abuses are not repeated and that research benefits are shared equally across communities. Community involvement is one of the safeguards. This is one reason why we so urgently need to provide the community with education on clinical research.

Addressing issues of racism, sexism, ageism and classism will have a direct impact on which communities step forward to participate in clinical research. Inclusion of diverse communities will not only help ensure that an AIDS vaccine works for multiple communities, but also that diverse communities accept the vaccine because they were involved in the development of it.

Moving forward

Making a difference in terms of developing an HIV vaccine can be as simple as sharing what you read in this article with a couple of your friends. Get conversations going so people you know are aware of current research and how to get involved.

If there are trials in your area, you or people you know could join a trial or you could join a Community Advisory Board (CAB) at the study institution and lend your knowledge and time to the effort. You could help just by making sure people know the truth about HIV vaccine research. Sometimes it is just the little things that can make a huge difference.

Children's Research—

A Mom's Experience

one family's struggle to survive

by Eva Powell

Not long ago my 17-year-old asked what motivates me. I was speechless for a moment while I conducted a quick inventory of my life. The last time he asked me a question I knew required as much thoughtfulness and consideration was when he was seven. We were on our way to his school when he turned to me and asked, "What exactly do I have that I have to take medicine?" For the first time, I gave the disease he lived with all of his life a name, although we had talked about it many times before in general terms. Along with learning the name—HIV, came the realization that the other children in the clinic, some who had died a few months before and who died shortly after, had the same disease. Soon his mood and behavior noticeably changed and it was impossible to get him to talk about what he was thinking and feeling. It was my hope that working with an art therapist would help him find a way to express and get out what he was feeling. Since then, I have tried many ways to provide a safe environment for him to talk about this, but it always seemed too difficult for him.

For several weeks leading up to his question about my motivation in life, our family therapy sessions had focused on encouraging him to find a reason to live and motivation to work in therapy and on relapse prevention. His mantra is, "I don't know how to begin. Life is too hard." I cringe every time I hear him say it. From the time we were diagnosed with HIV as a family in 1987, my focus has been to fight for our lives. I believed it was my job to instill the same fight in my son, resisting the urge to curl up and wait to die. I was determined to find a way to beat this disease.

Why do I have to take my medicine? This question was asked by my son starting with his first dose of AZT in the late 1980s and continued into adolescence. I always answered his question based on his age and level of understanding, including more information as his ability to comprehend increased. I took his cue he had the answer he needed when he stopped me to ask a completely unrelated question. Even with consistent, honest answers, there were times when it was almost as difficult to get him to take the liquid Norvir at 12, as it was to get him to take the AZT when he was three.

With the introduction of each new medication over the years, we would talk about the medicine he was expected to take and how it worked, although he seemed to not be able to remember its name. I would have to taste the new medicine. Or as he got older, I would express admiration that he could swallow a handful of capsules and pills in one gulp. There had to be a clear purpose for taking the medicine. What was the value to him? This was put to the test when his health declined and he got sicker and didn't have strength or energy. As he was able to understand more about HIV, the importance of taking the medicine made more sense to him, but he continued to stay shut down emotionally. It was important to me he believe what he was doing was helping him become and stay healthy. More importantly, he needed to be an active participant in his healthcare.

After his father's death in 1988, less than a year after our diagnosis, our future looked bleak. There wasn't much known about HIV, infected women and children were rare, and there weren't any treatment options, except a few for opportunistic infections. I expected to die before I reached 30 years. I was in a fog. I felt isolated. We were one of a half dozen families at Children's Memorial Hospital in Chicago. There I met Doctor Ram Yogev who kept telling me that I should be angry—and express it! This advice went against what I was taught and allowed to do growing up. When I decided to give it a try it took some practice but I soon got the hang of it. I found my voice. I enjoyed the power that expressing myself gave me. I wasn't going to sit around and wait for HIV to take hold of us. With my newfound power I focused on life and giving it to my son. My goal was to make it possible for him to realize he had power and control and the right to participate in the important decisions about his health. We talked a lot about why he was taking medicine emphasizing the risks of skipping doses and of keeping to

I am angry about how slow pediatric HIV research has developed.

the schedule. Of how the medicine is active for only a period of time, but that HIV is always busy working, and how that can lead to drug resistance.

I struggle with how unfair it must seem to him to have to choose between taking the medication or risk getting sick again. I can understand him trying to delay the taste and the side effects of the meds. It's hard to answer him when he asks, "My stomach already hurts, why do I have to take my medicine when it's only going to make it hurt worse?" I would give him those extra minutes as he stood, chin cupped in his hands, staring at the meds in front of him, finally taking a deep breath and knocking the liquid or handful of pills down the back of his throat.

Not quite a year after our diagnosis, I joined the ACTG 019 (AZT) study. This was my introduction to research, and a hard decision to make. How could I take what could be a life-saving medication, when there wasn't anything for my child? Not to mention the reality of having a toddler who wasn't sleeping through the night. I was a single parent working to maintain our household and continuing my education to get a better job with insurance. I juggled all of this with taking my son to the doctor, giving him his meds on schedule (eventually), getting myself to the doctor and trying to remember to take my own meds. I was exhausted. How was I supposed to remember to take those AZT capsules so many times throughout the day and night? In the early days of 019 the capsules were in individual plastic bubbles on cards. I went to several visits with the cards containing many capsules still in their bubbles. I was finally told that I needed to start taking them to remain on the study. I was even too tired to think about popping those remaining capsules out before heading in to my study visit.

I was frustrated the options for treatment were so bleak. Was AZT the only hope? Not so frustrated however, that I was willing for us to try anything or agree to participate in every research protocol. I began to educate myself, reading about treatment options, experiences of people using these treatments, indulging in discussions—and arguments—with Dr. Yogev and other care providers, thinking about how they did or didn't apply to our health.

As I attended seminars at my clinic at Northwestern Memorial Hospital during the early years I heard the latest news about HIV/AIDS research and treatments and felt more hopeful that lives could be sustained, but impatient children weren't yet enjoying this hope. Not only had I experienced my son's failing health but also knew and watched other children get sicker and sicker and die. My son became afraid to go to sleep at night for fear he would die and not have the chance to tell me goodbye. He told me he would rather be scared by the scariest movie, than by living with HIV. Eventually, he chose to self-medicate with drugs of his choice, saying he was relaxed for the first time in his life. All of his worries about death, getting sick, being bullied and made fun of disappeared. The downside, he lost his will and fight to live.

Yes, I am angry about how slow pediatric HIV research has developed. It has always seemed years behind asking the pertinent questions and finding the answers to the issues of the day. Instead of becoming bitter, I took advantage of the opportunities that at first were foreign and new. In the adult clinics were notices of AIDS Clinical Trials Group (ACTG) Community Advisory Board (CAB) meetings. What is a CAB? I thought, and didn't go. Then in 1996, Dr. Yogev approached another mom and I about starting a research CAB at Children's Memorial Hospital. I agreed. I had been searching for a way to put value into living with this disease. I also think Dr. Yogev used it as a way to divert my frustration at lagging treatment development from him to the Pediatric AIDS Clinical Trials Group (PACTG). Finally, an opportunity to have input into the research needs of children with HIV! Well, not exactly. The CAB didn't get information on protocols until they were already developed, and we didn't have the training or power to say what we thought the research needs of our children were. We struggled with how a CAB finds its purpose and to recruit and retain members. We began to develop projects. One of our first major projects was to review the informed consents for protocols to provide input to the research staff to make them more understandable and informative for the families. This was my first introduction to the Institutional Review Board (IRB). I admit at first the IRB seemed like yet another hoop we had to jump through to get treatment for our children. I started attending the PACTG meeting in 1997, to find the national CAB, the Pediatric Community Constituency Group (PCCG), brand new itself, having just gained independence as a subcommittee of the Adult ACTG CCG, and not able to provide a forum for CAB members at the meetings or support or advice on how to develop and maintain a CAB. Over the next few years the PCCG began to create a stronger presence among the investigators on the research agenda committees, at the meetings, and assigning members as community representatives on protocol development teams, but still struggled for credibility and was unable to reach out to the CABs.

Upon becoming a member of the PCCG in 2000, I had two main goals. The first, for the PCCG to become partners with the investigators and provide input on the research priorities of the community. And the second goal was for the PCCG to assume responsibility for supporting the development and maintenance of CABs at the Pediatric AIDS Clinical Trials Units (PACTU). Although the PCCG is a small group of 15 members, we share the same concerns and with determination and hard work we have met

these goals. In May 2002, we presented the PACTG leadership our first Research Priority Agenda for the PACTG that was developed as a result of a strategic planning retreat earlier in the spring. And in December 2003, we presented our first CAB retreat. The goals of the retreat were to provide an introduction to CAB members and site staff about the value of community involvement in clinical trial development, CAB purpose and function, the research process, and structure of the PACTG. With the ultimate goal for CABs to enhance the site's recruitment and retention, and to provide a broader demographic and geographic perspective on the research needs of children and families.

Although I had participated in studies, research seemed abstract. This was probably true when I was first approached to consent for my son to participate in studies. Sometimes I declined. I don't doubt I made the right decisions, however I'm sure it was not a fully informed decision. I know now I didn't completely understand what I was consenting to, which means my son didn't understand either. Now that I participate on protocol development teams I advocate that the informed consent process isn't the act of reading the consent and obtaining the parent's signature and child's assent. It is an ongoing educational process, starting well before being presented the consent form, and continuing throughout the course of the study.

For research to be tangible the parent and child need to hear how valuable their participation is. To give value, the investigators must convey that they appreciate the many factors going into the decision to consent, and acknowledge the burden to the family if the child participates. These factors include, but aren't limited to the frequency of visits and number of and types of tests there will be at the study visits. It is important for us to know how many times our children will need a blood draw or why a test as invasive as a lumbar puncture is required. I have refused to consent for a study when this has not been clear to me. We also must hear a thorough explanation about the risks and side effects and administration of the treatment. And the investigator should be aware of whether a family can manage the overall schedule of evaluations and keep their jobs and family intact.

Trusting the investigator and staff requires honesty and communication. It is important for parents and children to understand the benefit of participation and be told the objectives of the research and what the researcher wants to learn, in simple language. For example, is it to determine the safety or right dose of a medication? Is it to compare two medications or combinations of medications and find out which one is better? And, it's important for the family to know what other treatment options there are to consider instead of being in the study. Finally, it is crucial to provide updates throughout the study and a report regarding what was ultimately learned. And just as importantly, remember to regularly thank us for being in the study and not take our participation for granted.

Throughout the discussions, symposiums, studies and reports on adherence, I am always disappointed to hear investigators blame failure of a participant to adhere to the study regimen on dysfunctional families. I believe the participant's and family's ability to adhere to the study is a true test of the effectiveness of the informed consent process. We are doing the best we can with where we are in understanding the illness of our child. Our lives do not revolve around the needs of the researcher. The investigator should give consideration during the consent process whether the child or family is capable at that time to participate. The needs and readiness of the child and family must come before accrual of the study.

From the early days when Dr. Yogev's persistence helped to set in motion my freedom to express myself and my quest for knowledge, through the years as I have worked with researchers, doctors, nurses, social workers and other persons in the clinic providing care, the key has been knowledge and understanding. Working together doesn't mean being told what to do and doing it without thinking or asking questions. It means that I have spent time educating myself so I can talk about treatments and how they affect quality of life and other areas of concern regarding our health. It means the willingness on the part of the researchers and care providers to see my child and I as individuals who make valid contributions to our care decisions. We need each other. Without each other there are limits to what we can learn and the health we can maintain for children and families with HIV. I'm not advocating that every parent who comes through the clinic door should be expected to become involved as much as I am to be able to contribute to research. I do advocate that children and families must receive training and education before being expected to make a fully informed consent to participate in research.

So, what motivates me to get up every morning? What did I tell my son? Well, it has evolved over time. In 1988 my motivation to live was the belief that I am the best person to be my son's mother. As my health continued to stay good, I wanted to find work that made a difference so in the end I could look back on my life and say I made a difference. I have remarried and have the love and support of my husband that has given me the freedom and time to do more than I ever dreamed possible. And, the genetic seed of a strong-willed nature and stubbornness passed from my grandmother Eva, through my mother and on to me was nurtured over the years by the people I have had the good fortune to know and work with.

I wanted to find work that made a difference so in the end I could look back on my life and say I made a difference.

Going to Extremes to Stay Alive

From study to study until the cure

by Matt Sharp

In 1989 I took care of a lover who was struck by one life-threatening infection after another. I watched as he withered away and eventually lost his mind and died a terrible death. I was diagnosed then too, but was lucky to never get sick. It was a wretched time when all we knew how to do was be angry, stay mobilized and simply live to the next day.

There was only one drug available to fight HIV, AZT, and we all watched as people took it and still died. We resorted to try anything we'd heard that might be helpful. I took AZT and then I heard about a drug that was made on the underground called ddC (now under the brand name Hivid).

I ordered it from a San Francisco AIDS Buyers Club called Healing Alternatives because there were no clinical trials in Oklahoma where I was living at the time. Now we know ddC is probably useless, but then it was only the second anti-HIV drug. We took what was available even though we knew little about HIV and how to treat it.

I decided to move to San Francisco, the hub of the epidemic, where I would have cutting edge HIV care and get access to clinical trials that were enrolling for early experimental AIDS drugs.

All my friends who were not dying signed up to be guinea pigs in these studies since we were desperate to try anything to stay alive. Of course, some people were skeptical of being in studies. Everything was new—we didn't have viral load testing then!

But I was determined that HIV wasn't going to kill me, so I got access to new drugs through the clinical trials process. It was the safest way to have a chance against HIV. For me, it was a survival strategy. Be as proactive as possible and buy time!

But it wasn't just that. I also wanted to help find some answers for all people living with HIV and AIDS. I knew that together, for better or for worse, we could get the answers we needed.

In 1993 one of the first studies I enrolled in was at Stanford University, which is about 40 miles south of San Francisco. I remember many early morning drives down the foggy northern California highway winding my way to the elegant campus, known for its medical proficiency. In many ways, I enjoyed the drive even

though with each trip I saw my CD4 count drop; the new protease inhibitor Invirase was not stopping my HIV progression. In fact, I was merely adding a new drug on to a failed drug, which essentially stair-stepped me to more drug resistance.

We all now realize that using drugs in this way—one new drug on top of older used drugs—was a recipe for disaster. There are many survivors walking around today who have no options because of the days of sequential monotherapy, but there are also thousands now six feet under. At that time I was losing a friend a week to AIDS, yet some of my friends from those days are still kicking!

By adding tipranavir to my regimen of T-20 along with two nukes, I have had the lowest viral load ever for six months now. I am taking fewer pills than before, and my overall health and vitality is excellent. All this after 16 years of living with HIV!

The University of California at San Francisco (UCSF) put out an updated clinical trials guide that I combed through at every opportunity to find another study to enroll in. I also became involved with the university's community advisory board (CAB), one of the first in the U.S., so I could not only gain access to information about clinical trials at UCSF, but to also learn what new treatments were being studied through the federal ACTG or AIDS Clinical Trials Group (now called Adult AIDS Clinical Trials Group).

I even began attending the national group meetings where people with HIV and AIDS activists, mostly from ACT UP, forced their invitation. It was a steep learning curve for me, learning the science of HIV and at the same time demanding new drugs and better inclusion into clinical trials from the scientists and the feds. We made significant inroads into improving HIV research.

In 1995, I was able to qualify for my second protease inhibitor study with Crixivan, where I saw some good initial results. But again, since I was only adding essentially one new drug to older ones, I was building further drug resistance and soon was considered a "drug failure." (I didn't fail the drugs, the drugs failed me!)

Little did I know that Crixivan did not work very well after first use of Invirase. That information was learned through clinical trials.

By then studies for me were few and far between, and I felt driven to try alternative therapies being used in the community, including a smuggled drug called Compound Q.

The amazing thing about this drug was that it was administered at underground IV clinics at private homes. Clinical trials of Compound Q were enrolling but soon shut down because people were dying in the studies from the drug. I felt empowered taking this risky drug, but it had no effect.

In 1994 I started losing a lot of weight and was diagnosed with wasting syndrome. One activist friend of mine attended a medical conference where he found tucked into the program book a new therapy called human growth hormone (now called Serostim).

After months of activist persuasion, the company agreed to do wider studies, and a few of my friends who were also wasting away enrolled in the trial. After a placebo period using injections once a day, I saw I was not gaining any weight, but was eventually allowed use of the drug in a second phase of the study. Sure enough, I gained almost 10 pounds in one week while on the drug.

I still take Serostim, at a lower dose every day, not only to maintain my health, but to decrease the visceral fat around my stomach.

I took an outreach job at the San Francisco General AIDS Clinical Trials Unit (of the ACTG) in 1996. I went into minority communities talking about my experiences in clinical trials, how they had helped me and trying to encourage people to get into studies.

In talking with people I got a sense of dismay about enrolling. *"Why should I get in a study? I'm doing just fine."* Or, *"I'll never be in a study and risk my health."* Or, *"as an African American man, I wouldn't dare be in another Tuskegee experiment."*

It was a frustrating experience for me as I had seen the studies help so many people, but it also made me see the flaws in recruiting for AIDS studies. Much education needed to be done, but without people for the studies I knew we were doomed. The same paradox holds true today for many of the same reasons.

I was feeling pretty good even though my virus levels were high, but I was beginning to name my T-cells. No new protease inhibitors became available then, but I was able to enroll in an expanded access program at my doctor's office to a new drug from a different drug class called Rescriptor. It also proved to not help much as it was simply adding a drug to a failed background regimen.

We did find out that Rescriptor increases levels of some protease inhibitors, which I was also using at the time. We also learned that by using up this drug I developed cross-resistance to a newer and better drug called Sustiva that became available a few years later.

In 1997 I had the opportunity to do something real daring since I was essentially a ticking time bomb. I flew all the way across the country to join a clinical trial.

I was one of only a few HIV-positive people who signed up to receive a thymus transplant in a research center in Burlington, Vermont. The thymus is responsible for educating T-cells, telling what

foreign invaders to target. The thought was that transplanting thymus tissue would help stimulate my weakened immune system.

Even though the study was a very preliminary look-see if this technique would work, it did involve opening my abdomen through surgery, and gave me dangerous transplantation drugs (they suppress the immune system)—all procedures that had not been tried in HIV before. This was not a simple drug trial!

I flew back to San Francisco surviving the procedure, but will never know if there was a benefit to receiving the transplanted tissue. I was at least alive and empowered by doing something so daring to try to prolong my life.

We made significant inroads into improving HIV research.

There was no new clinical trial or therapy for the next several years that I would qualify for. I had tried almost every approved drug and none were working. Even though I was fairly stable, I knew according to my falling T-cells that it would only be a matter of time before I became susceptible to serious infections.

I had been meeting with a small company developing a compound in a new class of drugs called fusion inhibitors. This drug was T-20 (now called Fuzeon). I followed development of the drug before it ever entered into clinical trials and waited for the right time and place to get access.

Since I was moving to Chicago in 2000, I knew that Northwestern University was going to be a site and I pressured the clinic to start the study. After a frustrating several months when I began experiencing poorer health and falling T-cells, the study opened and I was enrolled into a placebo arm. About two months later, I was given access to the drug along with a background of five other drugs and reached undetectable virus levels for the first time.

Fortunately my virus numbers remained low and I've been injecting myself now for over two years, twice a day. The injections can be painful, but the drug has essentially been able to hold off virus reproduction, keeping it lower than ever before. The study eventually closed and the drug is now widely used.

I had been living on disability at the time, but realized that I now had the energy to hold a job again. This in spite of the fact that under the guidelines of the trial, my experience was considered a failure! And yet, I had been given a new lease on life. I was surviving and thriving with HIV.

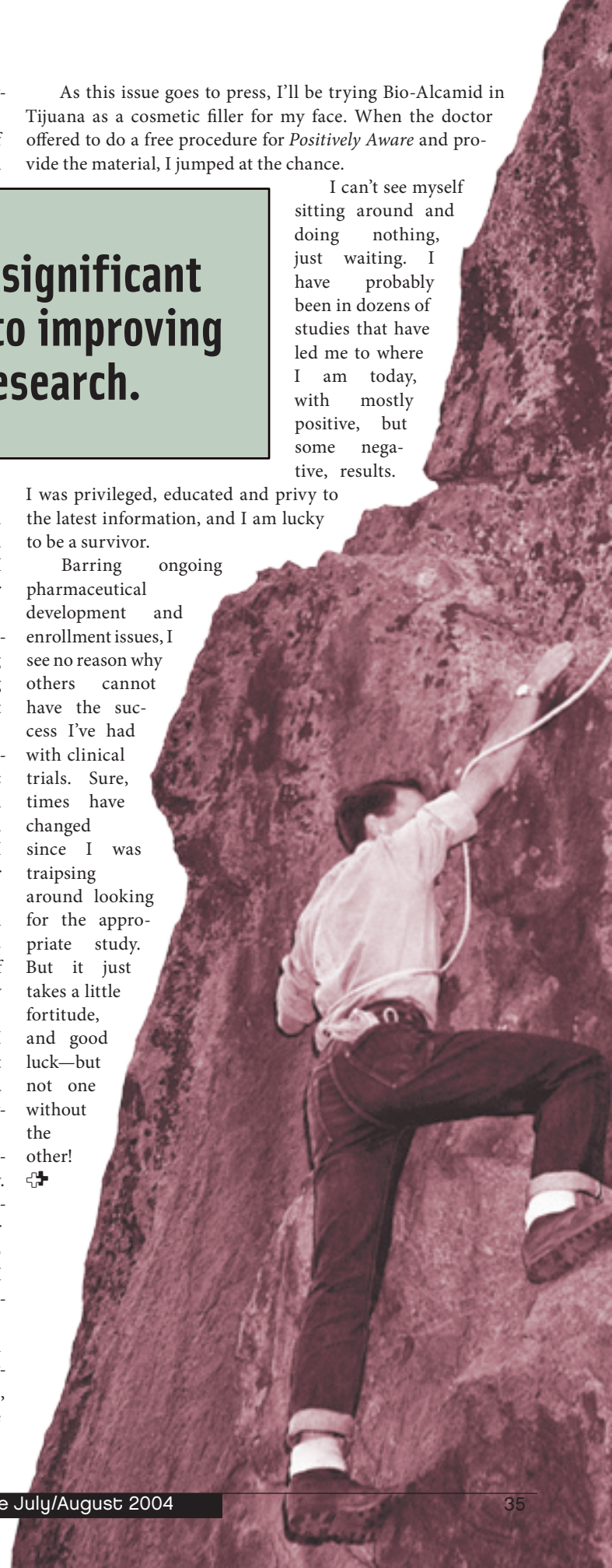
I likened my virus to Swiss cheese, holey and not able to reproduce, but I still needed a better drug and looked for another study. I then enrolled in a late stage trial of a new protease inhibitor, tipranavir, that is supposed to work against viruses resistant to older drugs. By adding tipranavir to my regimen of T-20 along with two nukes, I have had the lowest viral load ever for six months now. I am taking fewer pills than before, and my overall health and vitality is excellent. All this after 16 years of living with HIV!

So now I watch for another moment of opportunity that will afford me with better drugs. I long for a cure but will settle for buying a little more time as usual. The prospects are good for the future, but the studies will need to be inclusive and be able to answer the questions related to real world HIV.

As this issue goes to press, I'll be trying Bio-Alcamid in Tijuana as a cosmetic filler for my face. When the doctor offered to do a free procedure for *Positively Aware* and provide the material, I jumped at the chance.

I can't see myself sitting around and doing nothing, just waiting. I have probably been in dozens of studies that have led me to where I am today, with mostly positive, but some negative, results. I was privileged, educated and privy to the latest information, and I am lucky to be a survivor.

Barring ongoing pharmaceutical development and enrollment issues, I see no reason why others cannot have the success I've had with clinical trials. Sure, times have changed since I was traipsing around looking for the appropriate study. But it just takes a little fortitude, and good luck—but not one without the other!



Participating in a Clinical Trial

A factsheet from the New Mexico AIDS InfoNet

What is an AIDS clinical trial?

Before new drugs can be sold to treat HIV disease, they must be proved to be safe and effective. The Food and Drug Administration (FDA) approves new drugs and other treatments based on the results of laboratory tests, animal tests, and tests in humans (clinical trials).

New treatments are tested in humans only if there were good results from laboratory tests and animal studies. In the first clinical trials, the treatment is tested for safety in a small group of people. Later trials with many more participants test how well the treatment works. InfoNet Fact Sheet 105, How Drugs Get Approved, has more information on the phases of clinical trials.

A clinical trial is a carefully planned medical experiment. The guidelines for a clinical trial are called a protocol. The protocol is a document that describes exactly how the trial will be carried out.

Who can participate in a clinical trial?

The protocol explains the rules for participation in a clinical trial. Each trial is different. For example, some trials require certain viral loads or T-cell counts.

Should I participate?

You and your doctor should discuss the possible benefits and risks of taking part in a clinical trial. Here are some of the questions you should consider:

- What is the purpose of the study?
- How long will it last?
- Where is it being conducted?
- How will I take the medication (pills, shots, intravenous infusion, other?)
- What else do I have to do (records to keep, office visits, etc.)?
- What will I have to pay for?
- Can I be reimbursed for travel expenses?
- Is child care available?
- Will I be able to stay on the study treatment after the trial is over? Who will pay for it?
- What was learned in previous studies of this treatment?
- Will I have to stop any drugs or other treatments I am now using?
- Will taking part in this study exclude me from other clinical trials?

To find out more about clinical trials:

- For information about participating in clinical trials or trials availability throughout the U.S., call the AIDSinfo Health Information Service at 1-800-448-0440, or visit their Internet website at http://aidsinfo.nih.gov.

- The FDA website has information on the drug development process at http://www.fda.gov/cder/handbook/dev_rev.htm.

Visit www.aidsinfonet.org

Who's Afraid of the Big Bad Study?

Trials to think about

by Enid Vázquez

When people hear about clinical trials, many right away think of participants serving as guinea pigs, taking experimental drugs that do God knows what.

The reality is much more positive. For example, many clinical trials for HIV do not use experimental drugs at all. Why? There are so many drugs on the market, the goal is to compare them head-to-head. Or doctors are looking for the best treatment strategies to use with the drugs now on the market.

Trials can also have interesting benefits. One study provides an extremely expensive drug to people with HIV to see if it helps with their excess body fat. One study gave out palm pilots to keep track of side effects—I don't know if they asked for the palm pilots back!

Some studies do nothing more than collect one or two blood samples. Others don't involve study participants at all—researchers simply look at patient records, with the patient names blotted out.

Even these studies, however, can be risky or inconvenient. Free medications and lab tests are nice, but require a certain number of visits, at a set amount of time (every four months, for example). Drugs being studied may not work for you.

Still, it's a shame that more people don't realize how helpful and beneficial a study can be for them. On the following pages are some trials to think about. As Dr. Harold Kessler of Rush University Medical Center in Chicago said when he spoke at Test Positive Aware Network recently, "It's the clinical trials that develop the drugs which save lives."

Things to think about

- All the information you need is not listed here due to lack of space. For more information, contact the study coordinator. You will be asked if you meet the inclusion criteria (such as a certain number of T-cells) or have exclusion criteria (for example, viral hepatitis).

- You might prefer a study being funded by a pharmaceutical company because they often pay compensation. You might, however, still qualify for other studies—ask your trial provider about joining a government-sponsored trial. It's for a good cause!

- Speaking of which, clinical trial networks are pretty good at continuing a person's experimental medicine for free after a trial is over. Many of them can assign a social worker who can help set this up. Ask ahead of time what will happen if a medicine works for you, but the trial ends.

- If you do not qualify for a trial you're interested in, ask that you be kept in mind for future studies.

- Remember, you can drop out of the trial at any time (but do try your best to stick it out!).

- Take it from the ACTG clinical trial website: "To ensure reliable results, clinical trials follow precise medical guidelines or research plans called protocols. If you choose to participate, you accept the responsibility to observe these guidelines. So before you decide, make sure you know the number and length of appointments, medical tests required, and other medications allowed. You will need to commit the time required for the study and travel to your appointments. Although you can leave

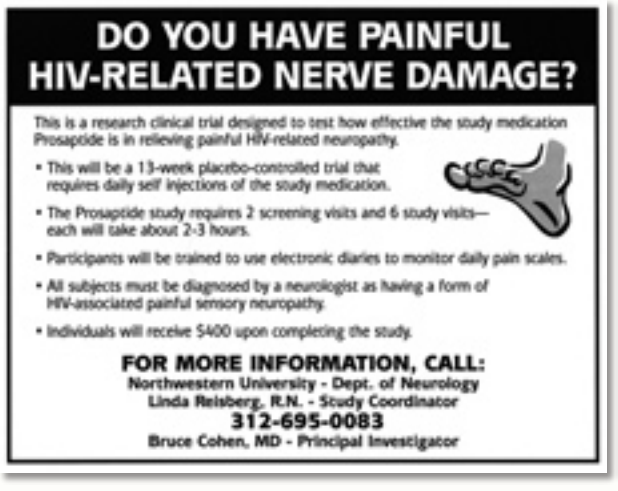
a clinical trial at any time, do not start one if you think you may drop out."

Trials to think about

For the study site nearest you, call 1-800-TRIALS-A (1-800-874-2572). Also call the AIDS Treatment Information Service at 1-800-HIV-0440 (1-800-448-0440). For HIV vaccine trials conducted by NIAID (National Institute of Allergies and Infectious Diseases), call 1-866-833-LIFE (1-866-833-5433). For studies beginning with the letter A, ask for the nearest AIDS Clinical Trial Unit (of the ACTG).

Experimental meds

BAY 50-4798 is an IL-2 analog, meaning that it's similar to IL-2; however, it has less toxicity. IL-2 is an injection drug used to increase T-cells. This Phase I/II study gives twice daily subcutaneous injections of BAY 50-4798 in-house (participants must spend a week in the hospital). In the Chicago area, call Janet Rindels at 1-312-942-5000, extension 21954.



Privately-funded studies often offer compensation.

Tipranavir

Boehringer Ingelheim in April expanded the Open Label Safety Study (OLSS) of its experimental protease inhibitor drug, tipranavir. The drug is boosted with a mini-dose of 200 mg Norvir. To qualify, people must have less than 100 T-cells and be unable to form a viable drug regimen from currently available drugs, or not qualified to join a current trial with tipranavir (now in advanced Phase III study). Side effects include diarrhea, nausea, vomiting and abdominal pain, fatigue, headache and dizziness. Tipranavir might be approved by the U.S. Food and Drug Administration (FDA) next year. For sites near you, call 1-800-632-2464 or visit www.clinicaltrials.gov.

Genetics

Earlier this year, ACTG researchers reported that genetics cause some people to clear Sustiva out of their body more slowly, leading to a greater risk of side effects. Moreover, this particular genetic finding was more common in African Americans than in whites.

Analyzing blood samples for genetic differences is a new field, and there's much work to be done. These trials often work off blood samples stored through a previous clinical trial, so you may not be able to just go in and have your genetics tested.

ACTG—If you have ever been in an ACTG trial, please contact them if you're willing to let them put your bloodwork into a genetic database. Fabulous! The database study number is A5128. (No, they can't do it without your consent, so please call!) You will need to go in and give one tube of blood.

Hepatitis

A5127 will see if people co-infected with hepatitis B will have a good response with two currently approved hep B drugs: Hepsera (adefovir dipivoxil) and Viread (tenofovir disoproxil fumarate). (Viread is also an HIV drug.) First one drug plus a placebo of the other drug will be tested, and then the drugs will be switched if your hepatitis doesn't respond to treatment.

Managing side effects

Prosaptide is an experimental, subcutaneous injectable drug for peripheral neuropathy (PN). PN is nerve damage that is a side effect of HIV and its treatment, which is often painful and debilitating. Prosaptide has been shown in early study to effectively treat pain in diabetics with PN with little side effects. It is also hoped that prosaptide will be able to regenerate nerve endings, not just treat pain. This is a pharmaceutical company sponsored trial, so there is financial compensation. The study is conducted with the Neurological AIDS Research Consortium (NARC). Visit www.centerwatch.com/patient/trials.html for a study site near you. Enter study number 2979 under keyword "Clinical Trials Search." Check for new sites on a regular basis.

Serostim (recombinant human growth hormone) is in Phase III study for the use of reversing the fat accumulating on the stomach. This is called the HARS study, for HIV-associated Adipose Redistribution Syndrome. "Adipose" refers to fatty tissue. The incredibly expensive Serostim has long been popular for melting stomach fat in people with HIV, but it can cause carpal tunnel syndrome and edema (severe water retention), among other side effects. See ACTG. In the Chicago area, call Kris Richards at 1-312-942-5000, extension 29156.

Monotherapy

Abbott M03-613 starts people who've never been on HIV therapy with a triple drug combination and then drops two of the drugs. This strategy is called "induction/maintenance." It has been unsuccessful in the past, but this study uses a powerful drug that's relatively new, Kaletra. Moreover, drug resistance is practically non-existent with Kaletra.

Abbott Laboratories is pharmaceutical *non grata* in the HIV community because of its announcement late last year that it was increasing the price of one of its HIV drugs by 400%. Nevertheless, this trial is exciting because of recent small studies finding outstanding therapy with Kaletra alone (monotherapy). Abbott M03-613 starts people off on Kaletra and Combivir, and then switches to Kaletra monotherapy after three undetectable viral load values (less than 50) after the first three months. A second group of people will be given Sustiva and Combivir, one of the most popular HIV

regimens in the country. In the Chicago area, call Kris Richards at 1-312-942-5000, extension 29156.

Newly infected

These are among the hardest trials to fill, as you can imagine. First people need to know that they've been recently infected with HIV (usually within the past six months), and then they need the presence of mind to seek medical care, much less a trial. Please know that these studies exist! Spread the word.

Among other things, these trials may look at the amount of virus in the tissues and reservoirs (where HIV "hides out") as well as the blood. They might also look at such things as strategies for managing acute (recent) infection.

Call for AIEDRP (Acute HIV Infection and Early Disease Research Program). According to the AIEDRP website, "Scientists believe that events occurring during acute and early infection may determine the ultimate course of disease in an individual." The ACTG is developing three new trials with AIEDRP.

SMART trial

This ambitious study follows thousands of people for more than five years. It tries to answer the question of whether to save therapy until T-cells are lower. (Medications are not provided.)

People will be randomly put into one of two groups. The first will stay on standard of care therapy. The second would be put on therapy when their T-cells drop to 250, and then taken off again when their T-cells go up to 350.

SMART stands for Strategies for Management of Anti-Retroviral Therapy. Call for The Terry Beirn Community Programs for Clinical Research on AIDS (CPCRA). In the Chicago area, call Ed Goodwin at 1-773-244-5804.

Therapeutic drug monitoring (TDM)

TDM measures the amount of drugs in your blood. It should help prevent treatment failure by finding that drug levels are either too high or too low for your body. TDM is not commonly used in the United States, although it is commercially available. TDM is more widely used in Europe for HIV care.

ACTG 5146 will see if TDM can help therapy succeed for people with low drug levels of a protease inhibitor. The study will work with your doctor to help determine your therapy, but will not provide medications. It will provide TDM and phenotype resistance testing on your virus. This is great for people with low levels of a protease inhibitor, but not so great for the other folks, who will only be followed as a comparison group.

Also, not everyone with a low level will get TDM; some will only be recommended a standard of care drug combination based on the results of their phenotype resistance test. (This is a help, however, because test results are hard to understand and doctors will appreciate getting an expert opinion.) You must be on least your second drug combination, with a viral load of 2,000 or more.

Vaccines

Ironically, one of the best things you can do for AIDS research is to sign up your HIV-negative friends and relatives. That's because they can help you in the search for an HIV vaccine—but these studies require thousands and thousands of more people than the average trial that brings a drug to market!

There are two different types of HIV vaccines—one to prevent infection in HIV-negative people and another to prevent disease progression in people who already have it.

ADVax is being tested in HIV-negative people by the Aaron Diamond AIDS Research Center (ADARC) and Rockefeller University in the New York City and Rochester areas. It uses synthetic DNA, containing only portions of genetic material, and cannot cause HIV infection. ADARC Director Dr. David Ho said that, "Each day, progress is being made in the search for an HIV vaccine thanks to continued community involvement in HIV vaccine research." The Center declared that a preventive vaccine is the world's best hope to stop HIV, and most doctors agree. Study participants must be between the ages of 18 and 45, and be at low risk for HIV (they check the vaccine's effect in test tubes of people's blood). Contact Elizabeth Londoño at 1-212-448-5126 or e-mail aidsvaccine@adarc.org.

Websites to check

http://hivinsite.ucsf.edu—from the University of California at San Francisco. This is a very useful site, especially for a list of studies. Don't use "www." Type "TrialScope" (one word) in the website's search function.

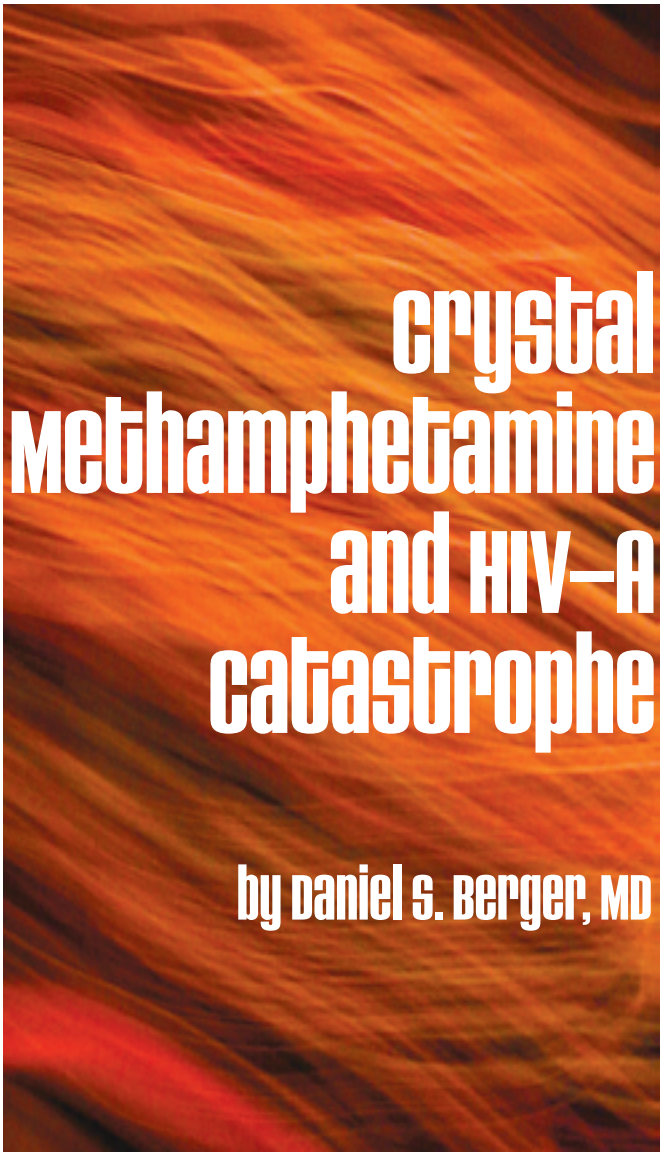
www.aidsinfo.nih.gov has information in Spanish as well. You can also go directly to www.clinicaltrials.gov. The site has a complete listing of HIV clinical trial networks funded by the National Institute of Allergies and Infectious Diseases (NIAID). These are:

- Acute HIV Infection and Early Disease Research Program (AIEDRP)
- Adult AIDS Clinical Trials Group (AACTG)
- Centers for AIDS Research (CFARs)
- Comprehensive International Program of Research on AIDS (CIPRA)
- Evaluation of Subcutaneous Proleukin in a Randomized International Trial (ESPRIT)
- HIV Prevention Trials Network (HPTN)
- HIV Vaccine Trials Network (HVTN)
- Pediatric AIDS Clinical Trials Group (PACTG)
- The Terry Beirn Community Programs for Clinical Research on AIDS (CPCRA)
- The Women and Infants Transmission Study (WITS)
- Women's Interagency HIV Study (WIHS)
- Multicenter AIDS Cohort Study (MACS)

www.acria.org is the site of the AIDS Community Research Initiative of America, and lists the organization's trials, available in the New York City area. Information about the studies is easy-to-read.

www.aidsmeds.com is a highly readable and comprehensive site. Among its forums is one for clinical trials.

Trial networks not listed here include Bastyr University AIDS Research Center (alternative medicines); the HIV Epidemiology Research Study (HERS); the Studies of Ocular Complications of AIDS (SOCA); the U.S. Military HIV Research Program (international) and the AIDS Malignancy Consortium.



The number of gay men using crystal methamphetamine is expanding and is tied to the increasing numbers of HIV seroconversions, especially among the youngest. Addiction to crystal methamphetamine is wreaking havoc on our community and it commonly destroys people's lives. It is slowly weakening the moral fiber and cohesiveness of our community.

It goes by many different names: Tina, Crystal, speed, zip, Cristy, meth.

There are various ways to administer: snorting, smoking, ingesting, and injecting.

Having surpassed more than 20 years into the AIDS epidemic, people's lives are greatly prolonged, but some are ruining their survival through crystal use.

Healthcare for HIV-positive persons during most of the 80's and early 90's was focused on maintaining quality of life, avoiding common opportunistic infections and trying to survive. Most HIV-positive patients who once faced the scary predicament of sickness and death are thankful for the developments in research and technology. Others, unfortunately, have put their lives at risk once again and are living on the edge with crystal methamphetamine. What has made this so incomprehensible is that individuals and the community have fought so hard to overcome AIDS.

Currently within our community and within our government there is no leading campaign to fight the epidemic of crystal abuse. There is no concerted effort to help educate our youngest members and there is no organized outreach by our community leaders. The bathhouses have become crystal crack houses. The gay Internet sites are being used for people to "hook up," often with recreational drug use. Circuit parties are defined by club drugs. And community leaders have made no issues with this problem and have done little to bring this problem to the forefront.

From a medical doctor's perspective in practicing in a large, gay-based private HIV practice, crystal meth use and recreational drugs are fast becoming the most frustrating problem. The problem is not solely an HIV-related problem, but one taking hold of our and other communities. It does seem to be quite prevalent among HIV-positives for reasons unknown. Perhaps it is that crystal numbs one's feelings and elevates peoples' low sense of self-esteem after experiencing HIV-positiveness. However, we are observing this among many seronegative members of the gay community and within people in other populations. Furthermore there has been an ensuing increase in seroconversion among the youngest in our community not unexpectedly associated with crystal meth use.

Common observations in clinical practice

As an HIV-specialty physician, it has been very unnerving to watch patients who have finally become medically stable develop

psychological breakdowns and medical complications. Like falling for a mirage in the dry desert, the desperate individual can unknowingly wind up thirsting to death in the black hole of crystal meth addiction.

The physicians at my practice, NorthStar Healthcare in Chicago, are seeing new crystal-related occurrences on a weekly basis. Not uncommonly, well-known patients present themselves with seemingly usual complaints during a normal HIV maintenance visit. However, what develops and emerges in the exam room is an accumulating list of persistent problems and illnesses that never resolve. Eventually it becomes known that the accumulating evils are nothing more than crystal related. Often valuable time is wasted because the patient lied about his abuse problems in the first place. Most everyone on crystal lies about their abuse.

Other common scenarios being observed at our clinic are patients who have been well employed with promising, sophisticated occupations and livelihood lose their job and career, become severely depressed and become burdened with credit card debt. Individuals fail at regaining employment. They become clinically depressed, lose weight and appear to be undergoing complications of wasting or lipodystrophy. Often therapy for wasting and lipodystrophy was unsuccessfully attempted by the naïve and unsuspecting physician who did not suspect that crystal was at the root of all the problems.

Epidemiology

According to one study of gay and bisexual men seeking treatment for crystal dependence (*Journal of Addictive Diseases 2002; 21:21-105*), 61% of the participants were HIV-positive. These HIV-infected patients were more likely to be using crystal by injecting and developing other sexually transmitted diseases (STDs) while involved in unsafe sex. All the patients in this study were in their mid-30's and most were college educated. These same subjects reported sex encounters with an average of 14 men in the 30 days prior to the study and 66 different men in the previous six months.

A study published in the *Morbidity and Mortality Weekly Report* in 2001 discussed an outbreak of 130 cases of syphilis in California and found that the most commonly used recreational drug of these patients was crystal methamphetamine, and that of the 57 patients who knew their HIV status, 60% were positive.

Some experts believe that perhaps now as much as 20% of the gay population used crystal in the last three months. Crystal support groups are overflowing and community psychologists are inundated with the associated psychological problems.

Drug effects and intoxication

Crystal, or methamphetamine, is a stimulant that is similar in chemistry to adrenaline, a central nervous system hormone that stimulates the body's response to stress. It speeds up the heart rate and increases blood pressure, which increases sweating. The drug is used recreationally for sexual enhancement and stimulation, to initiate more sex and to prolong the encounters.

But the drug also causes personality changes, paranoia, anorexia, weight loss, irritability and physical aggression. When one continues to use the drug, it is not uncommon for persons to go without sleep for several days at a time; this also leads to further personality changes, paranoia, and schizophrenic and psychotic symptoms. Individuals often manifest loss of reality as well as hallucinations. The irony is that individuals who are on the drug have a false feeling that they are intelligent and "making sense" when in truth they are often incoherent and out of touch with reality.

When using methamphetamine, the onset of action depends on how it is administered. After smoking, the effects begin in five minutes, while with ingestion it takes 20 minutes to feel the high. Some users insert it rectally. It takes 12 hours for the body to metabolize half the drug and it is detected in the urine for three to five days after usage.

Cardiovascular symptoms are well known and include hypertension, chest pain, and increased heart rate, which often result in irreversible cardiac changes such as cardiomyopathy (enlarged heart) and damaged blood vessels in the heart and brain. Many have sustained heart attacks and strokes, which often occur in

young patients. It is not uncommon for individuals to die during an acute usage of crystal from a cardiac event or collapse. Hyperthermia and convulsions can also occur and can result in death.

Many HIV experts believe that crystal also has direct effects on HIV as well as on antiviral medications. It is thought that crystal use reduces the effect of HIV medications, thus increasing viral replication. Additionally, patients who often use crystal miss doses of their HIV regimen as a consequence, thereby also increasing viral loads. This places HIV-infected individuals at risk for progression as well as increasing their ability to transmit the virus during unsafe sex.

HIV and crystal meth overlap

Both HIV and crystal meth drug use can cause depression, altered cognitive functioning, memory problems and sleep disorders. Naturally, if one is HIV-positive there should be the concern of developing cognitive problems down the road. There is some rationale to worry that abusing crystal may predispose an HIV-positive person for further memory problems, or more importantly, overt dementia. However, it may be too early for us to know since little research has been done in this area.

Additionally, depression has been a common problem that many HIV and AIDS patients endure during their infection course. Prolonged use with crystal methamphetamine is associated with withdrawal symptoms that occur 24 hours after usage, most commonly severe depression, fatigue and even suicidal thoughts. This, compounded with an underlying depression related to HIV disease, can result in more complexities related to psychological and psychiatric effects. Moreover, a study published in the *Journal of Neuropsychiatry and Clinical Neurosciences (2000: 12; 480-4)* demonstrated long-term chronic depression with crystal use. Other studies also documented that the majority of patients who have completed treatment for crystal methamphetamine abuse are dealing with depressive problems long after. Thus patients who become chronic users of crystal may have to deal with long-term psychological and psychiatric effects.

Conclusion

While it is difficult to understand the science of addiction, many men are being consumed by bingeing crystal daily. Thus they often manifest complex psychological and neurological problems, and frequently lose their jobs, ruin valuable careers and add to large financial debt. Individuals who want to recapture their lives will need aggressive tactics that combine education, support and medical treatment to combat their addiction.

What will it take for the community as a whole to wake up and for our community leadership to step up to the plate and say "Enough"? It certainly has reached the point of being a public health problem. As an HIV-specialty physician, it has been frustrating to watch the increasing numbers of addiction-related harms and lives devastated while the community sits by idly.

We were once a force that dealt with the HIV epidemic with muscle and vigor. Community leaders should launch another effective and concerted effort with AIDS service organizations and foundations to educate and fight the current destructive road we are traveling on. Owners and managers of community businesses and bathhouses should take responsibility in preventing the escalation of drug usage. In fact, it is well acknowledged that these businesses already have rules and guidelines regarding zero tolerance for drug use; however, the reality is this is not effective in and of itself. Community newspapers should also make this an issue in their publications so that it is brought to the public's attention.

It is understood that individuals who are users have to take ownership for their own actions. However, as a community we need to do a better job at not facilitating this problem by ignoring it, but strive to fight this epidemic.

Daniel S. Berger, MD, is medical director of Chicago's largest private HIV treatment and research center, NorthStar Healthcare, and Clinical Assistant Professor of Medicine at the University of Illinois at Chicago. Dr. Berger can be reached at DSBergerMD@aol.com or (773) 296-2400.

Let's Talk About It

Learning to trust, again
by Keith R. Green

"Brother, brother, brother, there's far too many of you dying"—Marvin Gaye

I hadn't given it a whole lot of thought before now. My close friends and family had all commented on it, and of course I had noticed it, but it had never really bothered me like it did today.

As I placed the makeshift ice pack onto the finger that I had just slammed in my car door (ouch!), I began to really pay attention to just how dark my hands had turned. I had first noticed it while I was hospitalized a couple of months back with issues pertaining to my digestive system. I don't know what caused the darkening of my skin or exactly when it began. I have tried to trace it to a particular medication, but I am on so many that the task is nearly impossible.

> Being in good health was a Black man's only sure ticket to securing work

I spoke with a brother from my support group here at TPAN, Brothers United in Support (BUS), who I've noticed is experiencing the exact same thing. But he is just as clueless as I am. I have asked several people in the medical profession and none of them seem to know.

Upon approaching my partner with my concerns today, he reminded me of the importance of African American participation in clinical trials. At first I really wasn't trying to hear him, because all I was thinking about was how I was slowly losing my "high yellow" complexion that I had grown to love. At first, I couldn't see what clinical trials had to do with that. But the more we talked about it, the more I understood where he was coming from.

Since HIV was initially recognized as a virus that only affected the gay, White community, most of the initial studies and research concerning the virus and medications that would be used to treat it were done on gay White males. African Americans and women were generally not a representative part of these studies and therefore, information on how the virus affects us specifically and how we react to the medications used to treat it is still relatively limited. But my hands and face have turned at least five shades darker in the past three months and seem to be getting darker every day. I am truly perplexed and now I am desperately seeking answers.

When my partner was initially diagnosed with CMV retinitis, he was told that he was guaranteed to lose sight in both of his eyes. Upon hearing this dreadful news, he had planned suicide, not able to live with the thought of being blind for the rest of his life. Thankfully though, through a paid study that follows the development of the infection, he has gone through experimental treatments, as well as a couple of surgeries, that have restored his sight and given him a whole new outlook on life, a life that he now lovingly shares with me.

As we continued to talk, I gave thought to the reasons why African Americans do not participate in clinical trials, particularly in relation to HIV.

Like victims of abusive relationships, learning to trust again has proven to be a difficult task for the African American community. Being brought to this country as slaves against their wills and then denied basic civil rights for many years, even after being legally set free, has taken its toll on a community of people who have never really been able to comfortably consider this country their home.

To African Americans living in the 1930s, nearly 70 years after the signing of Abraham Lincoln's Emancipation Proclamation, the question of what freedom truly was still loomed. Racism and segregation prevented them from accessing equal educational, employment, as well as equal health care opportunities.

Being in good health was a Black man's only sure ticket to securing work of any kind (generally manual labor) that would allow him to support himself and his family. Missing a day from work due to illness would usually mean a day without meals for his wife and children. The cost of seeing a doctor in regards to that illness probably meant several days without meals.

Therefore, when the government presented an opportunity to receive free health care in a little town known as Tuskegee, located in Macon County, Alabama, hundreds of illiterate African American sharecroppers willingly responded. What the respondents were not told was that they were being enlisted in an experiment that

was being carried out by the U.S. Public Health Service, designed to study the effects of syphilis on the human body.

Of the hundreds of respondents, 600 were accepted to receive free health care, 400 of whom had syphilis and 200 who did not. The catch, however, was that they were not told that they had syphilis, but were instead told that they had "bad blood." They were denied access to treatment, even for years after penicillin (found to be an effective treatment for syphilis) came into use in 1947.

When the study was finally exposed in 1972, 28 of these men had died of syphilis, 100 others were dead of related causes, nearly 40 wives had been infected and 19 children had contracted the disease at birth, which is now known to have caused mental retardation as well as many handicaps among them (from CNN Interactive's Tuskegee Study website). It was not until 1997 that the United States government offered an official apology for its Tuskegee experiments, which came through then-President Bill Clinton.

Fast forward to the year 2004. HIV is the leading cause of death for African American women between the ages of 25 and 44 as well as black gay men in the same age bracket. But before we can really begin to deal with the issue of African Americans not being willing to participate in clinical trials associated with HIV/AIDS, we must take a look at why we are dying from a disease that is preventable, with advanced medications available that are not only saving lives, but offer HIV-positive individuals a quality of life previously unobtainable.

Clinical trials are saving lives and improving the quality of life for those who are infected and affected with HIV. However, the fact that we as a community have neglected to participate in them, nor have we accessed of the proper care that is available and necessary to saving our own lives, is very frightening indeed.

The stigma that has always been associated with homosexuality as well as HIV/AIDS plays a huge role in helping to perpetuate this reality. Although my photograph rests on this page and you are reading my innermost thoughts via a journal that is geared towards the HIV/AIDS community, I am still not 100% comfortable with my AIDS diagnosis, and sometimes even my sexuality, as it relates to the African American community (95% maybe, but not 100). It is still not easy for me to have dialogue with people of color who are not gay, or not HIV-positive, about those subjects.

Don't get me wrong, I have these conversations. I am just not 100% comfortable doing so.

There are various reasons for that. One is because I know the views of the African American community towards homosexuality. In a lot of ways, we are like the military: "don't ask, don't tell." And if one does decide to tell, he/she is always associated with being "gay," and the rest of their identity, the most important parts, are disregarded or minimized.

Another reason is because I also know our views concerning people who contract HIV. I'll save the details for another article, but let's just say that those views are not pretty. The stigma associated with homosexuality and HIV/AIDS kept me in denial and in the closet about my own AIDS diagnosis for far too long and almost cost me my life.

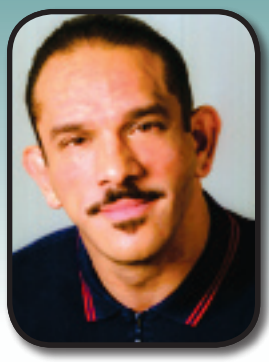
The stigma plays a huge role in helping to perpetuate this reality.

So, we could say that the reason why African Americans do not participate in clinical trials and are dying of AIDS at such an alarming rate is because of our mistrust of the government, particularly due to the Tuskegee experiment. Many of us still view HIV as a government invention, designed to kill off gays and blacks.

However, it can also be said that the stigma associated with HIV/AIDS plays an even bigger role in this devastating dilemma.

In the spirit of an African American legend and one of my many role models, I propose to you a question that simply asks, "What is really going on?" Let's talk about it.

E-mail k.green@tpan.com. Write to Keith Green, TPAN, 5537 North Broadway, Chicago, IL 60640.



I was a Viread guinea pig

With all my paranoia, baggage and skepticism
by Carlos A. Perez

Clinical trials are necessary, but who wants to be a guinea pig? Who wants to take a new chemical formulation that has only been tried on rats and monkeys? I'm far from a rat, despite what some people have said. And while I'm just a few genes away from being a monkey, the thought of being in a trial can be scary.

It is a difficult decision, but if we want to help each other and give medicine a chance to advance, clinical trials are necessary. Participants of clinical trials may be tomorrow's heroes.

Oddly enough, with all my paranoia, baggage, skepticism and distrust of authority figures, I entered into a clinical trial. The main reason I entered this study was financial. Clinical trials often mean free medical care. I also had a good relationship with my doctor at NorthStar Healthcare and trusted his insight enough to get over my doubts and jump into the research pool.

He also told me that this new drug had no side effects. Naturally, I didn't believe this for a second, but I had nothing to lose except my T-cells.

There are a million questions that rush through your mind when thinking about entering a clinical trial. What is this chemical? What are the side effects? Am I willing to deal with them? There are side effects the drug manufacturer knows about, but one of the reasons for the trial is to see what other side effects may occur.

Then there's the compliance component. Am I willing to come to this clinic or doctor's office as often as the protocol demands?

Then before you begin the trial they must be sure you are a good candidate. This may mean a million different things depending on the study. Are you treatment naïve? Is this your first or fourth regimen? Are you the correct gender, age and weight? Are you healthy enough? Are you sick enough? Qualify, qualify, qualify.

And then once you qualify, you must sign the paperwork. This was the only part that made my legs quiver because within all those documents you are signing there is one that says something like, "If I drop dead due to this study I will not hold this doctor or this company liable for my death." So you have to swallow, take a deep breath and realize that hopefully the odds of this really happening are very low and this is just part of this marvelously litigated nation.

After you have signed your life away you have much blood drawn, and after these results come back, you may be lucky enough to be chosen.

What cinched it for me was that I needed a new drug and here was the promise of one at the right price with no co-pays and free blood work and doctor visits. My current regimen had run its course, my viral load was climbing and my T-cells were dropping. I needed a third drug in order to beat down the virus and get up-to-date with the latest in HIV therapy efficacy.

So here comes this flat, round, chalky white pill without a name and I start to take it, as prescribed, twice daily.

The first three months I walked in there and the research technician took my vitals and asked me the same questions over and over. This was followed by an inspection of how many pills I had taken, literally. The tech would take my bottle and walk away and then come back always happy with me because I was 100% compliant.

After three months I was given a new batch of pills and told to stay on the regimen and not change a thing. The pills were now oval shaped and a pretty light blue. Within approximately six weeks my blood work had come back and my viral load had gone undetectable from somewhere around 120,000 copies and my T-cells soared to almost 400 from nearly 200. They didn't have to tell me that when the pill changed shape and color I had started on the real stuff.

The drug was Viread and my skeptical self could not believe that I had not experienced any side effects.

Not only has Viread proved to be effective as an antiretroviral drug, but Gilead Sciences reported huge profits this year based on the drug's position as the fifth best-selling antiretroviral drug in the U.S.

When someone is on a placebo like I was initially and the researchers find the drug is working, they will switch the patients from placebo onto the real drug as soon as they can because it would be unethical not to. This is why clinical trials have come full circle to a trusted and respectable way to go about helping science, yourself and your community.

If the trial comes to a close and the drug is not yet available on the market, in most instances the drug will be supplied to you so you may continue this new regimen. In a clinical trial you get exceptional treatment from doctors and support staff that want you to be pleased so you will stay the course and the trial will truly be a success. Nobody wants dropouts because the data is then skewed. You receive free medical exams, laboratory tests, and a drug that is not yet available to the general public.

You may even get success.

Photo © Russell McGonagle

Mind the Gap

Microbicides for the coot… and the boot

by Jim Pickett

This year, six vaginal microbicides are expected to enter into Phase III clinical trials, recruiting thousands of women who will be testing the efficacy and safety of these products. In the form of creams, gels, lubes or suppositories, vaginal microbicides will either kill or immobilize HIV, block HIV infection by creating a barrier between the virus and the cells of the vagina, or prevent the HIV infection from taking hold after it has entered the body.

The best vaginal microbicide(s) will employ two or more of the above mechanisms for extra effectiveness. By 2010, we could very well see one or more of these products on the market.

There are a total of 62 vaginal microbicide candidates in the development pipeline; 18 of which are in Phase I, II, or III clinical trials. The other 44 candidates are in pre-clinical development.

So, that's all fine and good for the coot (i.e., vagina.) And c'mon people, give us three cheers for the coot! It's about time women had some prevention options they could control, that wouldn't rely on some stupid man. Let's be clear, there is not a society on the planet that can be proud of its males in terms of how they behave (and misbehave) in heterosexual relationships. For women throughout the world, the strongest predictor for their own HIV risk is being married or involved in a committed relationship. Their perception of fidelity from their partners won't protect them from a man who has a different concept of fidelity, trust and direct, honest communication.

All hail vaginal microbicides! They can't get here too soon.

But hey, what about the boot (i.e., booty, butt, ass, culo, can). Just where are we at with rectal microbicides, which would be similar to vaginal products but would protect our precious triumvirate of anus, rectum and colon during anal intercourse? When will Booty Butter be on the shelf of your favorite grocer? How many products are in development?

None. Yet. Key word—*yet*.

Also know that in the United States, about seven times more heterosexual women have anal sex in comparison to the number of gay men who do. In fact, about 1/4 of all American women have had anal sex, and they are unlikely to engage in this activity with condoms. A study done by UCLA found that 35–48% of gay men reported having unprotected anal sex in the last year.

Can't we just use vaginal microbicides for the booty? If they work for the coot, why not the boot? Um, no, it doesn't work like that. The vagina is a very different environment from the Holey Trinity my dears.

For one, it is an enclosed pouch, where the rectum is essentially one big, open tube (think Holland Tunnel.) From anus to rectum to colon we're talking about two feet, right up to the spleen. Hello!

The epithelium of the rectum is only one cell layer thick and very fragile, the vagina is a much tougher customer with seven cell layers. The rectum is very vascular, very lymphatic, very vulnerable to infection, and any trauma (such as that caused by anal penetration) may facilitate HIV transmission. And even with the Holland Tunnel on the inside, the anus is very tight and micro-abrasions occur in even the most gentle and loving of sexual intercourse.

Another couple of interesting rectal tidbits are that HIV is present in the rectal mucosa of an HIV-positive person and that the cells in the wall of the rectum and colon are actually designed to take up foreign particles and transport them to immune cells inside the body to be destroyed. HIV diabolically takes full advantage of this system. With the rectum we also need to be mindful of fissures, fistulas, ulcerations, hemorrhoids, and human papilloma virus (HPV).

So no, we can't use vaginal microbicides in the rectum, though they definitely need to be made safe for the rectum, even if they won't be effective (first do no harm.) And while there is pre-clinical research happening in this area, no, we don't have any rectal candidates yet. But it doesn't have to be that way.

Research has shown that a vaginal or rectal microbicide that is only 60% effective could prevent as many as 2.5 million deaths worldwide over three years if only 20% of people with access used it 1/2 the time they did not use condoms.

What this means is that we got to get busy. We have to begin advocating for the booty. Gay men and heterosexual women need to mind the gap, we need to talk about anal sex at dinner parties and on golf courses. We need to be involved in the pre-clinical research, like giving up some rectal tissue samples for scientific study, or attending a focus group about anal sex practices.

We must ask for, no—demand, Booty Butter. And we can't make the asking while tittering behind our monogrammed handkerchiefs.

And we have to be patient. There are significant challenges to developing an effective rectal microbicide, challenges that are as much about human physiology as they are about politics and culture. We cannot be dissuaded or dismayed. Many gay men are already foregoing condoms for a host of reasons. We know women often don't use protection during anal sex. Wouldn't it be marvelous to be able to provide these lovely ladies and gentlemen with something to keep their bootys happy and healthy?

Clinical Trials Glossary

by Dawn Averitt

Clinical trial: A study of a medicine or disease in people.

Data: The information collected by researchers during a study to help better understand the study topic.

Dose-escalating: A dose-escalating study is usually an early study done to figure out how much of a medicine should be given to an individual. Dose-escalating means gradually increasing the amount of medicine until the correct amount is determined.

Double-blind or blinded: A blinded study is designed so that the participant does not know which treatment arm they are on. A double-blind study is one where neither the doctor nor the participant know which treatment arm the participant is taking.

Exclusion criteria: Factors that will prevent a person from participating in a specific study either for their safety or to make it easier to understand the study results. For example, someone might be excluded for having liver problems, or if they've already used a drug that is being studied.

Observational study: A study that observes participants and collects information about their medical history, but does not assign treatments or interfere with their health care.

Open-label: A study in which the participants know which treatment arms and medications they are on.

Placebo: A sugar pill that looks like the drug being studied, but does not contain medicine.

Protocol: A scientific plan that describes the reason for doing a study, how it will be done, and what the goals of the study are.

Placebo-controlled: A study that gives some people a placebo and some people a medicine so that the effect of the medicine can be compared to no treatment.

Randomized: Assigned by chance or randomly. This refers to the way people are assigned to different arms of a study.

Study arm: An arm of a study is a specific treatment being studied and involves a group of people usually being compared to another group, or arm, of the study.

Treatment-experienced: A person who has already taken at least one anti-retroviral medicine to treat their HIV disease.

Treatment-naïve: A person who has never taken anti-retroviral medicines to treat their HIV disease.

Inclusion criteria: Requirements that a participant must meet to participate in a specific study (such as T-cell count, viral load, age, or other laboratory values).

Reprinted courtesy of www.PositiveWords.com.

TPAN Events Calendar

All events held at TPAN unless otherwise indicated.
For additional information on these events please contact TPAN at (773) 989-9400.

July 2004

Date	Time	Event
Monday 5th		TPAN Closed
Wednesday 7th	7:30 pm	Committed To Living, The Future of Entry Inhibitors, Dr. Roger Trinh, supported by Roche Pharmaceuticals
Thursday 15th	7:30 pm	Legal Clinic with AIDS Legal Council of Chicago - Returning to Work
Thursday 29th	7-10 pm	PULSE 15th Anniversary Party with Emcees Jessica Halem of Lesbian Community Cancer Project and TPAN executive director Charles Clifton. Berlin, 954 W. Belmont

August 2004

Date	Time	Event
Wednesday 4th	7:30 pm	Committed to Living, Club Drugs, Dr. Ross Slotten, supported by Pfizer Pharmaceuticals
Wednesday 18th	7:30 pm	International Conference on AIDS Update, Charles Clifton, Dr. Tom Barrett, Matt Sharp, supported by GlaxoSmithKline Pharmaceuticals
Thursday 19th	7:30 pm	Legal Clinic with AIDS Legal Council of Chicago - Benefits for the Mentally Impaired
Thursday 26th	7-10 pm	PULSE Berlin, 954 W. Belmont

Programs and Meetings

All meetings held at TPAN unless otherwise indicated:
5537 North Broadway, Chicago.
Office hours: Monday–Thursday, 9 am–8 pm. Friday, 9 am–6 pm
phone: (773) 989-9400 • fax: (773) 989-9494
e-mail: programs@tpan.com • www.tpan.com

Support groups sponsored by the
Chicago Department of Public Health
Peer Support and Buddy programs sponsored by the
AIDS Foundation of Chicago

Monday

Medical Clinic

HIV/Syphilis/Hepatitis C testing and full medical care for HIV-positive clients is available. Program is offered by Access Community Health Network. Call for an appointment. From 10 am–6 pm.

TPAN Daytimers

A support group for people with HIV who prefer to meet during the day. Meets from 10:30 am–12:30 pm.

Spirit Alive!

Through a collaborative effort of AIDS Pastoral Care Network (APCN) and TPAN, Spirit Alive! fosters discussions on topics such as hope vs. despair or strength in times of adversity. Meets from 7:30–9 pm.

Tuesday

Medical Clinic

See description on Monday. Call for an appointment. From 9 am–12 pm.

Yoga

All levels of yoga are welcome. Meets from 10–11 am.

Positive Progress

A peer-led group for HIV-positive individuals in recovery. Special emphasis is placed on sobriety as a priority to effectively living and dealing with HIV. Meets from 7–9 pm.

Living Positive

HIV-positive individuals discuss how being positive affects life and relationships. Socials and speakers on occasion. Meets from 7:30–9 pm.

Wednesday

Needle Exchange Program

Through a collaborative effort of Chicago Recovery Alliance and TPAN, a free, anonymous, legal syringe exchange and HIV/AIDS prevention is offered Wednesdays from 5–7 pm, or by appointment.

SHE (Strong, Healthy and Empowered)

HIV-positive women discuss needs, concerns and issues facing women with HIV. Meets from 7:30–9 pm.

SHE Social

A social event every 4th Wednesday

Thursday

Yoga

All levels of yoga are welcome. Meets from 10–11 am.

Medical Clinic

See description on Monday. Call for an appointment. From 12 pm–8 pm.

TPAN Daytimers

See description on Monday. Meets from 10:30 am–12:30 pm.

Needle Exchange Program

See description on Wednesday. Thursdays from 2–5 pm, or by appointment.

BUS (Brothers United in Support)

Support group for HIV-positive gay and bisexual men of African descent. Monthly socials and speakers on occasion. Meets from 7–9 pm.

Positive Now

Support group for newly diagnosed HIV-positive individuals who seek support, education and the opportunity to share their experiences in a relaxing, empowering environment. Meets from 7–9 pm.

Pulse at Berlin

A weekly social for HIV-positive individuals and friends. Meets from 6–10 pm at Berlin Nightclub, 954 W. Belmont, Chicago.

Friday

Needle Exchange Program

See description on Wednesday. Fridays from 2–5 pm, or by appointment.

Poz Leathermen

Support and social group for HIV-positive leathermen and friends. Meets from 7:30–9 pm at Soul Cafe, 1301 West Hollywood, Chicago.

Scheduled By Appointment

FASN (Family AIDS Support Network)

A group for family, friends and caregivers. Call Betty Stern at (773) 989-9490.

Individual Counseling

AIDS Pastoral Care Network (APCN) professionals provide individuals with one-on-one counseling on Mondays. Ask for Sherry or Betsy at (708) 681-6327.

Peer Support Network/Buddy Program

Trained volunteers provide one-on-one peer, emotional support to individuals living with HIV. Call Paula at (773) 989-9400.

Speakers Bureau

Individuals are available to community groups to educate peers on HIV, safer sex, and harm reduction. Call Matt at (773) 989-9400.

TEAM (Treatment, Education, Advocacy and Management)

This peer-led program integrates secondary prevention and treatment education to provide individuals the training and knowledge to more successfully support other individuals impacted by HIV. Call Montré at (773) 989-9400.

Reiki

Energetic healing practice that utilizes hands-on touch and focused visualization. Meets Tuesdays and Thursdays by appointment only from 2–5 pm.

Miscellaneous

livingpos18to24@aol.com

An AOL chat room for young adults (ages 18–24) who are HIV-positive. Monday through Friday from 3–5 pm. Contact email livingpos18to24@aol.com

Positively Aware Reader Survey

Dear *Positively Aware* Reader,

In an ongoing effort to improve the quality of *Positively Aware* for our readers, we thank you in advance for taking a few minutes of your time to complete the Reader Survey.

We produce *Positively Aware* for you, our reader. This is why we need your valuable input and insight regarding the publication. There are no right or wrong answers, and you may choose to skip any questions you do not want to complete. The survey is completely anonymous, so please be candid with your responses as we value your honest feedback. This survey is also available online at www.tpan.com

Thank you in advance for helping us to make *Positively Aware* an even more valuable resource for you, our readers.

Sincerely yours,
The Publications Staff

Please tell us about yourself:

Age:

❍ 18 or under ❍ 19-24 ❍ 25-34
❍ 35-44 ❍ 45-54 ❍ 55+

Race:

❍ White/Caucasian ❍ African-American ❍ Latino
❍ Asian/PI ❍ Native American ❍ Other

Location:

❍ Rural ❍ Suburban
❍ Urban ❍ Incarcerated

Gender:

❍ Male ❍ Female
❍ Transgender M to F ❍ Transgender F to M
❍ Other

Sexual Orientation:

❍ Gay/Lesbian ❍ Heterosexual
❍ Bisexual ❍ Other

HIV Status:

❍ HIV-positive ❍ HIV-negative
❍ Unknown ❍ Anonymous

If positive, how long?:

❍ Newly diagnosed (under 2 years)
❍ 2-5 years ❍ 6-10 years ❍ 11-15 years
❍ 16-20 years ❍ More than 20 years

If positive, are you currently using HIV medications?

❍ Yes ❍ No

If not, please explain: _____
_____
_____
_____

If you are taking HIV medication, how many different drug regimens have you been on since you started HIV therapy?

❍ First drug regimen ❍ Second drug regimen
❍ Third drug regimen ❍ Fourth drug regimen
❍ More than four regimens

Annual Income:

❍ less than $10,000 ❍ $10,000–24,999
❍ $25,000–39,999 ❍ $40,000–54,999
❍ $55,000–69,999 ❍ $70,000–84,999
❍ $85,000–99,999 ❍ over $100,000

Education Level:

❍ Less than high school graduate
❍ High school graduate ❍ Some college
❍ College graduate ❍ Graduate/Professional degree

Employment Information:

❍ I do not work ❍ I work part time
❍ I work full time ❍ On disability
❍ Other

How long have you been a Positively Aware reader?

❍ Less than one year ❍ 1 to 2 years
❍ 3 to 5 years ❍ More than five years

How helpful is Positively Aware as a resource for making decisions about your HIV treatment?

❍ Not at all ❍ Somewhat helpful ❍ Very helpful
❍ Extremely helpful ❍ Don't know

What is your primary resource for information on HIV/AIDS?

(Choose one)

❍ Internet
❍ Hotlines
❍ Physician, nurse or other medical service provider
❍ Non-medical HIV/AIDS service organization
❍ Other people with HIV/AIDS
❍ Printed materials and publications

Do you share your copy of Positively Aware with any other readers?

❍ No ❍ Yes

If yes, how many other readers? _____

What do you like best about Positively Aware?

_____
_____

What do you like least about Positively Aware?

_____
_____

How would you rate the length of the articles in Positively Aware?

❍ Too long ❍ Just right ❍ Too short

What, if anything, sets Positively Aware apart from other magazines and journals for the HIV community?

_____

_____

What specific topics would you like to see more of?

_____

_____

How would you rate the readability of Positively Aware?

Too difficult to understand ❍ Just right
❍ Too simple ❍ Other

Please specify _____

_____

_____

What changes would you like to see occur with Positively Aware?

Please rate from 1 (most important) to 6 (least important)

_____ *Glossy paper stock*
_____ *More artwork*
_____ *Special issues on specific topic*
_____ *More issues per year*
_____ *No changes are needed*
_____ *Other*

Please specify _____

_____

Is there anything else you'd like to tell us about Positively Aware?

_____

_____

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Please Sponsor the Editor!

Please consider making a generous donation to TPAN and Positively Aware (PA) by sponsoring the Executive Director of TPAN and Editor of PA, Charles Clifton, for the **AIDS Run & Walk Chicago** on **Saturday, September 18, 2004.**

Because we hear from you often, we know how important this publication and your local AIDS service organizations are to you. But did you know that PA is the only national not-for-profit HIV/AIDS publication that is also produced by a local not-for-profit AIDS service provider, Test Positive Aware Network (TPAN) in Chicago? Monies raised in the AIDS Run & Walk Chicago benefit TPAN and other Chicago ASOs.

Simply fill out and mail back the form below, or visit www.tpan.com and go to the "Sponsor Charles" link and pledge online.

AIDS Run & Walk CHICAGO
Saturday, September 18, 2004

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City _____ State _____ Zip _____

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Charge my: ❍ Visa ❍ Mastercard ❍ American Express Total $ _____

Card Number: _____ Expiration date _____

Name on Card _____ Signature _____

I've enclosed a check, made payable to AIDS Run & Walk Chicago in the amount of $ _____

Donations to AIDS Run & Walk Chicago are tax-deductible to the full extent allowed by law.

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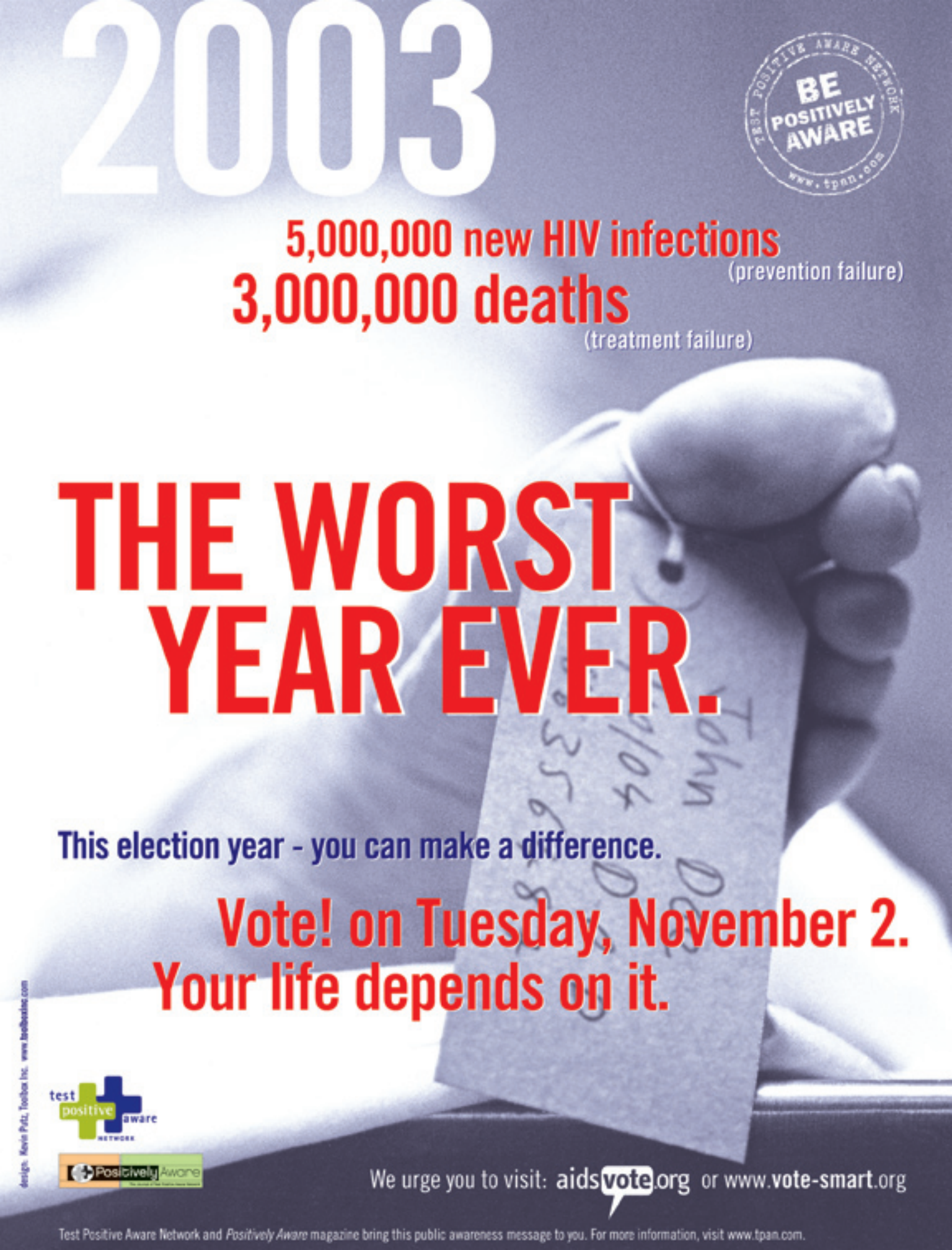
Call for more information at (773) 989-9400 or visit www.tpan.com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3,000,000 deaths
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