

The Joe Jacques HIV/AIDS Update



THE PATIENT NEWSLETTER OF THE INSTITUTE OF HUMAN VIROLOGY

IHV Applauds Marathon Man

In the last year, James Bolger has taken many steps to improve his life. In fact, too many steps to count. In October, he was one of about 3,000 runners who finished the Baltimore Marathon. Covering 26.2 miles is a feat even for the most highly trained of athletes. But Bolger, like a growing number of runners around the U.S. and the world, is a recreational runner who ventures out a couple of times a week with the ultimate goal of accomplishing what many may dream of but fewer still achieve. He traversed the hilly Charm City course in five hours and 48 minutes.

Bolger ran the first 16 miles at a nine-minute-a-mile pace, which would translate to a four-hour marathon. But at mile 16, his right knee gave out and his run became a walk. He trudged through the last 10 miles and as any first-time marathoner knows, just crossing the finish line is a feat in and of itself.

A classically trained flutist and

a former chef, Bolger draws on his experience as an artist to describe the joy of covering 26 miles—and of the joy he receives from the support of fellow HIV patients who meet weekly at the IHV to encourage one another in good times and bad. They cheered for him before the race and applauded him afterward.

"We don't all play the same note," the flutist told the

"Whatever you want to do in life, you have to prepare yourself."

JACQUES Initiative support group that meets weekly in the first floor conference room at 725 W. Lombard St. "But the most phenomenal orchestra is

the combination of many instruments, all different, but when they come together – what an awesome sound."

Together, these patients share a common desire to help others living with HIV – as well as putting myths and misconceptions to rest.

"No matter what your disability—whether it's diabetes, heart disease or HIV—you can do whatever you want to do," says Bolger, who is an advocate

of mind over matter, believing in one's self, believing in the power to motivate others, and focusing on the future and not the past.

"Change is difficult," he says. "With change comes fear. But change is important. If you're not changing, you're going backwards."

With race day behind him, Bolger acknowledges running a marathon isn't the easiest of goals. But, he says, it's one any of his peers can also achieve and he has already planted the seed that others should consider joining him next year to cover those 26 miles around and through Baltimore landmarks such as Druid Hill, Mount



James Bolger

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Pen Pal Shares Words of Encouragement

"A lot of people think they can't beat this thing. They can. I am living proof."

So says Willie Silver, a patient who denied his HIV status for years before beginning treatment. When he was diagnosed in 2003, he weighed just 115 pounds and could barely open the door to the patient clinic.

"You can beat it," he says. "But you have to stay focused and have a positive attitude. You have to focus and you can't give up."

Nearly three years after beginning treatment, Silver has gained about 40 healthy pounds. "Something is working."

He attributes his success to his three-drug combination regimen, his dedication to taking it as prescribed, a great support system that includes three children and a desire now to help others with some of the lessons he's learned.

He is a regular attendee of the JACQUES Initiative support group meetings as well as a frequent speaker. And, when a pen pal exchange program with Africa was announced, Silver was one among the first to commit to writing letters to those battling the disease on another continent, where resources aren't as plentiful and social support isn't as readily available.

Silver exchanges letters with a mother and daughter in Zambia and tries to send words of encouragement, something that has proven so invaluable to him and the patients he knows.

"I just kind of let her know not to give up. There will be some days where you are down and depressed and you want to give up. But you

don't. You continue on and you take your medicines."

Silver knows from first-hand experience the devastation of an HIV diagnosis and the nightmare toll

that it can take on your spirit and on your life.

His late wife, Vanessa Taylor Silver, was diagnosed with HIV in 1992. He believes he may have been infected then, but wasn't tested. "I don't know if I gave

it to her or if she gave it to me. If I did, I say a thousand sorries."

His wife struggled with the disease before the introduction of effective medications and she passed away in 2004, on Valentine's Day. She left behind her husband and three children, ranging in age from 5 to 21. One is also HIV positive and they all

"The only thing worse than a failure is a person who fails to try. It's either do or don't. Don't say I can't."

miss their mother terribly.

Silver has committed himself to answering their questions as best he can and being available as a parent.

"I cry myself to sleep sometimes, but I have to pick myself up. I really haven't had time to grieve."

Like so many HIV patients, Silver draws strength and encouragement from those around him and tries to

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Clinical Trials

A Phase Ib, double-blind, randomized, dose-cohort escalation study of intravenous PRO 140 or placebo in adult patients with HIV-1 infection

The chemokine receptor CCR5 serves as a fusion coreceptor for HIV. PRO 140 is a humanized monoclonal antibody to the chemokine receptor CCR5. Binding this coreceptor with this antibody prevents the virus from binding, thus, theoretically preventing cells from becoming infected.

Primary Objective: The primary objective of this clinical trial is to evaluate the tolerability of a single, intravenous dose of PRO 140; thus, this is not a treatment study.

Design: The study includes a single dose of double-blinded study medication followed by an observation period of 58 days. After screening to assess eligibility and viral status, patients will enter into 1 of 3 dose-cohorts. Within each cohort, patients will be randomized to receive either PRO 140 or placebo in a ratio of 10:3 and will receive a single dose of blinded medication. Sampling of the blood for levels and CCR5 will be performed in each cohort. Patients will then be

KP-1461: A Phase Ib, double-blind, placebo-controlled, dose escalating study of the safety, tolerability, and pharmacokinetics of multiple oral doses of KP-1461 in HIV+ adults who have failed two or more highly active antiretroviral regimens

KP-1461 is a pro-drug. The active metabolite incorporates itself into the proviral DNA. After multiple rounds of replication, the viral population becomes mutated beyond the threshold of viability. Thus, the virus mutates itself to death, or self-destructs.

Primary Objective: To assess the safety and tolerability of oral KP-1461 administered q12 hours for 14 days to cohorts of HIV+ subjects at successively higher doses.

Design: Cohorts of 10 subjects each will be randomized in a ratio of 4:1 to receive the study drug (KP-1461) or placebo. Subjects will discontinue antiretroviral therapy 14 days prior to dosing. Subjects will then be treated twice daily for 14 days, with an additional 14 days of follow up prior to restarting their antiretroviral medications. Three doses of this experimental medication will be tested.

Primary Endpoints: Safety and tolerability; dose finding for future development. If 2 or more subjects who receive KP-1461 have a clinically significant possible, probable, or definite study drug-related Grade ≥ 3 AE or clinical laboratory abnormality, dosing of the next cohort will be delayed pending review of all available safety data.

Duration: Each subject will participate in the study for 4 weeks (excluding

followed in a blinded manner for 58 days to determine virologic and safety responses. Patients who continue to show viral suppression or CCR5 blockade on day 59 should be followed until these parameters return to baseline. All patients in a cohort must complete the 29 day observation period before enrollment of the next cohort will be permitted.

Duration: approximately 2 months (not including the screening period)

Sample size: 40

Population:

- Males and females over 18 years of age
- HIV viral load greater than 5,000
- CD4 count greater than 250, and never less than 200
- Has not taken HIV medications in the last 3 months
- Normal EKG
- Chronic hepatitis B or C allowed as long as the patient is not symptomatic

POC: Onyine 410-706-5487

screening). Subjects may restart antiretroviral medications after the day 28 visit. If the subject restarts antiretroviral therapy, they will then be asked if they would be willing to participate in a longer follow-up. If so, blood will be collected for viral load and CD4+ count 4 to 6 weeks after re-starting antiretroviral therapy.

Sample Size: 40 subjects

Population:

- HIV+ adult men and women, ages 18-60 y.o.
- HIV viral load of 2,500 to 200,000
- CD4 cell count >100 cells/mm³ at screening
- Documented exposure to at least (2) different HAART regimens containing NRTIs, NNRTIs and at least two (2) protease inhibitors, excluding ritonavir, for a minimum of four months each (and switched because of inadequate viral suppression) OR documented resistance by genotypic and/or phenotypic analyses (historical or current) to at least three of the four classes of approved antiretroviral drugs AND in the opinion of the investigator, have few if any effective treatment options available.
- Subject needs to come off all antiretrovirals for at least 14 days prior to dosing of study medication

POC: Onyine 410-706-5487

IHV Applauds Marathon Man, *continued from page 1*



was at that point that he decided to pursue the goal of finishing a marathon, initially walking a few miles a day, then running. The runs became longer; but that wasn't enough. Bolger decided to initiate a fundraiser, called Running with JACQUES, and took pledges mostly from within the IHV. By the race's end, the drive had raised close to \$1,000 to give

Royal and Fort McHenry.

Several years ago, Bolger himself was so sick he could barely walk. He had numerous infections and wasn't on medication. "I was out of my mind really," he acknowledges. "I really didn't have any desire to live, to be honest." Bolger was diagnosed with HIV and with proper treatment, he has regained his strength and his health. With that intact, Bolger decided it was time to conquer new goals. "I have the energy now to give back that I didn't before," he recalls.

At the time, Bolger had taken a job at one of the university-affiliated gyms and was helping HIV patients who had volunteered to become part of an exercise study. The excitement was contagious and he soon became more goal-oriented himself, allowing no obstacles in his path. It

back to the Institute.

Personally, Bolger has begun playing the flute professionally again and would like to teach. He spends time reading, writing poetry, painting and completing other forms of art. He eats a healthy diet, practices yoga and meditation and is purging distractions such as television from his home. He sleeps on the floor. All, he says, in an effort to simplify his life and put his priorities in order.

"It hasn't all been a bed of roses," Bolger says of his remarkable recovery and his visible accomplishments. "The journey has been difficult. But it's been one filled with a lot of promise and hope. It all starts with a thought," he tells those who will listen. "The smallest little change in your belief system can change your whole life."

Patient Shares Words of Encouragement, *continued from page 1*

offer that same strength and encouragement himself.

"I've been taking my meds as honestly as I can. If I miss a dose, I make it up. That's my priority." He explains from a more direct perspective. "If you keep missing doses, you build a resistance to the drugs. Nothing will work and you will die."

Silver's viral load is undetectable now. "I love life. I love myself. And I love the people who have been there for me."

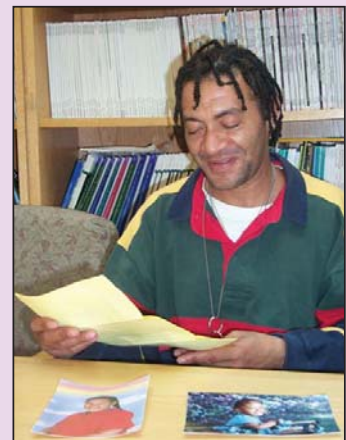
As for his pen pals, he says they talk of visiting the U.S.

"She has a lot of hope." He smiles. "I sparked something in her life. I made her laugh and gave her confidence in herself."

Sometimes success is as simple as that. "It's mind over matter," says Silver.

So he is now ready to answer questions, to give words of encouragement and to share a few words out loud or in writing.

"I guess from watching my wife go through what she did, it opened my eyes," Silver explains of the importance of a diligent approach



Willie Silver

to managing the disease proactively and letting HIV not manage you.

"My spirit was down and depressed at one time. I had given up, I guess. But Harriet and the others lifted my spirit up," he says. "Now I try to be as honest as I can. Someone dealing with the same thing, maybe you can give them hope."

Ask Dr. Kanno:



Dr. Metti Kanno

Q. How many people are currently living with HIV and has management of the virus gotten easier?

A. In 2003, more than 1 million people in the U.S. were estimated to be living with HIV. As a result of advances in treatment with Highly Active Antiretroviral Therapy or HAART since 1996, people infected with HIV are living longer than before and progression to AIDS has decreased.

Q. Who is most affected by AIDS?

A. The highest numbers of HIV/AIDS cases are concentrated among those ages 25-55 and correlates with increased participation in high-risk behaviors associated with HIV/AIDS. There are a growing number of teens and older adults who are diagnosed with HIV and the disease continues to be racially disparate. Although there has been a 5% decrease in AIDS among African Americans, rates among blacks remain 8.4 times greater than among whites. In the U.S., approximately 80,000 blacks, 45,000 whites and 29,000 Hispanics are living with HIV/AIDS. Among Asian Islanders, there has been a significant annual increase (9%) in HIV/AIDS cases; however, they still appear to be the least affected ethnic group.

Q. What are the reasons for these newest trends in HIV/AIDS?

A. The epidemic has continued to concentrate in groups that traditionally have had limited access to care. Women have a greater likelihood of encountering

high-risk heterosexual or bi-sexual male partners; there is a continued increase in risk behaviors such as having unprotected sex, especially in the men that have sex with other men (MSM); as well as a continued presence of unrecognized HIV/AIDS infection.

Q. In your opinion, what actions must be taken to curb the epidemic?

A. Prevention, prevention, prevention. We must recognize high-risk behaviors for what they are and promote safer sex. We must also ensure that resources are targeted to those at highest risk and establish partnerships between government public health programs and affected communities. Also, developing interventions that are culturally appropriate are essential in order to meet needs of all groups that are affected by the epidemic.

Q. What have been the most promising trends in recent years?

A. The significant annual decrease in HIV/AIDS detected in injection drug users has been one of the promising trends. The other positive impact has been the awareness and hence the participation of more states in name-based confidential HIV testing. To stop this pandemic, identification and management of every case, as well as broadened prevention techniques and public education, are absolutely essential.

HIV/AIDS headlines in the news

As AIDS cases grow, a call for new fight

Baltimore Sun
Feb. 7, 2006
By Jonathan Bor, Sun Staff

With Baltimore facing a growing AIDS caseload and an epidemic that increasingly strikes women, a city commission is urging officials to make good on a "state of emergency" declared three years ago.

Describing the city's response as splintered and lacking in direction, the group called yesterday for renewed attention to risk groups that also include African-American men and residents of hard-hit neighborhoods in West Baltimore.

"It's not an issue that's at the forefront as it used to be," Dr. William Blattner, the commission's chairman, said at a news conference. "But it's at the heart of the city and it's eating away at the heart."

Blattner and others lauded the city Health Department for its efforts to stem the epidemic but said there wasn't enough coordination among other city agencies—including housing, schools and social services.

"There really wasn't much of a response by the city agencies to this declaration of a state of emergency," Blattner, an AIDS epidemiologist at the University of Maryland Institute of Human Virology, said in an interview.

Although the number of new infections has fallen somewhat in recent years, the city has an ever-growing number of people living with the virus and needing services. This is due, in part, to the fact that new drugs and novel ways of combining them have made it possible for people to live much longer.

Certain neighborhoods beset by drug addiction, violence and poverty bear a disproportionate burden, especially those running along Park Heights Avenue, Liberty Heights Avenue and Reisterstown Road on the west side. One neighborhood, defined by the ZIP code 21217, has six percent of the city's population but 13 percent of people living with AIDS, according to the report.

Baltimore ranked fifth in the per-capita number of new AIDS diagnoses in 2003, trailing only New York, Miami, San Francisco and Fort Lauderdale, Fla. That year, almost 40 of every 100,000 people received the diagnosis.

The character of the AIDS epidemic

has shifted in recent years, with unprotected sex among heterosexuals overtaking needle-sharing as the leading mode of transmission. Also, women now account for about 40 percent of people diagnosed with AIDS—almost double the percentage diagnosed a decade earlier.

As it has for many years, the epidemic disproportionately strikes African-Americans, with 88 percent of new infections occurring within that group last year. Black men, according to the commission's report, are infected at 10 times the rate of whites.

Mayor Martin O'Malley declared a state of emergency on Dec. 2, 2002, after being lobbied intensely by black ministers and an AIDS commission organized by City Council President Sheila Dixon, who has lost family members to the disease.

A group called the Baltimore City Commission on HIV/AIDS was formed to monitor progress. There are 20 members, including doctors, clergy, business leaders and community activists. In the past year, the commission held monthly meetings to gather public input, leading to the drafting of a report and the news conference to discuss its key findings and recommendations.

O'Malley was not present yesterday, but spokeswoman Raquel Guillory later said the mayor was confident the city Health Department will implement better strategies to fight the disease.

"The report shows that we still have a lot of work left to do to fight the epidemic," she said.

Dr. Joshua Sharfstein, the city's new health commissioner, said the AIDS problem warrants a more focused response.

"Overall, the strain on the system is definitely increasing," he said. In 2004, there were about 14,000 people living with HIV infection or AIDS, compared with 4,100 a decade earlier.

Sharfstein said he is concerned about the future of federal funding through the Ryan White Act, which supplies \$19 million of the \$28 million being spent this year on AIDS prevention and treatment in Baltimore. Under a formula proposed by the Bush administration and pending before Congress, Baltimore could lose some Ryan White money that is allocated to the state and passed along to the city, he said.

Sharfstein said he plans to make available a new test at city health clinics that can detect genetic evidence of the virus immediately after a person is infected. The test now in use detects antibodies to the AIDS virus, which sometimes don't appear for a few months after infection.

Dr. Peter L. Beilenson, the former health

commissioner, said the city made significant inroads into the drug-related epidemic by drastically increasing the availability of drug treatment—including methadone—and starting the nation's largest city-run needle-exchange program.

But reducing sexual transmission is much harder, in part because much of it is driven by men who have unprotected sex with other men but don't identify themselves as gay. Some are married or involved in relationships with women, putting their female partners at risk.

One of the commission members, Dr. Rena Boss-Victoria of the Morgan State University School of Public Health, said many young men don't get tested, treated or educated about AIDS because they feel there is no hope for the future.

Terry Brown, a commission member who works with a group that provides mental health services in West Baltimore, said HIV infection in the prisons spills into the streets as inmates are released. In addition, children left unattended when their parents are incarcerated sometimes turn to prostitution to support themselves.

"Kids on the streets are having sex for survival," said Brown, a vice president of Baltimore Behavioral Health.

Shelton Jackson, a 28-year-old student at Morgan State, said he was surprised to find that people in Baltimore are reluctant to talk openly about being infected. Jackson said he has been HIV-positive for eight years.

"These last few years, I have been very open about my status—who I am," said Jackson, of Newark, N.J. "I got a lot of resistance after moving to Baltimore—people so shocked about my being open about being gay and about my status. We can't all be in the closet."

AIDS virus hits blacks harder in U.S.

Reuters

Just over half of new infections with the AIDS virus in the United States are in blacks, U.S. researchers reported recently.

A study of detailed data from 33 states shows that of 156,000 new cases of HIV infection between 2001 and 2004, 51 percent were in non-Hispanic blacks—although blacks made up just 13 percent of the population in those states.

The good news is that the rate of new infections declined in black women and in many black men—with the exception of men having sex with other men, the team at the U.S. Centers for Disease Control and Prevention reported.

The CDC's Tonji Durant and colleagues found that the rate of HIV diagnosis fell by 6.8 percent annually among black women and 4.4 percent annually among black men between 2001 and 2004.

The HIV diagnosis rate even fell by 9.7 percent every year on average among black male users of injected drugs, the CDC study found.

The human immunodeficiency virus that causes AIDS is spread by sex—homosexual and heterosexual—by sharing needles with someone who is infected, or via blood transfusions. Infected mothers can pass the virus to their babies.

The virus infects close to 40 million people worldwide and more than a million people in the United States. The CDC estimates that 40,000 Americans become infected with HIV each year.

A second study presented at the same conference found that 32 percent of black men in Baltimore who had sex with other men, which includes homosexual and heterosexual activity, were infected with HIV.

Greater attention to children affected by AIDS

Scoop Independent News

The international community must pay greater attention to children living with parents dying from AIDS as well as those who are themselves HIV-infected but lack access to appropriate treatments, the United Nations Children's Fund (UNICEF) reported recently.

"Children are missing from the world's response to the global AIDS pandemic," UNICEF Executive Director Ann M. Veneman said. "Less than 10 percent of the children who have been orphaned or made vulnerable by AIDS receive public support or services."

Orphans and other children traumatized by AIDS should receive counseling and psychosocial support, UNICEF said, adding that education is one of the most important weapons against the spread of AIDS. In countries with severe epidemics, young people with higher levels of education are more likely to use protective condoms and less likely to engage in casual sex than their less-educated peers. Educated children are also more likely to escape the poverty trap that ensnares orphans and forces children to take care of their sick or dying parents.



World AIDS Day

The Institute of Human Virology hosted and participated in a number of special events designed to promote community awareness of World AIDS Day on Dec. 1. Photos here show scenes from a candlelight vigil as well as a lecture series where speakers addressed the local and global AIDS epidemic. Original art created by the IHV's art therapy support group was on display in the IHV lobby as well as a photography exhibit that showed IHV staff at work around the world.

IHV

a center of
University of Maryland Biotechnology Institute
and affiliated with
University of Maryland Medical Center
University of Maryland School of Medicine



IHV PATIENT SUPPORT GROUPS

Art Therapy Group

Tuesdays, 1pm-2:30pm, EJC
POC: Lydia Cornelius, 410.328.0862

EJC Support Group

Wednesdays, 10:30am-Noon, EJC
POC: Katrina Clemons/Lydia Cornelius,
410.328.6527/410.328.0862

The Joe Jacques Support Group

Tuesdays, 6pm-8pm
IHV, First Floor Conference Room
POC: Jerry Thurber, 410.549.6537

The Gift of Life Support Group

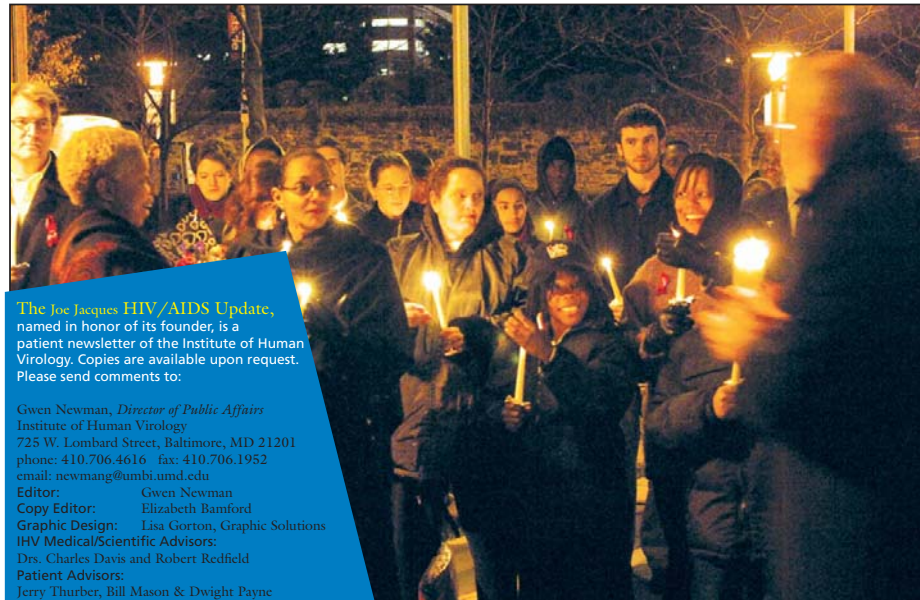
Saturdays, 2pm-4pm
New Song Community Church
1601 N. Calhoun Street
POC: Kathy Bennett, 410.448.1869

IHV Clinic Consumer Advisory Board

Second Tuesday of each month
Maryland General Hospital
IHV Clinic, 300 Armory Place
POC: Robyn Jones, 410.225.8387

HIV/HCV Co-infection Support Group

2nd and 4th Tuesdays, 4pm-6pm
IHV, First Floor Conference Room
POC: Bill Mason, 410.706.1477



The Joe Jacques HIV/AIDS Update, named in honor of its founder, is a patient newsletter of the Institute of Human Virology. Copies are available upon request. Please send comments to:

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IHV CLINIC LOCATIONS & HOURS

IHV physicians see patients in these off-site clinics:

Evelyn Jordan Center

16 S. Eutaw Street
Baltimore, MD 21201
410.328.1900

Mondays, 8am-3:30pm

Tuesdays, 9:30am-4pm

(9:30am-12:30am is women only)

Wednesdays, 8:30am-Noon

Thursdays, 8:30am-4pm

Fridays, 8am-2:30pm

Maryland General Hospital

827 Linden Street
Baltimore, MD 21201
410.225.8463

Mondays-Wednesdays, 8:30am-5pm

Thursdays, 8:30am-7pm

Fridays, 8:30am-3pm

Veterans Affairs Medical Center

10 Greene Street
Baltimore, MD 21201
410.605.7194 or 1.800.463.6295 ext. 7194

Wednesdays, 8am-Noon

HCV Clinic

Wednesdays, 1-4pm

Kaiser Permanente

10 Hopkins Place
Baltimore, MD 21201
410.263.7300

Mondays, 1-5pm

Thursdays-Fridays, Noon-5pm

visit: www.ihv.org