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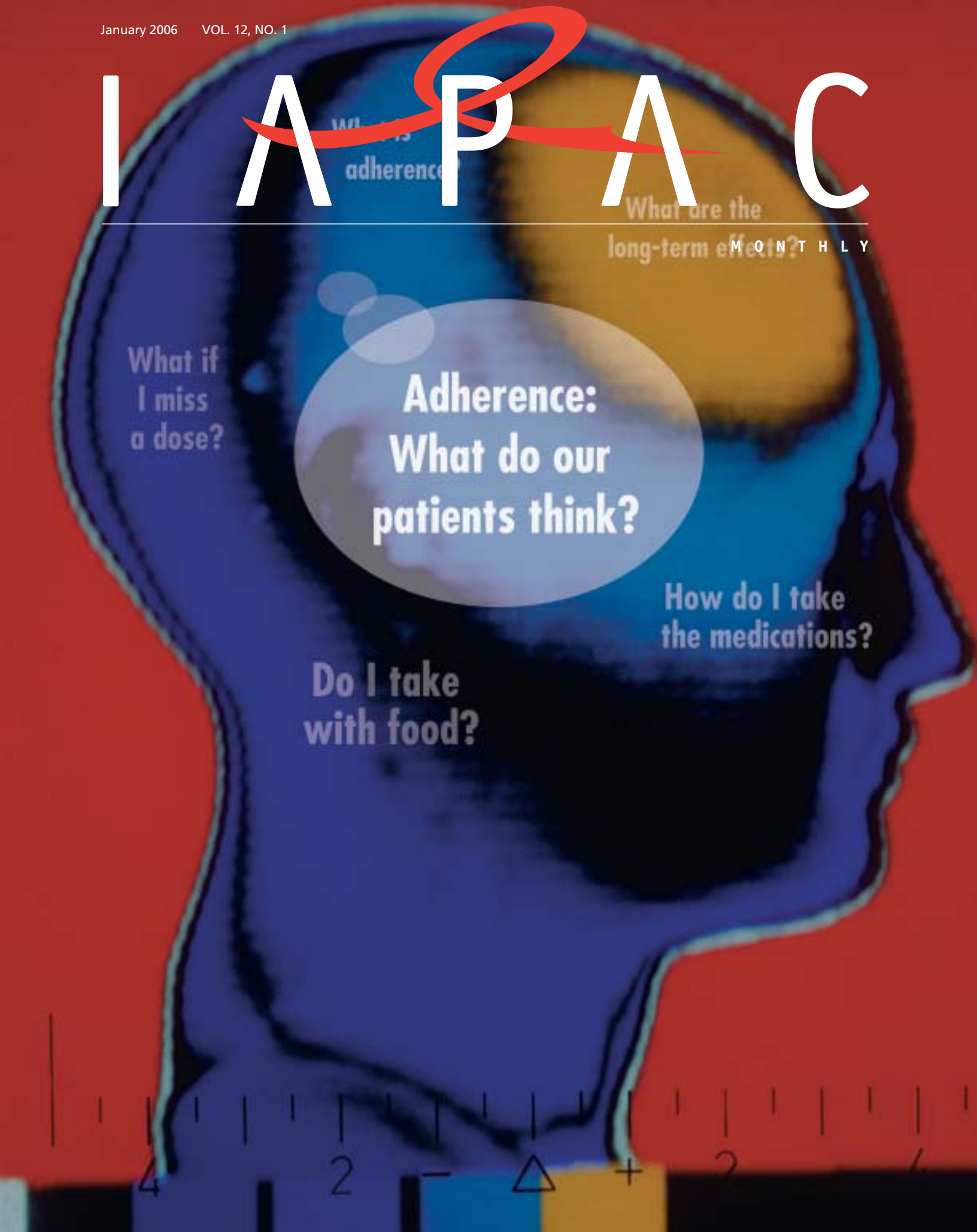

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12

Adherence: What our patients think

Judith Feinberg

Adherence is essential to getting the maximum benefit from antiretroviral therapy. But optimal adherence is difficult for many HIV-positive patients, and they and their health care providers often struggle with this subject. Judith Feinberg reports on an on-line survey of HIV-positive patients that revealed attitudes toward and compliance with adherence strategies.

DEPARTMENTS

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A coeur vaillant…

José M. Zuniga

With the decade anniversary of the advent of highly active antiretroviral therapy (HAART) upon us, I have found myself reflecting on 10 years of successes and disappointments, as well as pondering what the future holds for HIV/AIDS care and treatment. A call from an Associated Press reporter a few days ago reminded me of the winding, sometimes tortuous path we have followed in our attempts to control the epidemic and minister to HIV-positive patients. Indeed, throughout the past decade we have advanced, reversed course, and moved forward yet again, many times over. As the French proverb goes, "*A coeur vaillant, rien d'impossible*" (With a valiant heart, nothing is impossible).

To remind myself of the progress already made against this insidious disease, I re-read *AIDS Doctors: Voices from the Epidemic*, an oral history expertly edited by Ronald Bayer (Columbia University Mailman School of Public Health, New York) and Gerald M. Oppenheimer (Brooklyn College), and published in 2000 by Oxford University Press. In researching this chronicle the editors interviewed 76 US physicians whose stories reflected the starting point of a dramatic arc that took us from a time in which HIV disease was considered a death sentence to a time in which it has for many gradually transformed into a serious, yet potentially manageable, chronic condition.

In the face of a burgeoning AIDS epidemic in New York City in 1984, Victoria Sharp[1] worked as a resident in the emergency room at Roosevelt Hospital in Manhattan. She tells of a patient who complained that he was a little short of breath when he climbed the stairs from

the subway. "Two weeks later [he was] dead," Sharp recalls. "Not one patient that we sent to the [Intensive Care Unit] on a respirator ever came out."

In 1987, the first antiretroviral drug—the nucleoside reverse transcriptase inhibitor (NRTI) zidovudine (ZDV)—was approved, a momentous event in the history of HIV treatment. James Campbell,[2] a San Francisco physician who treated many of the earliest HIV-positive patients in the Bay Area, was alarmed by the ravaging nature of HIV disease. "I was just as scared as they were, and much of the time didn't really know what to say to reassure them. I said, 'Everything will be okay.' They would look at me and ask, 'Are you sure?' And I would think, 'No, I'm not sure.'"

By the mid-1990s, four more NRTIs (didanosine [ddI], zalcitabine [ddC], lamivudine [3TC], and stavudine [d4T]) had been approved, allowing physicians more options in attacking the virus. After the approval of this limited number of antiretroviral drugs, New York City gastroenterologist Donald Kotler[3] and his fellow physicians continued to feel hopeless as their patients continued to die, notwithstanding the potent new antiviral weapons at their disposal. "After the first time, are you going to be stupid enough for the second drug? For ddI? Is that the cure? Is d4T the cure? Is 3TC the cure? What it takes to not be a stupid fool is to accept the fact the first time you see the patient that the patient will die of this disease."

What allowed many of the pioneers in HIV medicine to keep fighting in spite of the perceived invincibility of the rampant disease? For Los Angeles physician Jerome Groopman[4] and many of his colleagues, the answer in the mid-1990s was faith. "I believe, right? That's the basis of faith. I believe that science has the potential to improve the situation. It has the creative impulse. There's no guarantee that it will happen or that the time frame will be anything that we want, but it's done it before, and I think it has a real possibility of doing it again."

It is that faith (and investment) in science, as well as the courage to persevere and act unconventionally, that have brought us to where we are today. Health care professionals worked day after day with desperately ill people despite being fully aware that they had no way to cure this disease. Researchers used the data collected in the essentially *ad hoc* laboratories of physicians' practices to discover revolutionary new therapeutic interventions. Thanks to these efforts, slow but steady progress was made, and momentum built as the years passed. By building the ship as it was sailing, physicians, nurses, allied health care professionals, and, as important, millions of HIV-positive patients (some still with us, many long passed),

stared the human immunodeficiency virus in the face, defiant against its seeming implacability.

Further progress was made when the first protease inhibitor (PI), saquinavir (SQV), was approved in 1995, and the first nonnucleoside reverse transcriptase inhibitor (NNRTI), nevirapine (NVP), followed in 1996. That year was the first to record a decrease in annual AIDS deaths in the United States, reflecting the benefit of both the new antiretroviral drugs and the increasing expertise of physicians in prescribing those drugs. The tenacity and willingness of patients to suffer discomfort was also important in the days before simplified dosing, when regimens were complex and difficult, with some patients taking 30 pills per day. Since then several more drugs in the NRTI, NNRTI, and PI classes have been approved; simplified dosing of and reduced pill burdens for previously cumbersome antiretroviral regimens have improved adherence; and science gave birth to an entirely new class of antiretroviral drugs, the fusion inhibitors.

What does this expansion and subsequent re-tooling of the antiretroviral drug armamentarium mean? Rochelle Walensky (Harvard Medical School, Boston) presented data at the 12th Conference on Retroviruses and Opportunistic Infections (CROI) showing that 2 million patient life-years have been saved due to HAART in the United States;[5] indeed, in the decade since HAART's advent, deaths from AIDS have dropped by more than 60% in the United States, falling from a peak of 48,000 in 1995 to approximately 16,000 in 2004. Similar decreases have been noted in Western Europe and Australia. Almost overnight, HAART created a generation of what Lisa Sterman (University of California, San Francisco) calls "HIV survivors."

That is not to say we should be lulled into a sense of complacency. Each day the medical literature reminds us that survival comes with a price. HIV-positive patients face side effects, including some life-threatening toxicities; antiretroviral drug resistance; and some antiretroviral regimens that still hinder adherence. Still, while the challenges looming ahead may be daunting and humbling, they are nonetheless accompanied by a wealth of previously unimagined opportunities.

To help consolidate the hard-won wisdom of the last 10 years and attempt to apply that knowledge to the future, the International Association of Physicians in AIDS Care (IAPAC) will host an historic two-day meeting entitled, "Decade of HAART: Historical Perspectives and Future Directions." Scheduled to take place September 25-26, 2006, in San Francisco (immediately preceding the 46th Interscience Conference on Antimicrobial Agents and Chemotherapy [ICAAC]), the objective of this meeting is to review our collective progress and prospects, in an attempt to forecast HAART's impact over the next decade.

The first day of the meeting will feature cohort leaders from 12 countries with 10 years' experience in the delivery of HAART—Australia, Canada, Denmark, France, Germany, Italy, Mexico, The Netherlands, Spain, Switzerland, the United Kingdom, and the United States—who will be asked to discuss issues such as common clinical practices being challenged by new data, the greatest threats to HIV containment and viral control, and the pressing issues for HIV research in the next decade. The second day of the meeting is dedicated to projections regarding the impact of HAART through 2008 in five critical areas: morbidity and mortality, prevention, cost, cardiovascular health, and antiretroviral drug resistance. I extend a warm invitation for your participation.

As Anthony M. Fauci (US National Institute of Allergy and Infectious Diseases, Bethesda) reminds those of us who fill conference lecture halls to absorb his sage words, it is obviously not enough to look back: "The catastrophic potential of the [AIDS] pandemic may still not have been fully realized." But only by reflecting upon what has been accomplished over the past decade from both a scientific and public health perspective can we effectively plan our ongoing engagement with the viral equivalent of a weapon of mass destruction. ■

José M. Zuniga is President/CEO of the International Association of Physicians in AIDS Care (IAPAC), and Editor-in-Chief of the IAPAC Monthly.

Notes/References

1. Victoria Sharp is currently the Director of the HIV Center for Comprehensive Care at St. Luke's-Roosevelt Hospital Center in New York City.
2. James Campbell has retired from his private practice in San Francisco.
3. Donald Kotler is now Chief of the Division of Gastroenterology and Liver Disease at St. Luke's-Roosevelt Hospital Center in New York City.
4. Jerome Groopman is now the Dina and Raphael Recanati Chair of Medicine at Harvard Medical School in Boston; he is also Chief of Experimental Medicine at the Beth Israel Deaconess Medical Center.
5. Walensky RP, Paltiel A, Losina E, *et al*. Two million years of life saved: The survival benefits of AIDS therapy in the United States. 12th Conference on Retroviruses and Opportunistic Infections. February 22-25, 2005. Boston, Massachusetts. [Abstract 143LB]

Zuniga to remain at IAPAC helm through 2008

The Board of Trustees of the International Association of Physicians in AIDS Care (IAPAC) voted in November 2005 to approve a contract renewal with José M. Zuniga, extending his term as President/CEO through December 2008.

In making the announcement, IAPAC Chairman Allen I. Freehling stated that under Zuniga's leadership during the past six years, "IAPAC has transformed itself into one of the world's leading professional medical associations addressing the needs of men, women, and children living with HIV/AIDS. We look forward to another three years of strong and inspired leadership as we meet the opportunities and challenges in the rapidly changing world of HIV medicine."

Zuniga, who has served as IAPAC's chief executive since December 1999, said he is "honored to serve at the pleasure of a Board of Trustees that offers both guidance and support, with a dedicated international membership of physicians and allied health care professionals whose lives are dedicated to the well-being of their patients, and through a cadre of staff that is committed to advancing our work." He added that the years ahead pose a unique challenge for IAPAC and the broader HIV/AIDS community, "one we must meet with innovation, collaboration, and commitment." ■

48-week RESIST data confirms TPV benefit

Chris Gadd

Findings from the Randomized Evaluation of Strategic Intervention in Multi-Drug ResiStant Patients with Tipranavir (RESIST) studies have shown that the new protease inhibitor (PI) tipranavir (TPV) continues to provide potent activity against HIV in patients with substantial treatment experience after 48 weeks of treatment. The data were presented at the 10th European AIDS Conference, held November 17-20, 2005, in Dublin.

Tipranavir is the latest PI to be approved in Europe and the United States, where it is licensed for use in patients who have experienced failure of previous PI-based regimens. The drug's approvals were based on 24-week data from the phase 3 RESIST-1 and RESIST-2 studies, showing that patients taking TPV had better outcomes than those in a comparator group.

The results of the 48-week follow-up of the two studies were presented in a combined fashion at the Dublin conference because the two studies are similar in their design. The studies recruited 1,483 patients with experience of all three major classes of antiretroviral drugs. For inclusion in the study, the participants were required to have taken at least two PI-based regimens and to have at least one primary PI mutation. All of the patients were taking a failing PI-based regimen, with a viral load above 1,000 copies/mL.

The investigators randomized patients to receive either 500 mg of TPV twice daily boosted with a twice-daily dose of 200 mg of ritonavir (RTV), or a comparator PI. This PI consisted of the best option, based on resistance testing, from a choice of RTV-boosted lopinavir (LPV), indinavir (IDV), saquinavir (SQV), or amprenavir (APV). All patients also received an optimized background regimen that was chosen for each patient based on the results of genetic testing.

At 48 weeks, 34% of the patients taking TPV had a viral load at least 1 $\log_{10}$ lower than at the start of the study. This compared to 15% in the comparator arm, a difference that was highly statistically significant ($P < 0.001$). There was also a highly significant difference in the time to treatment failure. While the median time to failure was 113 days in the TPV arm, more than half of the patients in the comparator arm did not respond to their drug combination, resulting in a median time to failure of zero days ($P < 0.001$). This corresponded to a 37% lower probability of treatment failure in the TPV-treated patients ($P < 0.001$).

The superior outcome in the patients taking TPV was also reflected in the mean reduction in viral load (1.14 versus 0.54 $\log_{10}$; $P < 0.001$) and in the proportions of patients with viral loads below 50 copies/mL at the end of the 48-week follow-up (23% versus 10%; $P < 0.001$). The TPV group also had greater increases in CD4 counts (44.8 versus 21.1 cells/mm^3; $P < 0.001$).

As in the 24-week results, the potency of TPV was greater when it was combined with additional active antiretroviral drugs, particularly enfuvirtide (ENF). The side effect profile was also similar in the 48-week analysis. While the incidence of severe side effects was similar across the two arms, more patients taking TPV experienced elevations in liver enzymes and blood fats. ■

Editor's Note: *Reprinted with permission from www.aidsmap.com (first e-published November 30, 2005, and November 28, 2005, respectively).*

Reference

Cahn P, Hicks C. RESIST-1 (R-1) and RESIST-2 (R-2) 48 week meta-analyses demonstrate superiority of protease inhibitor (PI) tipranavir + ritonavir (TPV/r) over an optimized comparator PI (CPI/r) regimen in antiretroviral (ARV) experienced patients. 10th European AIDS Conference. November 17-20, 2005. Dublin, Ireland. [Abstract PS3/8]

LPV monotherapy: 72-week data

A small pilot study has shown that ritonavir (RTV)-boosted lopinavir (LPV) taken alone is effective in controlling HIV after up to a year and a half of follow-up. These findings were presented at the 10th European AIDS Conference, held November 17-20, 2005, in Dublin.

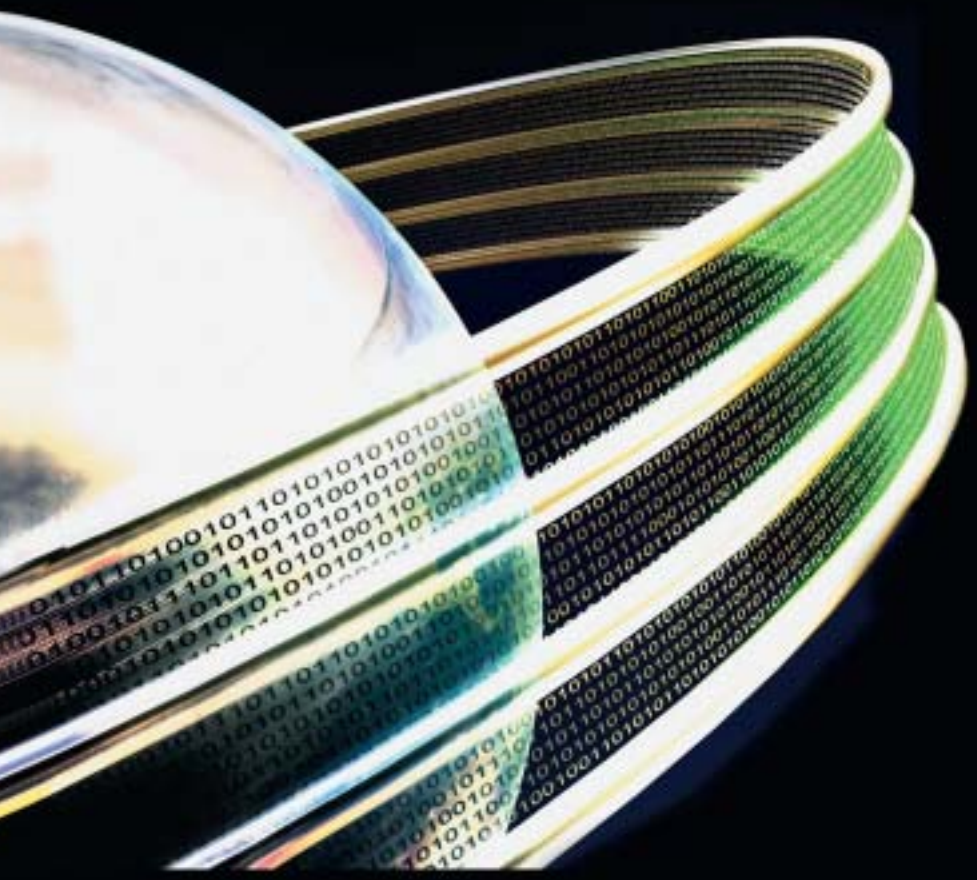
The Only Kaletra (OK) study is a small open-label trial being carried out in Spain. Its aim is to assess the anti-HIV activity of simplifying treatment from a successful three-drug antiretroviral regimen to LPV monotherapy. The investigators recruited 42 patients for the study, all of whom were taking LPV plus two nucleoside reverse transcriptase inhibitors (NRTIs), and had had viral loads below 50 copies/mL for at least six months. The patients were randomized to remain on their LPV-based regimen or to stop taking the NRTIs but continue with LPV monotherapy.

After 72 weeks, 81% of the patients taking LPV alone had viral loads below 50 copies/mL. This was similar to the proportion in the three-drug group (91%; $P = 0.38$). The two groups also had similar increases in CD4 counts (112 versus 50 cells/mm^3; $P = 0.31$). Four patients in the monotherapy arm experienced virological failure, but no consistent pattern of resistance mutations in the protease gene was seen. All four patients managed to re-suppress their HIV to below 50 copies/mL after re-introduction of the NRTIs. The investigators did not observe any serious side effects across the two arms. ■

Reference

Pulido F, Arribas J, Delgado R, *et al*. Lopinavir/ritonavir as single drug for maintenance of HIV-1 viral suppression. A randomized, controlled, open label, pilot, clinical trial (OK Study): 72 weeks analysis. 10th European AIDS Conference. November 17-20, 2005. Dublin, Ireland. [Abstract PE7.5/5]

IAPAC joins World Community Grid



Members urged to help fight AIDS with their computers

Imagine if each of the world's estimated 650 million personal computers (PCs) were linked to focus on fighting AIDS. To make this dream a reality, the International Association of Physicians in AIDS Care (IAPAC) has become a partner of World Community Grid, joining the IBM Corporation and more than 60 associations, companies, foundations, and academic institutions.

World Community Grid establishes a permanent, flexible infrastructure that provides researchers with a readily available pool of computational power that can be used to solve problems plaguing humanity. Grid technology joins together many individual PCs, creating a large system with massive computational power that exceeds the power of a few supercomputers.

Over the past year, World Community Grid ran the Human Proteome Folding Project, which has been providing scientists with data on how individual proteins within the human body affect human health, enabling them to identify new candidate drugs for diseases such as malaria and tuberculosis. Scientists now have descriptions of 120,000 protein domains that are critical to human well-being; without the benefit of this free grid technology, it would have taken five years to achieve these results, compared with just 12 months on World Community Grid.

World Community Grid launched FightAIDS@Home on November 21, 2005. Sponsored by The Scripps Research Institute, FightAIDS@Home is using computational methods to design therapeutic approaches that are effective in the treatment of HIV/AIDS in the face of antiretroviral drug resistance. The pool of potential drug molecules, as well as that of possible mutant HIV proteins that may evolve, is enormous. World Community Grid's massive computing power will address the prediction of relevant interactions between these two pools of molecules to design a new generation of AIDS therapies.

"World Community Grid is a promising and innovative way of helping reduce the impact of AIDS around the world," said José M. Zuniga, IAPAC President/CEO. "We are proud to be a partner and help further this important research effort."

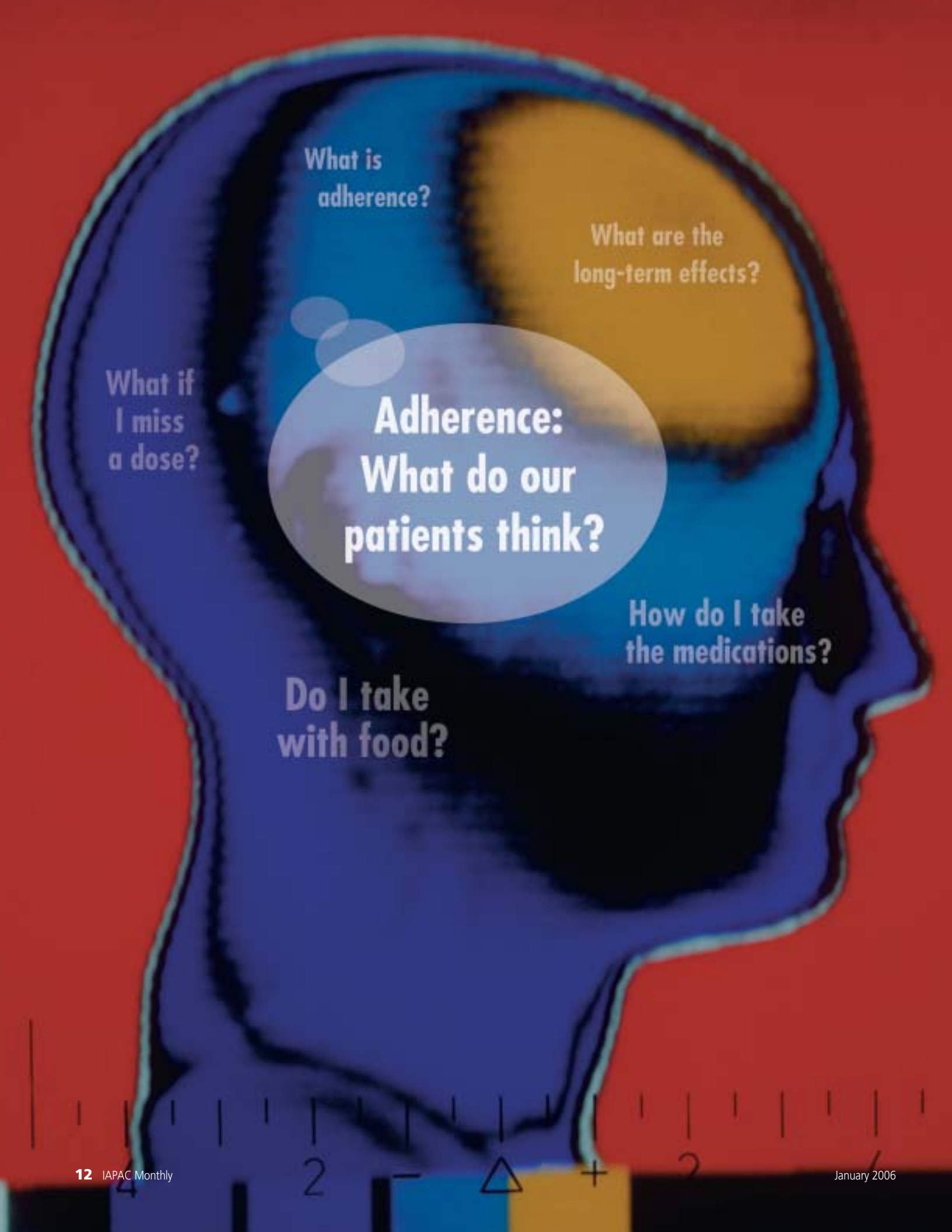
IAPAC is encouraging members to contribute their idle PC time to World Community Grid as "IAPAC Team" members. Visit www.worldcommunitygrid.org and click on the IAPAC logo located on the Partners page. You will next download and install a free software program on your PC. Once installed, and when your PC is idle, it will request data from the World Community Grid's server. Your PC will perform computations using these data, send the results back to the server, and prompt the server for more work. ■

An ounce of prevention ...

Counsel your HIV-positive patients about safer sex. An ounce of prevention is worth everyone's effort!

IAPAC

battling complacency
advancing commitment


What is adherence?
What are the long-term effects?
What if I miss a dose?
Adherence: What do our patients think?
How do I take the medications?
Do I take with food?

By gaining a better understanding of our patients, we improve our ability to focus on their specific needs; after all, if our patients do not take their medications as prescribed, we cannot strive to win the battle against HIV.

Judith Feinberg

Adherence is essential to getting the maximum benefit from antiretroviral therapy (ART). Non-adherence can lead to higher viral loads and viral resistance, while proper adherence is linked with viral suppression.[1,2] Data show that adherence of ≥95% is needed for effective viral suppression.[3] Adherence to antiretroviral drugs is critical because of the increased risk of developing drug resistance and, according to the US Department of Health and Human Services (DHHS) HIV/AIDS Bureau, "a treatment's success can begin to diminish when patients are less than 95% compliant."[1]

But optimal adherence is difficult for many HIV-infected patients, and they and their health care providers often struggle with this subject.[4] In order to gain insight into how patients view adherence and how we as health care providers can help them to achieve better adherence, a recent Internet-based survey of people living with HIV asked participants how well they followed their prescribed antiretroviral regimens, whether any problems were contributing to nonadherence, and what adherence strategies they have found useful. This survey is one of the largest national surveys administered on this topic to date. By gaining a better understanding of our patients, we improve our ability to focus on their specific needs; after all, if our patients do not take their medications as prescribed, we cannot strive to win the battle against HIV. The following is an overview of the survey and its findings.

The survey was conducted online in June 2005 by Richard Day Research of Evanston, Illinois, and was underwritten by Bristol-Myers Squibb. To take part in the survey, the participants had to be HIV-positive and currently on ART.

The survey consisted of 52 questions, many of which had multiple subtopic areas. Many questions were framed in a multiple-choice format; some were open-ended with a write-in category. A number of questions asked the respondents to rank-order their answers. The survey was designed by Richard Day Research and edited by the author.

A total of 403 HIV-infected persons taking ART responded to the survey invitation over a four-day period (June 2-6, 2005).[5] The average age was 45; ages ranged from 19 to more than 60 years old.[5] Eighty-one percent of respondents were men; 75% were white, 12% were black or African American, and 7% were Hispanic or Latino.[5] Twenty-eight percent were heterosexual; the rest described themselves as gay or bisexual (2% preferred not to answer the question).[5] On average, survey participants had been diagnosed with HIV 11 years ago, had been on HIV treatment for eight years, and had switched treatment regimens four times.[5] Only 16% were still taking the regimen that they had been initially prescribed.[5] The main reasons for switching medications were side effects (the reason stated by 39% of respondents for their most recent switch) and ineffectiveness of the regimen (38%).[5]

In this survey, "complete adherence" was defined as taking all antiretroviral drugs on time at least 95% of the time. It was clear that participants had some misconceptions about what it means to be adherent, even though they had an average of eight years of experience taking antiretroviral drugs.[5] While 85% reported they understood how to take their medications properly, only 69% reported "complete adherence."[5] Fifty-five percent and 38%, respectively, reported it was "very easy" or "somewhat easy" to take all their medications every day at the correct time; 40% said doing so was "much easier" and 20% felt it was "a little easier" than they had expected, while only 12% felt it was more difficult.[5] The vast majority (91%) felt confident they are able to take their medications when they are supposed to, and almost as many (87%) reported feeling both a strong commitment to taking their medications correctly and to following their health care provider's orders *exactly* as to when to take their medications and with what food restrictions (if any).[5] Eighty-five percent said they understood "very well" the requirements of their medications, including what they were supposed to take, at what times, and whether to take their medications with food or on an empty stomach.[5] Thirteen percent said they "somewhat" understood the requirements of their regimens.[5]

The good news from this survey is that more patients are sticking to their regimens. Eighty-five percent believed taking their medications will have a positive effect on their health, and 66% reported that taking their antiretroviral drugs has improved their quality of life in a number of specific ways.

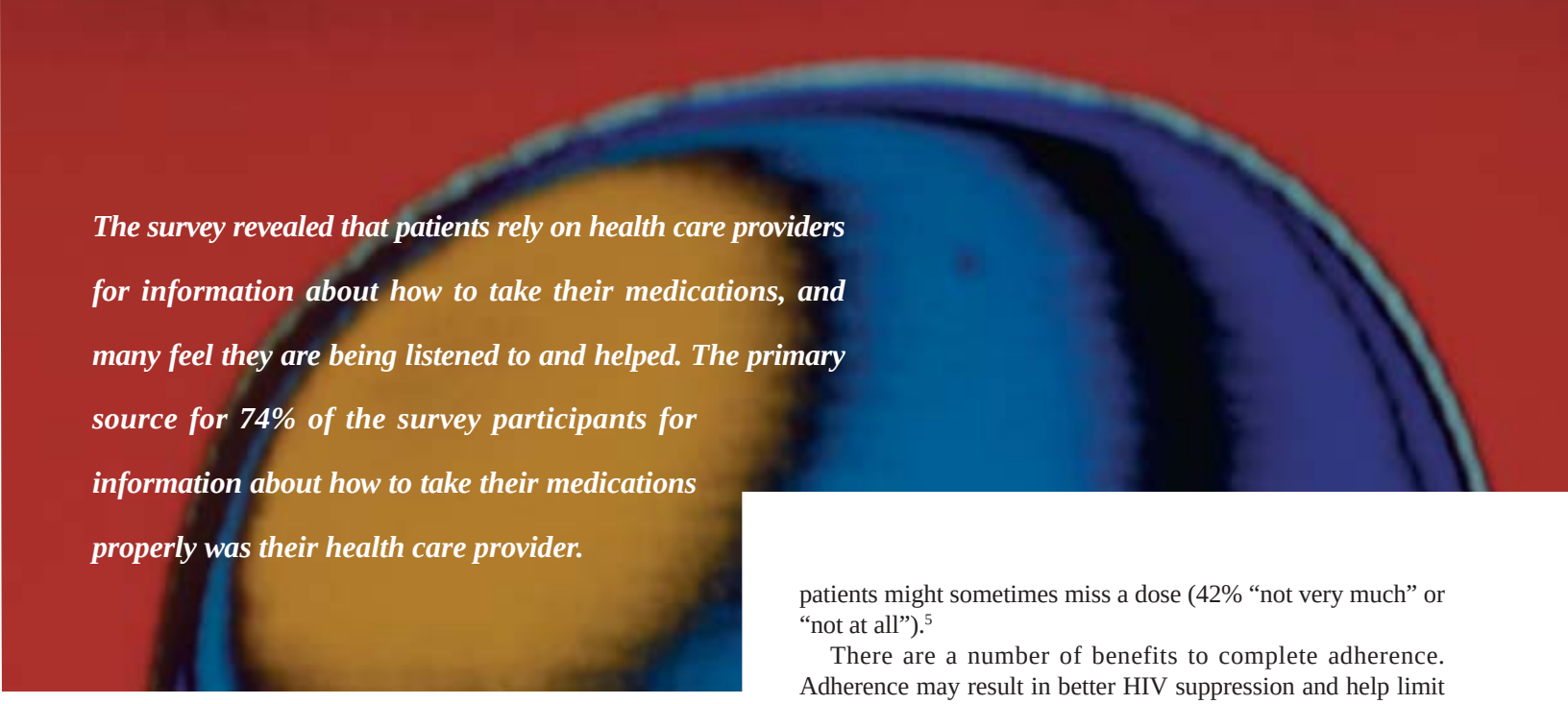
However, despite confidence in and commitment to staying adherent, a sizable minority of patients was not as successful as is required for optimal outcomes. As this survey defined adherence in terms of doses missed or taken late, the results showed only 48% of survey participants were considered adherent.[5] Based solely on the number of doses *missed* during the past seven days, 69% were considered adherent (defined as taking 95% or more of all required doses), while 31% were not.[5] Sixty-six percent said they were fully adherent in that they had not missed a single dose in the past week, while 17% reported missing a single dose and another 17% reported missing two or more doses within the past seven days.[5] Fifty-five percent agreed or somewhat agreed it was acceptable to take their medications earlier or later than the prescribed dosing intervals if they had a busy or changing schedule.[5] The following beliefs were elicited: 20% said they believed their health would be okay even if they do not take all pills when they are supposed to; 14% believed it is acceptable to miss a dose every few days; and 10% thought it was all right to miss a dose as long as they made up for it with an extra dose the next time a dose was scheduled to be taken.[5]

Study participants were taking an average of 13 pills each day, of which seven were antiretroviral drugs; 61% were on twice-daily dosing and 18% were on once-daily dosing.[5] Compared to when they first began ART, almost half (43%) stated they have become more consistent in taking their antiretroviral drugs, while 10% have become less so and 18% said their adherence varies.[5] The primary reason for becoming more adherent (cited by 33% in open-ended format) is that patients were taking regimens with better dosing schedules.[5] Nineteen percent reported their adherence had improved once they got used to taking their medications and it became routine.[5]

Why is adherence still such a thorny issue? According to survey participants, the primary reason for becoming less adherent (cited by 29% in open-ended format) is due to being busy with work or life demands.[5] More than one third (38%) reported that although they "strongly" or "somewhat agree" that they want to take their medications, they sometimes forget or fall asleep.[5] Twenty-two percent said forgetting to carry their medications with them when they were away from home was a problem.[5] Psychological and personal control issues are important barriers for some patients, who do not yet feel they are managing HIV as they continue to be challenged by side effects and by disruptions to their daily routines and eating habits. Consistently, one quarter to one third of respondents felt they are not yet controlling how HIV affects their lives: 33% reported they have had to tailor their lives to their HIV treatment regimen, 24% agreed that "HIV is controlling me, instead of me controlling it," and 37% said having to take antiretroviral drugs means having less freedom.[5] Twenty-seven percent felt having to take antiretroviral drugs was embarrassing.[5]

While 87% felt a strong commitment to taking their antiretroviral drugs as prescribed, side effects (47%), feeling ill (21%), or being depressed (23%) were the most frequently cited reasons offered for why adherence can be difficult.[5] Respondents reported that the following side effects had the greatest influence on adherence: fatigue (42%), diarrhea (40%), nausea (29%), problems with sleep (28%), depression (26%), and body shape changes (26%).[5] In addition, 34% cited concerns about the long-term effects of antiretroviral drugs as a reason staying adherent to ART can sometimes be difficult.[5] Although cited less often than side effects, other barriers to adherence included too many pills to take at one time (23%); difficulty coordinating medications with one's daily schedule, with a changing schedule, or with a job (19%); pills too large and hard to swallow (19%); or difficulties when medications need to be taken with food (19%).[5] However, it is noteworthy that the *frequency of dosing* was cited as a major barrier by only 11%.[5] In open-ended format, 46% of respondents cited "being too busy" and "forgetting" as the top reasons for having missed specific doses or having taken them late within the past seven days.[5]

The good news from this survey is that more patients are sticking to their regimens. Eighty-five percent believed taking their medications will have a positive effect on their health, and 66% reported that taking their antiretroviral drugs has improved their quality of life in a number of specific ways: feeling in control of HIV (62%), worrying less about having HIV (44%), feeling healthier (43%), possessing a sense of well-being (41%), and thinking about having HIV less often (32%).[5] Fifty-



The survey revealed that patients rely on health care providers for information about how to take their medications, and many feel they are being listened to and helped. The primary source for 74% of the survey participants for information about how to take their medications properly was their health care provider.

seven percent of participants were focused on controlling their viral load as the most important reason they are adherent.[5]

Sixty-two percent have been able to work with their health care providers to tailor antiretroviral regimens that suit their lifestyle.[5] Patients said taking personal responsibility for their own success was essential, and recommended strategies to keep dosing easy and pills accessible. Ninety-three percent declared *they* themselves had the strongest influence on their success with adherence; 22% cited the influence of their health care providers, and 20% relied on immediate family members and partners.[5] The most effective adherence strategies were ranked and the ones most frequently cited were using a pill container (48%), keeping pills in an obvious place (42%), switching to simpler regimens with lower pill burdens (40%), linking dosing to specific aspects of their daily routines (37%), working with their provider to tailor a regimen that suits their daily schedule and lifestyle (20%), and switching to a regimen with more tolerable side effects (30%).[5]

The survey revealed that patients rely on health care providers for information about how to take their medications, and many feel they are being listened to and helped. The primary source for 74% of the survey participants for information about how to take their medications properly was their health care provider; no other source was rated as the primary source for such information by more than 6% of the respondents.[5] This finding underscores the fact that the patient-provider relationship is as important in successfully managing HIV disease as it is for other lifelong chronic illnesses. Topics that were stressed by respondents' health care providers included the importance of taking medications according to schedule (61% discussed this with their health care provider "a lot," 28% did "somewhat"), expected side effects (52% "a lot," 33% "somewhat"), reviewing a dosing schedule in detail (45% "a lot," 37% "somewhat"), how to manage side effects (45% "a lot," 34% "somewhat"), and what to do if a dose is missed (43% "a lot," 34% "somewhat").[5] Areas that were less well covered include strategies and tips to maintain adherence (34% discussed this with their health care provider "not very much" or "not at all"), and reasons why patients might sometimes miss a dose (42% "not very much" or "not at all").[5]

There are a number of benefits to complete adherence. Adherence may result in better HIV suppression and help limit the emergence of resistance. As this survey showed, other important benefits are the improved sense of control over HIV infection reported by 62% of respondents, less worry about having HIV (44%), feeling healthier (43%), and possessing a sense of well-being (41%).[5]

However, it is disappointing that nearly one quarter (22%) of the survey respondents did not believe their health care providers really understood how hard it is for them to take their antiretroviral drugs.[5] Twenty-six percent said they had not been given a choice of antiretroviral regimens that would suit their lives best.[5] According to the DHHS, health care providers *can and should* adjust regimens to suit a patient's lifestyle, and address other issues such as side effects.[6] When this is done, the chance of adherence success has been found to increase.[1]

It is reassuring that this survey showed better overall adherence than has been estimated in the past for other chronic diseases, where it averaged about 50%.[1] However, there is still much health care providers need to know in order to counsel their patients on how to successfully adhere to their HIV medications. Adherence is both the challenge of a lifetime and a challenge *for* a lifetime. To best support our patients and help them derive maximum benefit from therapy, we need to work together with our patients every step of the way. We must have candid, straightforward discussions about side effects and lifestyle/schedule issues that can affect adherence, and we must be attentive to our patients' concerns. ■

Judith Feinberg is Professor of Medicine at the University of Cincinnati.

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Clinical Infectious Diseases

Virological control during the first six to 18 months after initiating highly active antiretroviral therapy as a predictor for outcome in HIV-infected patients: A Danish, population-based, six-year follow-up study

Lohse N, Kronborg G, Gerstoft J, et al.

BACKGROUND: Our objective was to examine whether virological control during the first six to 18 months after highly active antiretroviral therapy (HAART) initiation is a predictor for viral suppression, CD4 count increase, and mortality in human immunodeficiency virus (HIV)-infected patients 18 to 90 months after initiation of HAART. *METHODS:* We conducted a population-based observational cohort study in Denmark. Patients were divided into three groups, according to the proportion of time each patient had a detectable HIV RNA load (ie, ≥400 copies/mL) during the six to eight months after HAART initiation: 0% of the time interval (group 1), 1% to 99% of the time interval (group 2), and 100% of the time interval (group 3). The proportion of patients with undetectable HIV RNA, CD4 count changes, and mortality were examined by logistic, linear, and Cox regression analyses, respectively. We constructed cumulative mortality curves. *RESULTS:* We observed 2,046 patients, for a total of 8,898 person-years of follow-up that started at 18 months after HAART initiation. Mean CD4 count increase rates during 72 months of follow-up were as follows: group 1, 3.3 x 10^6 cells/L per month (95% confidence interval [CI], 2.9 to 3.7 x 10^6 cells/L); group 2, 2.9 x 10^6 (95% CI, 2.5 to 3.3 x 10^6 cells/L); and group 3, 2.6 x 10^6 (95% CI, 2.0-3.3 x 10^6 cells/L). Survival at 72 months was as follows: group 1, 92.7% (95% CI, 90.5% to 94.4%); group 2, 85.6% (95% CI, 82.1% to 88.5%); and group 3, 76.1% (95% CI, 70.6% to 80.7%). At 72 months, 96% of group 1, 83% of group 2, and 57% of group 3 had an HIV RNA load of <400 copies/mL ($P < 0.01$). Treatment interruption before baseline was a predictor of mortality in group 2 (adjusted rate ratio, 2.94; 95% CI, 1.75 to 4.92]). *CONCLUSIONS:* Viral suppression during the first six to 18 months after HAART initiation predicts viral suppression, CD4 count progression, and survival at 72 months.

Clin Infect Dis. 2006;42(1):136-144.

Journal of Acquired Immune Deficiency Syndromes

Structured treatment interruptions in primary HIV-1 infection: The ANRS 100 PRIMSTOP Trial

Hoen B, Fournier I, Lacabaratz C, et al for the PRIMSTOP Study Group.

BACKGROUND: Whether structured treatment interruptions (STIs) can induce anti-HIV immune response and control HIV replication following discontinuation of highly active antiretroviral therapy (HAART) in patients with primary HIV infection is controversial. *METHODS:* In this multicenter, prospective trial, patients with early symptomatic primary HIV infection were given HAART continuously for 34 weeks. Afterward, patients with plasma viral load (PVL) <50 copies/mL entered the STI phase, which consisted of three consecutive periods of two, four, and eight weeks off HAART, each separated by 12 weeks on HAART. Highly active antiretroviral therapy was permanently stopped at week 84 and patients were followed up for 24 weeks. The primary endpoint for definition of virologic success was a PVL <50 copies/mL during the six months following HAART discontinuation. *RESULTS:* Of the 29 patients enrolled, 26 completed the trial. Six months after HAART discontinuation, only one patient (3.8%, 95% confidence interval [CI]: 0.1% to 19.6%) had PVL <50 copies/mL, whereas six of 26 (23.1%, 95% CI: 9.0% to 43.7%) had PVL <1,000 copies/mL. Female gender was the only parameter significantly associated with a PVL <1,000 copies/mL. No other parameter, either at baseline or before HAART discontinuation, predicted virologic success at week 108. A major protease inhibitor resistance mutation (L90M) developed in three patients. *CONCLUSIONS:* This trial failed to confirm that a significant proportion of patients with primary HIV infection can maintain suppression of viremia after a sequence of HAART/STIs followed by HAART discontinuation.

JAIDS. 2005;40(3):307-316.

Acquired Immune Deficiency Syndromes

Deaths in the era of HAART: Contribution of late presentation, treatment exposure, resistance, and abnormal laboratory markers

Sabin CA, Smith CJ, Youle M, et al.

OBJECTIVES: To describe the characteristics of deaths that occur among HIV-positive individuals in the highly active antiretroviral therapy (HAART) era. *DESIGN:* Observational database. *METHODS:* Deaths were reviewed that occurred among HIV-positive individuals seen at the Royal Free Hospital, London, between January 1998 and December 2003. *RESULTS:* Over the study period, there were 121 deaths; death rates declined from approximately 2.0/100 person-years of follow-up in 1998 through 2000 to approximately 1.0/100 person-years of follow-up in 2001-2003. Approximately one half of deaths (45.5%) were from AIDS-related causes and 74 deaths (61.2%) occurred in individuals who had received HAART: patients had been exposed to a median of seven (range two to 14) antiretroviral drugs and two fifths had started treatment in the pre-HAART era. Another 15 patients had received only non-HAART treatment regimens prior to death. The median pre-death CD4 counts were 68 cells/μL and 167 cells/μL among those who had and had not received HAART; 23 (31.1%) and four (8.5%) had HIV RNA <400 copies/mL, respectively. Of the patients exposed to HAART for at least six months and who experienced viral rebound, information was available on resistance for 26 (21.5% of the total deaths) and 19 of those tested had at least one resistance mutation (median five, range one to 16). *CONCLUSIONS:* While mortality rates among HIV-infected individuals at our center have fallen since 1988, the deaths that do now occur are more diverse and are the result of a number of factors, including late presentation, delayed uptake of HAART, and the previous use of treatment combinations that are now viewed as suboptimal.

AIDS. 2006;20(1):67-71.

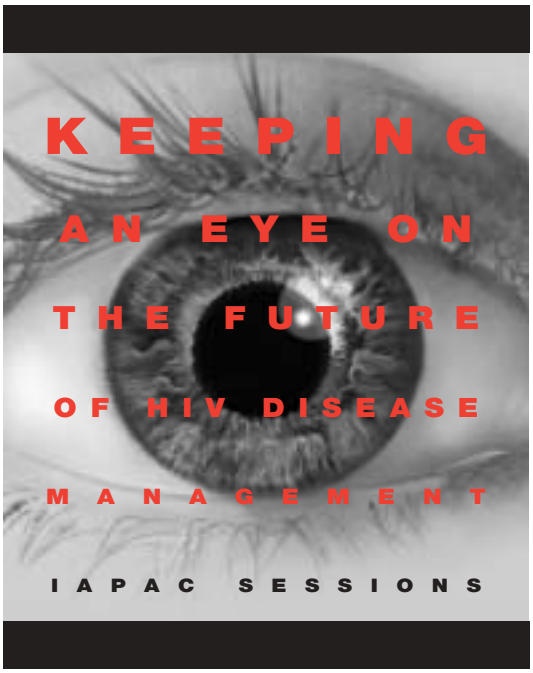
Seminars in Arthritis and Rheumatism

Rheumatic complications of human immunodeficiency virus infection in the era of highly active antiretroviral therapy: Emergence of a new syndrome of immune reconstitution and changing patterns of disease

Calabrese LH, Kirchner E, Shrestha R.

OBJECTIVE: To describe the impact of the introduction of highly active antiretroviral therapy (HAART) on the nature and frequency of rheumatic complications in human immunodeficiency virus (HIV)-infected patients. *METHODS:* Case report and systematic review of a newly described syndrome of rheumatic immune reconstitution syndrome and prospective longitudinal cohort study analyzing the frequency and nature of rheumatic complications in the setting of HIV infection from 1989 through 2000. *RESULTS:* A newly described syndrome of either the *de novo* appearance or the exacerbation of clinically occult autoimmunity following immune reconstitution from HAART is described. Including the present case report, 32 cases have been individually described with sarcoidosis and autoimmune thyroid disease being most common, with arthritis and various forms of connective tissue disease making up the rest. The mean onset to their appearance following HAART was nearly nine months, and most resolved with little or no therapy. In addition, a longitudinal analysis of 395 HIV-infected patients from 1989 to 2000 designed to detect the appearance of rheumatic complications has revealed a dramatic decline in certain problems such as reactive arthritis, psoriatic arthritis, and various forms of connective tissue disease. New rheumatic complications, possibly due to the effects of longer survival and metabolic derangements associated with this form of therapy, are now being described and may become more formidable problems in this population in the future. *CONCLUSIONS:* Highly active antiretroviral therapy has had a profound beneficial effect on survival in HIV-infected patients but has also contributed to both an altered frequency and a different nature of rheumatic complications now being observed in this population. Rheumatologists need to be aware of these changes to provide optimal diagnosis and treatment for this group.

Semin Arthritis Rheum. 2005;35(3):166-174.



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Increased RBV dose for better HCV treatment response

Edwin J. Bernard

In order to improve response to hepatitis C virus (HCV) treatment, HIV/HCV-coinfected patients should increase their dose of ribavirin (RBV), according to a presentation delivered at the 2nd International Workshop on HIV and Hepatitis Coinfection, held January 12-14, 2006, in Amsterdam. Interim results from an ongoing Spanish study suggest that RBV should be dosed by body weight, rather than the standard 800 mg/day recommended in current guidelines.

Vincent Soriano (Hospital Carlos III, Madrid), the principal investigator of the ongoing multi-site Pegasys Plus Ribavirin for HCV Treatment in HIV/HCV Coinfection (PRESCO) study, presented data comparing results at week 4 and week 12 in two studies that combined pegylated interferon (PEG-IFN alfa-2a) with RBV to treat HIV/HCV-coinfected individuals[1]—PRESCO and the AIDS Pegasys Ribavirin International Coinfection Trial (APRICOT)—as well as the registrational study for PEG-IFN alfa-2a with RBV that was conducted in HCV-monoinfected individuals.[2] Soriano picked week 4 and 12 data because, he argued, HCV viral load at week 4 has the strongest positive predictive value of a sustained virological response (SVR) to anti-HCV treatment, and HCV viral load at week 12 has the best negative predictive value (for example, those individuals who do not achieve at least a two-log drop after 12 weeks are unlikely to achieve an SVR).

The PRESCO study, interim results of which were first presented at the 44th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in November 2004, will eventually include data from approximately 350 individuals with a CD4 count above 300 cells/mm^3, most of whom are on stable antiretroviral therapy. Exclusion criteria include psychiatric illness, alcohol abuse, didanosine (ddI) use, and cirrhosis. About 50% of the almost 200 individuals enrolled so far are infected with HCV genotype 1 and 10% have genotype 4—the two genotypes most difficult to treat. Another 40% have genotypes 2 or 3. Participants receive PEG-IFN alfa-2a 180 µg/week plus RBV dosed between 800 and 1,200 mg/day, according to weight: 800 mg/day for those who weigh less than 65 kg; 1,000 mg/day for those who weigh between 65 kg and 85 kg; and 1,200 mg/day for those who weigh over 85 kg. The median baseline weight is around 68 kg, so most participants are dosed at 1,000 mg/day.

The APRICOT trial was the largest of its kind; it included 860 HIV/HCV-coinfected participants from 19 countries who were receiving anti-HCV treatment for the first time. Final results published in 2004 found that, overall, 40% of HIV/HCV-coinfected patients treated with 180 µg/week of PEG-IFN alfa-2a in combination with 800 mg/day RBV achieved an SVR after the completion of therapy, although the SVR was only 29% in those infected with HCV genotype 1.[3]

Concern over side effects

The comparison between the studies included only individuals who tolerated the treatment, and intention-to-treat analyses were not provided. In the subsequent discussion, it was pointed out that higher doses of RBV may lead to side effects that cause patients to stop treatment; in particular, hemolytic anemia. In fact, interim results of PRESCO presented at the 44th ICAAC in 2004 found a high rate of treatment discontinuation due to adverse events, with 23% of patients withdrawing from the study before completing even 24 weeks of treatment. In addition, around one third of participants required RBV dose reductions.

Marion Peters (University of California, San Francisco), who was a member of the panel that discussed the implications of both sets of data presented at the conference, summed up the feeling of the conference toward increased RBV dosing:

"This study is very valuable. But this data says, 'let's give weight-based appropriate dosing,' and not just as much as possible. Perhaps 800 mg a day of RBV is not adequate and going to weight-based daily 1,000 mg to 1,200 mg is the way to go," side effects notwithstanding. ■

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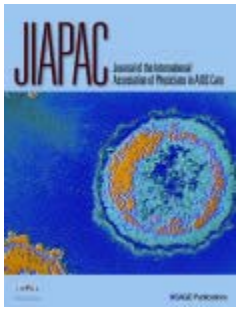

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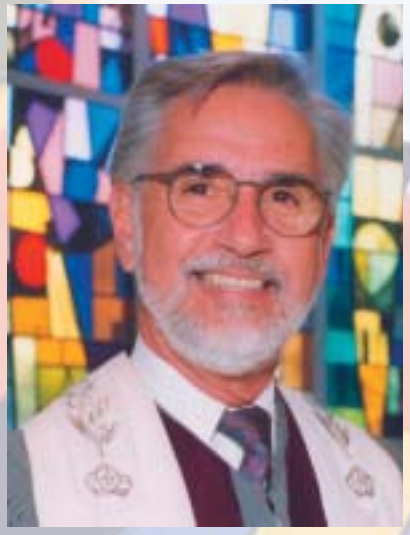

Allen I. Freehling

For more than three years the *IAPAC Monthly* has featured members of the International Association of Physicians in AIDS Care (IAPAC), who are asked to bare their souls by answering a series of questions similar in nature to those asked in the famous *Proust Questionnaire*.

This month, *IAPAC Monthly* is proud to feature Allen I. Freehling, Executive Director of the City of Los Angeles Human Relations Commission, in Los Angeles. He has served as the Chairman of IAPAC's Board of Trustees since 1995.

What proverb, colloquial expression, or quote best describes how you view the world and yourself in it?
Be strong, be strong, and let us strengthen one another.

What activities, avocations, or hobbies interest you? Do you have a hidden talent?
Scuba diving, travel, writing, speaking, reading, and attending films, plays, and concerts.

If you could live anywhere in the world, where would it be?
On a ship, so the entire world could be explored and the needs of all people could be responded to.

Who are your mentors or real life heroes?
The Bible's prophets, the world's great thinkers, the people—young and old alike—who endure and surmount challenges.

With what historical figure do you most identify?
Presidents such as Abraham Lincoln and Franklin Delano Roosevelt, and some contemporary rabbis and pastors who champion the cause of social justice (eg, Martin Luther King Jr.).

Who are your favorite authors, painters, and/or composers?
Author: David McCullough. Composer: All of the dynamic composers of classical music.

If you could have chosen to live during any time period in human history, which would it be?
I find that this is a time that is both challenging and rewarding.

In your opinion, what are the greatest achievements and failures of humanity?
We are so blessed with God's abundant gifts, but—all too often—we waste them.

What is your prediction as to the future of our planet one full decade from present day?
If we fail to heed the lessons of the past and present, the future could be terribly bleak, so we have no choice but to rise up out of our slumber and do what we must for the sake of our children and grandchildren, and all of our global peers. ■

SAY ANYTHING

We are not yet in a position to have universal access, but the fact that poor people will be able to access drugs is major progress.

Babatunde Osotimehin, Chairperson of Nigeria's National Action Committee on AIDS (NACA), in a January 6, 2006, Reuters report about Nigeria's plans to double the number of its free AIDS Treatment Centers. The country currently has 33 such centers, which offer free antiretroviral therapy (ART) to people who previously were required to pay 1,000 naira (US$8) per month for ART. The Nigerian government and various donors, including the World Bank, the US government, and the Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund), pay for the antiretroviral drugs. Though a Global Fund-convened panel expressed numerous doubts in 2005 about the program and its administration by NACA, Osotimehin stated that all the issues raised by the panel have been redressed.

By giving [prisoners] a condom you are telling them to go ahead and do it.

Ignatius Mainga, spokesperson for the prison services of Namibia's Ministry of Safety and Security, in a January 3, 2006, Inter Press Service report. Namibia's government has declined to distribute condoms in prisons, stating it would violate the country's 1977 Criminal Procedures Act, which criminalizes sex between men. Mainga further stated that the prisoners did not want condoms, and that no case of rape in prison has ever been reported.

By the time I was tested I wasn't just HIV-positive. The disease had progressed to full-blown AIDS, because I was too scared to get tested. There was such a stigma.

An anonymous Chicago-area professional, in a December 27, 2005, article in the Chicago Tribune *about a change in the reporting of HIV cases in Illinois. Although it will still be possible to get an anonymous HIV test identified only by a number, once an HIV-positive patient goes to a physician or a hospital, the treating physician will be required to report the patient's name to local health authorities. Though activists have not protested the change, because continued federal funding is contingent upon implementation of the change, they worry that the new policy will deter at-risk individuals from being tested for HIV.*

One of our biggest concerns is the public is going to lose confidence in HIV testing. We can't afford for that to happen.

Jim Key, a spokesperson for the Los Angeles Gay and Lesbian Center, in a December 16, 2005, Los Angeles Times *article that reported that the center had stopped using the OraQuick Advance rapid-result oral HIV test. The center found that the OraQuick test was resulting in an unacceptably high number of false-positive results; from now on they will use blood tests for rapid-result testing. The center reported that in November 2005 they found 13 false-positive results using the OraQuick test. Doug Michels, President of OraSure Technologies, the makers of the test, said the company is taking the complaint very seriously, and continues to have "extreme confidence in the reliability of the test."*

I think we need to win [the] war against this insidious disease, and I think Vietnam gives us the opportunity to win a battle. I think if it does, it would spark a lot more help from other countries to say, "Yes we can. Look at Vietnam."

Tommy Thompson, former US Health and Human Services Secretary, in a January 9, 2006, Associated Press report about the HIV epidemic in Vietnam. Thompson stated that Vietnam can still control its epidemic, and that the country should increase its focus on sexuality education for young people and prevention awareness among injection drug users and commercial sex workers. According to Thompson, "You've got 250,000 people [who are HIV-positive]. You could cap it at that and then start seeing a reduction, and that would be a huge victory going forward. You could do that within a year."

The protesters are giving our negotiators bargaining power.

Thaksin Shinawatra, Prime Minister of Thailand, in a January 10, 2006, article in the Guardian *about protests occurring at free trade negotiations between Thai and US officials. Many AIDS activists were among the thousands protesting in Chiang Mai. Among other concerns, they stated that the free trade agreement (FTA) could extend patent laws for antiretroviral drugs, disallowing the manufacture and sale of generic equivalents, which would be a hardship for the largely poor HIV-infected population. Shinawatra stated that the protesters were in fact bolstering the position of Thai negotiators, and stated "I want to reassure protesters that my government will not sign the agreement if I find that we do not benefit from it."*

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