

IAPAC



MONTHLY

**Stakeholder
consultation
to address
issues related
to tenofovir
prophylactic
research**

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Stakeholder consultation to address issues related to tenofovir prophylactic research

Yasmin Halima and Chris Collins

The ethics controversy over developing-world research to ascertain tenofovir's role as HIV prophylaxis led the International AIDS Society to host a consultation in May 2005, the outcome of which was a call for increased collaboration and vigilance.

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Plugging the medical brain drain

José M. Zuniga

European Union leaders vowed several years ago to make the union “the most competitive and dynamic knowledge-based economy in the world by 2010.” But a worrying sign of potential failure is the continued drain of Europe’s brightest minds, a significant number of whom pursue careers in the United States. The flight of bright minds to safer havens and/or greener pastures is nothing new:

- Political and religious persecution drove luminaries such as Albert Einstein and Enrico Fermi across the Atlantic.
- The exodus continued in the 1950s and 1960s, as the United States poured billions into defense-related research and created magnetic clusters of scientific excellence, staffing them with the world’s best minds and prompting Britain’s Royal Society to coin the term “brain drain.”
- Europe’s rigid hierarchies and frustrating scientific fragmentation also pushed people away through the 1960s and 1970s—and, some would argue, they still do to this day.
- America’s investments laid the foundation for the tech booms of the 1980s and 1990s, which drew yet more entrepreneurial professionals westward.
- In North America, recent statistics confirm that career physicians are quitting medicine in frustration with the health care bureaucracy and the impossible financial conditions to which they are subjected. As one physician recently complained to me, “When Medicare pays you 45% of your charges and your overhead comes to 65%, what are you going to do?”

Yet, as damaging as this exodus may be to health care systems in the North, it



pales in comparison to the medical brain drain experienced in the South. Developed nations are recruiting countless health professionals from overseas to plug the gaps in their health systems. In the process, they contribute to a brain drain that entices physicians and nurses away from resource-limited countries. In other words, when Canada runs short of nurses or cannot cajole Canadian physicians to relocate to country towns, the solution is simple: Buy a job lot of health care professionals from some poor, Third World country.

Australia, for example, recruits 4,000 to 5,000 trained overseas nurses every year, many from wealthy countries, but increasingly also from under-resourced countries such as South Africa and Zimbabwe. In certain areas of this affluent country, an estimated 40% of the medical

work force is trained overseas and drawn from poor countries. How does this translate? In South Africa, for example, Gauteng province reports an attrition rate of 30% for physicians, and 10% for nurses within the provincial health care system. Indeed, at a time when that country’s most populous province’s hospitals and clinics are seeing approximately 600,000 more patients this year than last, there are a reported 1,600 fewer health professionals today than two years ago.

Lest I fail to single out the worst offender, the United States attracts most of the skilled workers from other countries. Forty percent of the foreign born adult population in the United States has been educated beyond the secondary school level. Twenty-three percent of medical personnel now working in the United States received their diplomas in a foreign country. Skilled immigrants can be found in virtually every aspect of American society and, increasingly, their origin is Africa.

What can be done to stem this migration of health professionals to developed countries? Some posit that outright restrictions should be considered, given the gravity of the brain drain that plagues so many developing countries. But the most enduring intervention lies outside of policies that would attempt to restrict migration (and which represent, in many respects, a violation of the human right to free movement, not to mention the pursuit of happiness and a better life). Among these interventions are:

- Financing better training delivered at well-funded and better-equipped academic institutions within developing countries.
- Delivering and directing aid to bolster wages for poorly remunerated health professionals.

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Expanding medical education services

Brian M. Hujdich

The International Association of Physicians in AIDS Care (IAPAC) continues to provide important services to members by offering a variety of useful and informative publications and activities. During the past year, we have expanded our reach in two significant ways. We solidified our offerings to patients and AIDS service organizations, enhancing the link between physician and patient by providing tools to aid discussion and patient counseling. We also expanded our reach beyond North America to include a greater focus on Western Europe.

Following is an overview of our medical education activities. We hope you will take advantage of the products and services offered. In a future issue of the *IAPAC Monthly*, Nathalie Kaunda, the new Executive Director of IAPAC's African Regional Office (IAPAC-AFRO), will provide details on medical education efforts in Africa.

Materials for physicians and allied health care providers

The **Guidelines Regimen Information Program (GRIP)** continues to expand. Several new posters have been added to the program, along with new GRIP Guides (detailed below). The new posters include "Building Boosted PI Regimens," (Figure 1), "Strategies Against Antiretroviral Resistance," and a poster detailing drug interactions that was created specifically for Western Europe.

GRIP Guides. Key resistance information is provided in 17 GRIP Guides, including separate guides for almost all antiretroviral drugs. These guides are similar in style to the instructional and

Figure 1.



regimen GRIP Guides.

Regimen sequencing wheel. This wheel, the first of a series, focuses on the nonnucleoside reverse transcriptase inhibitor (NNRTI) class, and walks the physician through regimen sequencing considerations in four areas—potency, tolerability, side effects and adherence (Figure 2).

ARV class comparison charts. Two charts, in which all approved nucleoside reverse transcriptase inhibitors (NRTIs) and NNRTIs are compared against each other, by class, across a number of areas, provide an easy reference for physicians (Figure 3).

European once-daily dosing poster. A quick reference for currently approved

Figure 2.



once-daily antiretroviral drugs in Western Europe.

Cardiovascular risk brochure. This brochure features a review of lipids, and includes information about reducing cardiovascular disease risk and the impact HIV medications may have on that risk.

Materials for HIV-positive patients and AIDS service organizations

Adherence slide rule. Patients slide the rule to show the number of days in one week they typically adhere to antiretroviral therapy (ART). On the other side of the rule, physicians are shown how that adherence translates into potential treatment success and risk of resistance (Figure 4).

Patient guide to guidelines. This guide contains a patient-friendly review of key information from the latest US Department of Health and Human Services (DHHS) adult ART guidelines, providing information on new developments and their impact on treatment.

Mental health flyers. A series of four flyers covering depression, insomnia, anxiety,



Women and HIV

Stephen Lewis

I well realize that this is a conference on women's global health, and everything I'm about to say will apply to that generic definition. But the more I thought of the subject matter, the more I want to use HIV/AIDS in Africa as a surrogate for every international issue of women's health, partly because it's what I know best; partly because it's an accurate reflection of reality.

I've been in the [United Nations (UN)] Envoy role for four years. Things are changing in an incremental, if painfully glacial way. It's now possible to feel merely catastrophic rather than apocalyptic. Initiatives on treatment, resources, training, capacity, infrastructure and prevention are underway. But one factor is largely impervious to change: the situation of women. On the ground, where it counts, where the wily words confront reality, the lives of women are as mercilessly desperate as they have always been in the last twenty-plus years of the pandemic.

Just a few weeks ago, I was in Zambia, visiting a district well outside of Lusaka. We were taken to a rural village to see an "income-generating project" run by a group of women living with AIDS. They were gathered under a large banner proclaiming their identity, some 15 or 20 women, all living with the virus, all looking after orphans. They were standing proudly beside the income-generating

project... a bountiful cabbage patch. After they had spoken volubly and eloquently about their needs and the needs of their children (as always, hunger led the litany), I asked about the cabbages. I assumed it supplemented their diet? Yes, they chorused. And you sell the surplus at market? An energetic nodding of heads. And I take it you make a profit? Yes again. What do you do with the profit? And this time there was an almost quizzical response as if to say what kind of ridiculous question is that... surely you knew the answer before you asked: "We buy coffins of course; we never have enough coffins."

It's at moments like that when I feel the world has gone mad. That's no existential spasm on my part. I simply don't know how otherwise to characterize what we're doing to half of humankind.

I want to remind you that it took until the [XV International AIDS Conference in 2004 in Bangkok]—more than 20 years into the pandemic—before the definitive report from the [Joint United Nations Programme on HIV/AIDS (UNAIDS)] disaggregated the statistics and commented, extensively, upon the devastating vulnerability of women. The phrase "AIDS has a woman's face" actually gained currency at the [XIV International AIDS Conference in Barcelona] two years earlier, in 2002, and even then it was years late. Perhaps we should stop using it now as though it has a revelatory dimension. The women of Africa have always known whose face it is that's withered and aching from the virus.

I want to remind you that when the Millennium Development Goals were launched, there was no goal [for] sexual and reproductive health. How was that possible? Everyone is now scrambling to find a way to make sexual and reproductive health fit comfortably into HIV/AIDS or

women's empowerment or maternal mortality. But it surely should have had a category, a goal, of its own. Interestingly, the primacy of women is rescued (albeit there's still no goal) in the Millennium Project document, authored by Jeffrey Sachs [of the Earth Institute at Columbia University].

And while mentioning maternal mortality, allow me to point out that this issue has been haunting the lives of women for generations. I can remember back in the late 1990s, when I was overseeing the publication of *State of the World's Children* for [the United Nations Children's Fund (UNICEF)], and we did a major piece on maternal mortality and realized that the same number of annual deaths—between 500,000 and 600,000—had not changed for 20 years. And now it's 30 years. You can bet that if there was something called paternal mortality, the numbers wouldn't be frozen in time for three decades.

I want to remind you that within the UN system, there's something called the [UN Secretary-General's] Task Force on Women, Girls and AIDS in Southern Africa. Permit me to tell you how it came about, and where it appears to be headed... and I beg you to see this as descriptive rather than self-indulgent. In January of 2003, I traveled with the Executive Director of the World Food Programme (WFP), James Morris, to four African countries beset by a combination of famine and AIDS: Zimbabwe, Zambia, Malawi, and Lesotho. We had surmised, at the outset, that we would be dealing primarily with drought and erratic rainfall, but in the field it became apparent that to a devastating extent, agricultural productivity and household food security were being clobbered by AIDS. We were shocked by the human toll, the number of orphans,

Editors note: Transcript of a speech delivered by Stephen Lewis, United Nations (UN) Special Envoy for HIV/AIDS in Africa, at the University of Pennsylvania's Summit on Global Issues in Women's Health, held April 26, 2005, in Philadelphia.

and the pervasive death among the female population. In fact, so distressed were we about the decimation of women, that we appealed to the Secretary-General of the UN to personally intervene.

And he did. He summoned a high-level meeting on the 38th floor of the UN Secretariat, with television conferencing outreach to James Morris in Rome and to the various UN agencies in Geneva, and after several agitated interventions, the Secretary-General struck a Task Force on Gender and AIDS in Southern Africa, to be chaired by Carol Bellamy of UNICEF.

If memory serves me, Carol Bellamy determined to focus on seven of the highest prevalence rate countries: studies were done, recommendations were made, costs of implementation were estimated, monographs were published. And here's what festers in the craw: the funding for implementation is not yet available. The needs and rights of women never command singular urgency.

There's an odd footnote to this. Within the last two months, a number of senior students at the University of Toronto Law School compiled papers dealing with potential legal interventions on a number of issues related to HIV/AIDS in Africa. One of the issues was, predictably, gender. Not a single student, over the course of several weeks, whether on the Internet or [in] wider personal reading, came across the UN Secretary-General's Task Force (although one student said that she had a vague recollection that such a thing existed). The Task Force findings are clearly not something the UN promotes with messianic fervor.

I want to remind you that as recently as March, there was tabled, internationally, the Commission on Africa, chaired by UK Prime Minister Tony Blair... indeed established by Tony Blair. It has received nothing but accolades, particularly for the analysis and recommendations on Official Development Assistance, on trade and on debt. The tributes are deserved. The document goes further down a progressive road than any other contemporary international compilation.

With one exception. I want it to be known—because it's not known—that the one aspect of this prestigious report which fails, lamentably, is the way in which it deals with women. There is the occasional obligatory paragraph which signals that the Commission recognizes

that there are two sexes in the world, but by and large, given that women are absolutely central to the very integrity and survival of the African continent, they are dealt with as they are always dealt with in these auspicious studies: at the margins, in passing, pro forma. And it's not just HIV/AIDS; it's everything, from trade to agriculture to conflict to peace-building.

Maybe we should have guessed what was coming when there were only three women appointed out of 17 commissioners. They had the whole world to choose from, and they could find only three women... it doesn't even begin to meet the Beijing minimum target of 30%. We're not just climbing uphill; we might as well be facing the Himalayas.

I want to remind you, finally, of the arrangements we've made within the UN itself. HIV/AIDS is the worst plague this world is facing; it [wreaks] havoc on women and girls, and within the multilateral system, [which is] best placed to confront the pandemic, we have absolutely no agency of power to promote women's development, to offer advice and technical assistance to governments on their behalf, and to oversee programs, as well as representing the rights of women. We have no agency of authority to intervene on behalf of half the human race. Despite the mantra of "Women's Rights are Human Rights," intoned at the [World] Conference on Human Rights in Vienna in 1993; despite the pugnacious assertion of the rights of women advanced at the Cairo International Conference [on Population and Development] in 1994; despite the [Fourth World Conference] on Women in 1995 in Beijing; despite the existence of the Convention on the Elimination of [All Forms of] Discrimination against Women, now ratified by over 150 countries; we have only the UN Development Fund for Women (UNIFEM), with an annual core budget in the vicinity of US\$20 million, to represent the women of the world. There are several UNICEF offices in individual developing countries where the annual budget is greater than that of UNIFEM.

More, UNIFEM isn't even a free-standing entity. It's a department of the United Nations Development Programme (UNDP). Its Executive Director ranks lower in grade than over a dozen of her colleagues within UNDP, and lower in rank than the vast majority of the Secretary-General's Special Representatives.

More still, because UNIFEM is so marginalized, there's nobody to represent women adequately [within] the group of cosponsors convened by UNAIDS. You see, UNAIDS is a coordinating body: it coordinates the AIDS activities of UNICEF; UNDP; the World Bank; the UN Educational, Scientific, and Cultural Organization (UNESCO); the UN Population Fund (UNFPA), the World Health Organization (WHO), the UN International Drug Control Programme (UNDCP), the International Labour Organization (ILO), and the WFP. UNIFEM asked to be a cosponsor, but it was denied that privilege.

So who, I ask, speaks for women at the heart of the pandemic? Well, UNFPA in part. And UNICEF, in part (a smaller part). And ostensibly UNDP (although from my observations in the field, "ostensible" is the operative word).

Let me be clear: what we have here is the most ferocious assault ever made by a communicable disease on women's health, and there is just no concerted coalition of forces to go to the barricades on women's behalf. We do have the Global Coalition on Women and AIDS, launched almost by way of desperation by some international women leaders like Mary Robinson and Geeta Rao Gupta, but they're struggling for significant sustainable funding, and their presence on the ground is inevitably peripheral.

I was listening to the presentations... last night, and thinking to myself, when in heaven's name does it end? Obstetric fistula causes such awful misery, and isn't it symptomatic that one of the largest—perhaps the largest—contributions to addressing this appalling condition has come not from a government but from Oprah Winfrey?

I was noting, just in the last 48 hours, that Save the Children in the United Kingdom has released a report pointing out that fully half of the 300,000 child soldiers in the world are girls. And if that isn't a maiming of health—in this case emotional and psychological health—then I don't know what is. And perhaps you notice the rancid irony: women have achieved parity on the receiving end of conflict and AIDS, but nowhere else.

Female genital mutilation; the contagion of violence against women, sexual violence in particular; rape as a weapon of war—Rwanda, Darfur, Northern Uganda, Eastern Congo—marital rape; child defilement, as it is called in Zambia; sexual trafficking;

maternal mortality; early marriage... I pause to point out that studies now show that in parts of Africa, the prevalence rates of HIV in marriage are often higher than they are for sexually active single women in the surrounding community; who would have thought that possible?

The overall subject matter you're tackling at this conference strike[s] to the heart of the human condition. All my adult life I have accepted the feminist analysis of male power and authority. But perhaps because of an acute naiveté, I never imagined that the analysis would be overwhelmed by the objective historical realities. Of course the women's movement has had great successes, but the contemporary global struggle to secure women's health seems to me to be a challenge of almost insuperable dimension.

And because I believe that, and because I see the evidence month after month, week after week, day after day, in the unremitting carnage of women and AIDS—God it tears the heart from the body... I just don't know how to convey it... these young, young women, who crave so desperately to live, who suddenly face a pox, a scourge which tears their life from them before they have a life... who can't even get treatment because the men are first in line, or the treatment rolls out at such a paralytic snail's pace... who are part of the 90% of pregnant women who have no access to [programs for] prevention of mother to child transmission (PMTCT), and so their infants are born [HIV-] positive... who carry the entire burden of care even while they're sick, tending to the family, carrying the water, tilling the fields, looking after the orphans... the women who lose their property, and have no inheritance rights, and no legal or jurisprudential infrastructure which will guarantee those rights... no criminal code which will stop the violence... because I have observed all of that, and have observed it for four years, and am driven to distraction by the recognition that it will continue, I want a kind of revolution in the world's response; not another stab at institutional reform, but a virtual revolution.

Let me, therefore, put before the conference two quite pragmatic responses which will make a world of difference to women, and then a much more fundamental proposal.

Many at the conference will not know this, but the Kingdom of Swaziland recently made history when it received

from the Global Fund [to Fight] AIDS, Tuberculosis and Malaria, money to pay a stipend—modest of course, but of huge impact—to 10,000 caregivers, looking after orphans, the vast majority being women. The Swaziland National AIDS Commission, reeling from the exploding orphan population, made the proposal to the Global Fund, and it swept through the review process with nary a word. The amount is roughly US\$30 [each] month, or a US\$1 a day... not a lot, to be sure, but clearly enough to make a great difference.

My recommendation is that this conference orchestrate the writing of a letter, to be signed by people like Mary Robinson, Geeta Rao Gupta, and prominent women from academia, and have that letter sent to every African Head of State and Minister of Health, urging them to ask for compensation for caregivers, using the Swaziland precedent.

And the second pragmatic proposal? I would recommend, with every fiber of persuasion at my command, that the conference collaborate directly with the International Partnership for Microbicides, whose remarkably effective Executive Director, Zeda Rosenberg, will be here... She will tell you what she needs and how to go about getting it. The prospect of a microbicide, in the form of a gel or cream or ring, which will prevent infection, while permitting conception—the partner need not even know of its presence—can save the lives of millions of women. The head of UNAIDS, Peter Piot, recently suggested that the discovery of a microbicide may be only three to four years off. That's almost miraculous: short of a vaccine—and we must never stop the indefatigable hunt for a vaccine—a microbicide can transform the lives of women, and dramatically reduce their disproportionate vulnerability. What's needed is science and money. You can help with both.

On the more fundamental front, I want to suggest that the process of UN reform, now urgently underway, be confronted with arguments that spare no impatience.

I have heard the President of Botswana use the word extermination when he described what the country is battling. I have heard the Prime Minister of Lesotho use the word annihilation when he described what the country is battling. I sat with the President of Zambia and members of his cabinet not long ago,

when he used the word holocaust to describe what the country is battling.

The words are true; there's no hyperbole. The words apply, overwhelmingly, to women. That being the case, there has to be a proportionate response. It seems to me that the response should proceed on two simultaneous fronts.

First, let me say that I was thrilled by the suggestion from Mary Robinson and others that Pennsylvania State University act as a kind of coordinator for the surprising number of initiatives, unrelated one to the other, occurring under the auspices of many universities. The practice of twinning, the practice of using various faculties as training centers, the practice of American and Canadian universities bridging the gap in capacity until the developing country can take over... all of that is to the good, and it needs coordination. But there's more, I would submit, for you to do. Within multilateralism, that is within the UN system, wherein lies the best hope for leadership, there must be a change in the representation of women. There must emerge, for women's global health, and certainly for HIV/AIDS, an agency, an organization, a powerful think tank, whatever the entity—it can start on the outside, and then claim equal presence among the cosponsors of UNAIDS, and thrust its advocacy upon the secretariat, the agencies, the member states, in unprecedented volume and urgency. Nor does this entity confine itself solely to women's global health, although that is the entry point. It insists on the 50% rule... just start your evidence-gathering by identifying the numbers of senior women, agency by agency, secretariat department by secretariat department, diplomatic mission by diplomatic mission, and when you've recovered from the shock of learning that the multilateral citadel knows nothing of affirmative action, then begin your unrelenting advocacy. This must become a movement for social change. It needs leadership. Why not this university, why not this conference? And let me emphasize; there's nothing limiting about this concept. We're looking towards the day when governments are finally made to understand that women constitute half of everything that affects humankind, and must therefore be engaged in absolutely everything. Why would it not be possible to build a movement, committed to the rights of women, in the first instance among nursing and medical faculties

across the world, and take the world by storm? You have resources, knowledge and influence available to no others. The terrible problem is that you've never marshalled your collective capacities.

Second, a similar movement must be directed, I would submit, to Africa itself. I'm hesitant here, because there are enough neo-colonial impulses around without my being presumptuous in making recommendations for Africa, and indeed for women. But I must bring myself to say what I know to be true: the African leadership, at the highest level, is not engaged when it comes to women's health. There's so much lip service; there's so much patronizing gobbledegook. The political leadership of Africa has to be lobbied with an almost maniacal intensity on the issues of this conference, or nothing will change for women.

That, too, will take a monumental effort. In my fantasies, I see a group of African

women, moving country to country, President to President, identifying violations of women's health specific to that country, and demanding a change so profound that it shakes to the root the gender relationships of the society. I know that African women leaders like Wangari Matthai and Graça Machel and many prominent cabinet ministers, committed activists and professionals think in those terms; what is needed is a massive outpouring of international support from their sisters and brothers on the planet.

I'm 67 years old. I'm a man. I've spent time in politics, diplomacy, and multilateralism. I know a little of how this man's world works, but I still find much of it inexplicable. I don't really care anymore about whom I might offend or what line I cross: that's what's useful about inching into one's dotage.

I know only that this world is off its rocker when it comes to women. I must

admit that I live in such a state of perpetual rage at what I see happening to women in the pandemic, that I would like to throttle those responsible, those who've waited so unendurably long to act, those who can find infinite resources for war but never sufficient resources to ameliorate the human condition.

I'm excited of course about the Millennium Development Goals, and I'm equally excited that with the leadership of the British, this next G8 Summit in the summer [of 2005] might just possibly spawn a breakthrough. And there are countless numbers of people working to that end.

But I have to say that I can't get the images of women I've met, unbearably ill, out of my mind. And I don't have it in me either to forgive or to forget. I have it in me only to join with all of you in the greatest liberation struggle there is: the struggle on behalf of the women of the world. ■

Plugging the medical brain drain

Continued from page 158

- Increasing twinning opportunities for health professionals from the North and South to share experiences and develop a bi-directional exchange of information.

As focused as we are on expanding access to antiretroviral therapy (ART) in resource-limited settings, we must pay equal attention to matters beyond the numbers of patients initiated and maintained on ART. There is a great strain being placed on already overburdened health care delivery systems that, if overlooked, could threaten to slow if not reverse progress we wish to make in the delivery of more complex care for HIV disease. For example:

- According to a US Agency for International Development (USAID) study, in countries such as Ethiopia and Tanzania, the physician-to-patient ratio stands at 1:≥30,000; the situation is not much improved in countries such as Côte d'Ivoire and Senegal (1:10,000); and, while certainly more reassuring, the physician-to-patient ratio in more affluent countries such as Botswana and South Africa (1:5,000) remains an obstacle to the provision of quality care.

- A recent study in support of the US President's Emergency Plan for AIDS Relief (PEPFAR) looked at various scenarios, including a scale-up of access to ART for 10,000 patients in Zambia. Under this scenario, the researchers estimated a need for 206 physicians dedicated to delivering ART by 2006; a figure that represents almost one third of Zambia's existing physician workforce. When one third of a country's physicians are required to deliver quality ART-based care, the challenge of delivering other priority and non-priority health services becomes glaringly evident.

As has become obvious to anyone engaged in ART scale-up efforts, the issue of financing is quickly becoming less of a limitation given mechanisms such as PEPFAR and the Global Fund to Fight AIDS, Tuberculosis, and Malaria. It is the burden shouldered by an already weakened health professional workforce—one weakened by both disease and chronic deficiencies in training, distribution, and retention—that now jeopardizes our ability to successfully implement sustainable ART scale-up. ■

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



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1999



TOP 10

10 Most Important Developments in HIV Medicine



1. According to the *World Health Report 1999*, published by the World Health Organization (WHO), AIDS became the world's leading cause of death by infectious disease.

2. South Africa won the first round in a patent rights-related lawsuit brought against it by multinational pharmaceutical companies. The case concerned South African legislation enabling local companies to manufacture lower-cost, generic versions of antiretroviral drugs. The pharmaceutical companies argued that the South African legislation violated patent protections.

3. Russia experienced an explosive increase in new HIV infections caused by needle sharing among injecting drug users (IDUs). In the first nine months of 1999, Moscow reported three times more cases than it had in all previous years combined.

4. Enfuvirtide (ENF), the first drug in the new class of fusion inhibitors, received fast-track designation from the US Food and Drug Administration (FDA).



5. Kenya's President, Daniel arap Moi, declared AIDS a national disaster and called for the immediate creation of a National AIDS Control Council. However, he stated that his government and the country's churches would not advocate the use of condoms to prevent HIV transmission because it would encourage promiscuity among young people.

6. Researchers at the University of Alabama announced their finding that HIV-1 may have been originally transmitted to humans by a West African subspecies of chimpanzee, *Pan troglodytes troglodytes*.

7. United Kingdom health officials announced that all pregnant women would be offered an HIV test in an attempt to reduce the incidence of mother-to-child transmission of HIV; a goal was set to reduce the number of new perinatal infections by 80% by 2002.

8. In March 1999, VaxGen began phase III trials of AIDSVAX in Thailand; the first large-scale, human vaccine trial in a developing country.



9. Early results of the HIVNET 012 trial were published, with important potential applications for the prevention of mother-to-child transmission of HIV in less-developed countries because of the simplicity and low cost of a single-dose nevirapine regimen versus a zidovudine-containing regimen.

10. Amprenavir (APV) gained accelerated FDA approval in April 1999.

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**Stakeholder
consultation
to address
issues related
to tenofovir
prophylactic
research**



*Yasmin Halima and
Chris Collins*

Tenofovir (TDF) is currently approved for treatment of HIV disease, and is also being studied to determine whether it is appropriate for use as pre-exposure prophylaxis (PREP) for the prevention of HIV infection. If TDF demonstrates safety and effectiveness in PREP studies, it could be a powerful new HIV prevention tool to be used in conjunction with existing HIV prevention interventions.

There are currently six ongoing or planned human clinical trials testing TDF as PREP. Several of these trials encountered difficulties when host communities or advocacy groups raised concerns about what they perceived to be ethical shortfalls in trial design and implementation and inadequate consultation with the communities involved. To date, because of these difficulties, one TDF PREP trial has been closed and another has been put on hold. A further PREP study in Nigeria was stopped due to an inability to meet protocol requirements.

The International AIDS Society (IAS) convened a meeting May 19-20, 2005, in Seattle on behalf of the trial sponsors: the Bill and Melinda Gates Foundation, the US Centers for Disease Control and Prevention (CDC), and the US National Institutes of Health (NIH). Over 50 stakeholders attended, representing the diverse communities participating in the TDF prophylactic trials, host governments from the respective countries, leading advocacy groups, senior researchers, all trial sponsors, and representatives from TDF's manufacturer, Gilead Sciences.

The objectives of the meeting were to:

- Foster meaningful dialogue between key stakeholders engaged in TDF prophylactic research;
- Identify the ethical and operational challenges that obstruct existing research and work towards the resolution of these challenges; and
- Identify strategies for ongoing problem management, including reporting of emerging challenges to named individuals or agencies and mechanisms for resolving these.

The fundamental goal of the meeting was to promote successful and ethical PREP research that is relevant, respectful, and acceptable to the host communities within which these trials are taking place. The meeting highlighted the four key challenges that have been identified as significant obstacles to these studies; namely, providing treatment and care to trial participants, the standard of care for prevention interventions offered to participants, research literacy for potential participants and community advocates, and mechanisms for community involvement. Principal investigators of PREP trials, trial sponsors, researchers, and community advocates addressed these issues through formal presentations followed by group dialogue. Several times during the course of the meeting attendees broke into smaller working groups that focused specifically on issues related to trial-site countries: Botswana, Cameroon, Ghana, Malawi, and Thailand.

The meeting was characterized by a sense of willingness among participants to work collaboratively to address concerns with current PREP trials. One theme that clearly emerged was the importance of involving community members, advocates, and researchers within the trial countries early in the trial planning process, and creating systems to respond effectively to concerns raised during the course of the trial. Importantly, the country-specific working groups produced a series of recommendations on the four challenge areas posed. They also specified the challenges particularly relevant to their country trial sites and suggested ways of addressing these.

Summary of collective and country-specific discussions

There were several issues that were consistent across trial sites. Regarding the standard of care for prevention support,

it was felt that some of the trial sites need immediate review and improvement to ensure that the current level of counseling support that participants receive is significantly improved, and that there is access to male and female condoms. All groups felt that mechanisms were required to ensure access to treatment and care for individuals screened for enrollment in the trials who are found to be HIV-positive, as well as trial participants who become infected during the course of the trial. A number of country groups recognized the need for national guidelines to be established to inform and improve civil society engagement. It was acknowledged that, while efforts were made by researchers, this process was at times ill-informed and inconsistent. Similarly, all groups reinforced the need for clear mechanisms for feedback and conflict resolution when problems arise at research sites. A shared concern regarding the registration status, and availability and price of TDF was highlighted. The representative from Gilead Sciences confirmed that in many of the countries where these studies are taking place, TDF is already being made available at cost. In countries where intellectual property protection does not apply, such as South Africa, generic drug manufacturers are free to produce generic versions of TDF.

Each group raised specific [issues] unique to the situation within that country. For provision of treatment and care, the Cameroon working group suggested a number of recommendations, including referral to the National AIDS Treatment Program for those individuals who are found to have HIV infection at the time of screening for entry into the trial (and [who are] therefore ineligible for enrollment in the trial). A recommendation was made by this group that the cost of the laboratory tests that are needed to qualify for the national treatment program should be met by the study sponsors. Further recommendations included provision of prevention of mother-to-child transmission (PMTCT) services for trial enrollees who become infected with HIV during the trial, as well as treatment for hepatitis B and hepatitis C virus coinfection with HIV, if needed.

Of great concern to many was the issue of research literacy to ensure that participants and advocates understand clinical research and are able to fully engage in the consultation process. In the Botswana working group, the development of a range of educational resources in

multiple languages and media was considered necessary. This included not only raising awareness of the processes of clinical research, such as informed consent, but also understanding and improving the process by which research ethics are agreed [upon] and implemented. The importance of training researchers and protocol reviewers to improve their communication with community members, trial participants, and the media was strongly emphasized.

Following both collective and country group discussions, specific follow-through actions were agreed [upon] with members of the working groups. The Thai group agreed to hold a community meeting later in May [2005] and to hold meetings that involve multiple stakeholders later in the year to discuss issues of concern. The group agreed that having begun the process, the issue of promoting participant safety, especially for injecting drug users and commercial sex workers, would be addressed at specific meetings over the coming months. The Thai group also asked the Joint United Nations Programme on HIV/AIDS (UNAIDS), as part of its ongoing consultation on HIV prevention research ethics, to develop best practices on trial counseling and other issues. There was agreement to hold training on research ethics later in the year, with the probable involvement of the Global Campaign for Microbicides, the AIDS Vaccine Advocacy Coalition, and Treat Asia.

The Cameroon group planned a two-day stakeholder meeting to be held in Cameroon at the end of June 2005. A variety of invitees, representing many different stakeholder groups, were identified. Consultations will be held and a smaller working group will be formed to prepare for the meeting.

The Botswana group agreed to initiate a process spearheaded by the Ministry of Health to develop a guidance document. It also agreed to consult with others on the educational materials needed, and to assess the interest of journalists in media training. The group agreed to work with the Ministry of Health to determine the content of research literacy training, and those to be invited.

Going forward

Several speakers expressed satisfaction with the outcome of the meeting and interest in continued collaborative efforts. A variety of ideas were suggested for follow-up,

including more funding to foster capacity of local community members, discussion of the issues [to be] raised at the XVI International AIDS Conference [to be held in 2006] in Toronto, better involvement of developing country researchers as full partners in research, and analysis of national ethical review boards.

There appeared to be broad support for creation of a global stakeholders group on PREP research that would take these issues forward, and all the trial sponsors expressed willingness to consider resourcing additional consultation forums. A small steering committee will be formed to make recommendations on the best way to maintain greater communication and coordination of these trials. It was agreed that progress in the field could be monitored by periodic updates of the country-level activities suggested at the meeting. A full meeting report from this consultation will be issued in the summer of 2005.

It was acknowledged that many of the concerns discussed during the meeting may have already become important issues in HIV prevention research studies beyond PREP. Many delegates confirmed that the shared challenges identified at this meeting and the resolution strategies suggested will help promote the successful, ethical implementation of other critical health research, particularly in the prevention of HIV infection. The results of the meeting will be incorporated into the broader ongoing UNAIDS consultation towards revised ethical guidance for HIV prevention research in resource-constrained countries. The commitment, passion, and diligence of the researchers, advocates, and all those that make up the stakeholder community were deeply acknowledged.

The success of the TDF PREP trials rests on the execution of many of the recommendations discussed at this meeting. The meeting closed with the clear message that all those engaged in TDF PREP research [must] take responsibility to engage in continued and meaningful dialogue with all stakeholders, and [to] influence action to deliver these commitments. ■

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A B S T R A C T S

AIDS

Nelfinavir and nevirapine side effects during pregnancy

Timmermans S, Tempelman C, Godfried MH, et al.
for the Dutch HMF Study Group

BACKGROUND: The risk of vertical transmission of HIV has been substantially reduced since the introduction of highly active antiretroviral therapy (HAART); however, the impact of taking HAART during pregnancy on the woman, the fetus, and the infant is not yet understood. **METHODS:** In 15 centers specializing in HIV in the Netherlands, data on patient characteristics, HAART, adverse events, viral load response, mode of delivery, and HIV status of the neonate were obtained from medical records of HIV-infected pregnant women who received HAART during pregnancy between January 1997 and June 2003. These data were compared with a control group of HIV-infected non-pregnant women that was obtained from the Dutch HIV-monitoring foundation database. **RESULTS:** Data from 186 pregnant and 186 non-pregnant HIV-infected women using a nelfinavir- or nevirapine-containing regimen were analyzed. The pregnant women were younger, used a nelfinavir-containing regimen more often, had higher CD4 counts, and lower HIV RNA levels. Nelfinavir-related gastrointestinal symptoms ($p < 0.001$), hyperglycemia ($p < 0.001$), and nevirapine-related hepatotoxicity ($p = 0.003$) occurred more often during pregnancy. The risk of nevirapine-induced rash was not increased. No major adverse events occurred. **CONCLUSION:** Nelfinavir- or nevirapine-containing HAART regimens during pregnancy are well tolerated. Side effects of antiretroviral therapy are more frequent in pregnant than in non-pregnant women.

AIDS 2005;19(8):795-799.

Hormone Research

Impact of tuberculosis on serum leptin levels in patients with HIV infection

Prabha C, Karthic S, Sulochana DD, et al.

AIM: Tuberculosis (TB) and human immunodeficiency virus (HIV) are classical wasting diseases accompanied by immunosuppression. As leptin is involved in weight regulation and cellular immunity, we investigated the role of leptin levels in the coinfection of HIV and TB (HIV/TB). **METHODS:** The study group consists of the patients with asymptomatic HIV infection ($n = 20$), patients with HIV/TB coinfection ($n = 20$) and healthy control subjects ($n = 20$). Serum leptin levels and the concentrations of IFN- γ , TNF- α , IL-12 and IL-4 cytokines were measured by ELISA before the start of the treatment. CD4 T-cell counts were determined in patients with HIV and HIV/TB by flow cytometry. Body mass index (BMI) of the study subjects was calculated. **RESULTS:** Serum

leptin levels and BMI were significantly lower in the patients with HIV/TB than control and HIV-infected subjects. Multivariate regression analysis showed that serum leptin concentration was significantly dependent on BMI and sex but not on age and the disease groups. The leptin levels did not correlate either with CD4 T-cell counts or with any of the serum cytokines in HIV and HIV/TB patients. **CONCLUSION:** Thus our finding suggests that the leptin concentrations were strongly associated with BMI and gender but not with the disease state or with the circulating cytokine levels.

Hormone Research 2005;63:228-233.

Journal of Infectious Diseases

Relationship between adherence and the development of resistance in antiretroviral-naive, HIV-1-infected patients receiving lopinavir/ritonavir or nelfinavir

King MS, Brun SC, Kempf DJ.

BACKGROUND: Relationships between adherence to protease inhibitor (PI)-based therapy and resistance development have not been fully characterized. **METHODS:** We conducted a double-blind, randomized, controlled study of lopinavir/ritonavir versus nelfinavir, each administered with stavudine and lamivudine, in 653 antiretroviral-naive, human immunodeficiency virus (HIV)-1-infected patients. Relationships between adherence and probability of resistance development were evaluated by local linear regression or logistic regression. **RESULTS:** A higher risk of detectable HIV-1 RNA loads after week 24 was associated with lower adherence (odds ratio [OR], 1.08 per 1% decrease in adherence; 95% confidence interval [CI], 1.05-1.10; $p < .001$) and nelfinavir use (OR, 2.4 versus lopinavir/ritonavir; 95% CI, 1.6-3.6; $p < .001$). Among all nelfinavir-treated patients, a bell-shaped relationship between adherence and the risk of nelfinavir resistance was observed, with a maximum probability of 20% at 85%-90% adherence. No lopinavir resistance was observed. A bell-shaped relationship was also observed for the probability of lamivudine resistance, with a maximum probability of 50% at 75%-80% adherence to nelfinavir and of 15% at 80%-85% adherence to lopinavir/ritonavir. **CONCLUSIONS:** Bell-shaped relationships between adherence and resistance were observed. Irrespective of adherence level, the risk of detectable HIV-1 RNA loads or of PI or lamivudine resistance was significantly higher in nelfinavir-treated patients than in lopinavir/ritonavir-treated patients.

J Infect Dis 2005;191(12):2046-2052.

Alcoholism, Clinical and Experimental Research

Alcohol use and sexual risk behavior among human immunodeficiency virus-positive persons

Stein M, Herman DS, Trisvan E, et al.

BACKGROUND: This study was undertaken to determine if alcohol use is associated with sexual risk taking among human immunodeficiency virus (HIV)-infected persons. **METHODS:** Cross-sectional interviews of 262 HIV-infected patients in the Brown University AIDS Program were performed. Factors associated with any sexual activity, unsafe sexual activity, and a four-fold typology of sexual risk were examined. Alcohol measures included drinking days, drinks per drinking day, binge drinking, and hazardous alcohol use. **RESULTS:** The sample was 58% male and 40% white; 67% of patients were self-identified as heterosexual, and 48% drank alcohol. Nearly two thirds of patients reported sexual activity in the past six months, with 38% reporting unprotected sex during that period. All measures of alcohol use were significantly associated with any sexual activity and with unsafe sexual behavior. As an example, controlling for age, HIV transmission risk, marital status, and HIV clinical indicators, hazardous drinkers were 5.64 times more likely to report unprotected sex and have multiple partners ($p < 0.01$) than were those not drinking at hazardous levels. **CONCLUSIONS:** A high proportion of HIV-infected persons were sexually active and having unsafe sex. Alcohol, at all levels of use, was associated with increased sexual risk taking.

Alcohol Clin Exp Res 2005;29(5):837-843.

International Journal of Infectious Diseases

HAART with didanosine once versus twice daily: Adherence and efficacy

Roca B, Lapuebla C, Vidal-Teodor B.

BACKGROUND: Highly active antiretroviral therapy (HAART) containing didanosine (ddI) taken twice daily was compared with HAART containing ddI taken once daily in terms of adherence and efficacy. **METHOD:** This was a self-controlled prospective cohort study, carried out in a tertiary-level hospital. A total of 49 HIV-infected patients were included. They were prescribed HAART according to guidelines. After six months taking HAART containing ddI twice daily, patients continued with the same regimen of HAART, but once daily. Thereafter they were followed up for a further nine months. Adherence and virological efficacy were assessed at three-month intervals, for a total of six times, in every patient. **RESULTS:** Overall, adherence was poor, with only 19 patients (39%) showing adequate adherence for all six visits. Adequate adherence was observed in 29 patients (59%) three months before ddI switching, and in 37 patients (75%) three months after ddI switching ($p = 0.034$). Pooled HIV RNA results of the first three visits were higher than the same results for the last three visits ($p = 0.05$). **CONCLUSIONS:** Non-adherence is common among patients who take HAART. Simplification of regimens is useful to improve adherence and efficacy.

Int J Infect Dis 2005;9(4):195-200.

HCV viremia = poorer immune response to HAART

Michael Carter

Hepatitis C virus (HCV) viremia has a role in CD4 cell response to highly active antiretroviral therapy (HAART), according to an Italian study published in the June 15, 2005, edition of *Clinical Infectious Diseases*. The investigators believe that this finding has significant implications for treatment strategies for individuals coinfecting with HIV and HCV, and suggest “treatment of hepatitis C in [coinfecting] patients could not only potentially eradicate [HCV], but also reduce the possible interference of hepatitis C in a patient’s response to HAART.”

Some earlier studies have suggested that HIV-positive individuals coinfecting with HCV have a poorer immune response to HAART than individuals who are not infected with HCV. These studies did not, however, provide any information about the impact of hepatitis C viral load or genotype on response to antiretroviral therapy (ART). An improved knowledge of the effects of HCV viremia and genotype on HIV-positive patients taking HAART would allow for a better understanding of how the two viruses interact, and help the timing of treatment in coinfecting patients.

Investigators from the Italian Cohort Naive for Antiretrovirals (I.Co.N.A) therefore evaluated whether CD4-cell response to HAART in treatment-naive individuals was different in patients coinfecting with HCV from those only infected with HIV. The investigators also assessed if response to HAART varied according to HCV viral load and hepatitis C virus genotype.

The study population comprised 1,219

HIV-positive individuals who were uninfected with HCV, and 284 HIV-positive patients antibody-positive for HCV with hepatitis C viremia. Individuals who were not infected with HCV were more likely to be female ($p=0.05$) and less likely to be injecting drug users ($p<0.001$). Alanine aminotransferase (ALT) levels were significantly higher at baseline amongst patients with hepatitis C viremia compared to HCV-negative individuals ($p<0.001$).

The median pre-HAART hepatitis C viral load was 6.09 log₁₀ IU/ml. Genotypic analysis was performed on 138 of the HCV-infected patients. Of these, 49% were infected with HCV genotype 1, 33% with genotype 3, 16% with genotype 4, and 3% with genotype 2.

Before the initiation of HAART, patients infected with genotype 1 had a median CD4 count of 260 cells/mm³, which was significantly lower than patients infected with genotype 3 (315 cells/mm³) or genotype 4 (305 cells/mm³, $p=0.04$).

A total of 1,258 patients (84%) experienced an increase in their CD4 count of 100 cells/mm³ or more after the initiation of HAART. Individuals who were negative for HCV achieved this increase significantly faster than patients coinfecting with HCV (23 weeks versus 29 weeks, $p=0.001$). The investigators also found that individuals with HCV viremia were less likely to achieve an increase in their CD4 count of 100 cells/mm³ (adjusted hazard ratio [HR], 0.82, $p=0.06$), although this was only of borderline statistical significance.

When the investigators undertook further analysis, they found that the presence of HCV viremia significantly increased the time taken to achieve an increase in CD4 count of 300 cells/mm³ ($p=0.01$).

However, the amount of HCV did not have a significant impact on CD4 cell response after starting HAART.

Data on HCV genotype and CD4 count increase were also analyzed. There was no difference between the HCV genotypes in terms of achieving a CD4 cell increase of 100 cells/mm³ after commencing HAART.

In further analysis, the investigators found that patients infected with HCV genotype 3 had a reduced chance of achieving a CD4 count of 300 cells/mm³ compared to patients infected with HCV genotype 1 ($p=0.02$).

“We found that the chance of achieving a CD4 count increase of 100 cells/mm³ or more for [HCV-viremic] patients was 18% less than the chance for [HCV]-negative patients,” write the investigators, adding “this difference was not statistically significant... but similar effects were observed in sensitivity analyses using alternative end points...in particular, for [HCV-viremic] patients the adjusted relative hazard (RH) of achieving a CD4 cell increase of 300 cells/mm³ or more was significantly reduced by 31% after initiation of HAART ($p=0.01$).”

They conclude that their findings suggest that not only could treatment for HCV achieve eradication of the virus but might also improve an individual’s response to HAART. Therefore “among coinfecting persons for whom [ART] may be safely deferred, treatment for [HCV] infection should be considered appropriate regardless of the extent of [HCV]-associated hepatic damage and may precede initiation of HAART.” ■

Reference

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I N T H E L I F E



Neal Rzepkowski

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 Neal Rzepkowski, HIV Consultant for the New York Department of Corrections, who resides in Cassadaga, New York. Rzepkowski has been HIV-positive since before 1983, and continues to do well and share that information with patients.

What proverb, colloquial expression, or quote best describes how you view the world and yourself in it?

"This above all: To thine own self be true, and it must follow, as the night the day, thou canst not then be false to any man."

What activities, avocations, or hobbies interest you? Do you have a hidden talent?

Native American spirituality, gardening, hiking, camping, complementary/alternative medicine. I am a registered medium in Lily Dale, New York.

If you could live anywhere in the world, where would it be?

Near Chamonix, France.

Who are your mentors or real life heroes?

As a child: My parents, my counselors at summer camp. As an adult: Penny Donovan, a spiritual teacher; Ken Roberts (investing/futures); and the Dalai Lama.

With what historical figure do you most identify?

I most identify with Red Jacket (Iroquois).

Who are your favorite authors, painters, and/or composers?

Author: Ralph Waldo Trine. Painter: Claude Monet. Composer: Wolfgang Amadeus Mozart.

If you could have chosen to live during any time period in human history, which would it be?

I am here in the right place at the right time—NOW!

If you did not have the option of becoming a physician, what would you have likely become, given the opportunity?

Either a forest ranger or a chiropractor.

In your opinion, what are the greatest achievements and failures of humanity?

Achievements: We have always realized there is a "higher power" greater than us. Failure: We still have not grown up enough to stop playing "war."

What is your prediction as to the future of our planet one full decade from present day?

Women will have an HIV microbicide to prevent them from infection, the Internet will continue to create a global community, psycho/neuro-immunology will continue to be more important. ■



SAY ANYTHING

e
Somehow the penny hadn't dropped that this was something that was at the whole core of human development, this was a human tragedy, and it could be averted, and it could be treated.

Outgoing World Bank President, James Wolfensohn, in a May 17, 2005, AFP/Yahoo! news report covering his last scheduled public speech as that institution's head. After a series of speeches commemorating Wolfensohn's 10 years leading the World Bank, including a laudatory speech delivered by Peter Piot, Executive Director of the Joint United Nations Programme on HIV/AIDS (UNAIDS), Wolfensohn spoke about his regrets, and said that he was "late" in bringing the issue of HIV/AIDS to the forefront of discussion. Wolfensohn said that although he had led the institution "across the starting line" in addressing the epidemic, the World Bank is still "not where it should be, on the question of AIDS."

e
We are removing that language.

Kevin W. Keane, spokesman for the US Department of Health and Human Services (DHHS), in a May 18, 2005, Washington Post article reporting the rescission of a policy requiring all nongovernmental organizations (NGOs) receiving money from the US federal government for overseas AIDS prevention or treatment programs to declare that they were opposed to prostitution and sex trafficking. The US Centers for Disease Control and Prevention (CDC) recently released two requests for applications for contracts that would support AIDS programs in Africa, which

contained language requiring NGOs to make the declaration. Randall L. Tobias, who spearheads the US President's Emergency Plan for AIDS Relief (PEPFAR), rescinded the policy stating that, "It is not something that I would want to sign off on one way or another."

e
Are we making this so complicated that nobody will do research trials? If we stop tenofovir, we may stop something that could prevent millions of infections.

Helene Gayle, Director of the Bill and Melinda Gates Foundation's HIV, TB, and Reproductive Health Program, in a May 18, 2005, Wall Street Journal article about a meeting scheduled that week in which drug research sponsors, scientists, and AIDS activists were to attempt to resolve ethical conflicts that have arisen in a trial of tenofovir (TDF) that was cancelled in Cambodia and suspended in Cameroon due to protests. The trial's goal was to determine whether TDF can prevent HIV infection. Activists are demanding that trial participants who acquire the virus during the trial receive life-long health care and antiretroviral therapy equivalent to that dispensed in developed countries.

e
Without a doubt, this is the worst public health crisis that has ever affected African Americans in this country.

McArthur Flournoy, HIV/AIDS specialist with the California Department of Health Services Office of AIDS, in a May 14, 2005, San Francisco Chronicle article about a meeting of AIDS activists and pastors of

African-American churches during which pastors spoke of the need to talk about sex, prevention, and condom use from the pulpit, and signed a covenant of commitment to outreach and education programs to be implemented at their churches. In 2001, AIDS was the leading cause of death in the United States for African-American women aged 25 to 34 and African-American men aged 35 to 44. In the State of California, African Americans make up 7% of the population, but 18% of HIV/AIDS cases.

e
[W]hen it comes to transforming this bold posture into acts that benefit the Brazilian population, the government resembles a toothless tiger.

From a May 10, 2005, statement released by Médecins Sans Frontières (MSF) regarding the Brazilian government's failure to act on its pledge to break patents on lopinavir/ritonavir (LPV/RTV), efavirenz (EFV), and tenofovir (TDF) if the pharmaceutical companies did not offer the drugs at reduced prices or allow Brazil to produce generic equivalents. MSF's statement emphasized that the World Trade Organization (WTO) TRIPS Agreement, which covers intellectual property issues, allows governments to grant licenses to produce generic versions of patented drugs. Although the Brazilian government has in the past induced pharmaceutical companies to drop their prices by threatening to break patents, it has admitted that it is reluctant to actually take this action, since it takes time to begin manufacturing a new generic drug, and pharmaceutical companies may retaliate by refusing to supply the drugs at all in the interim.

WHY DOES EVELYN CISNEROS WEAR THE BRACELET?



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She wears it to raise desperately needed funds for HIV/AIDS care services, education and vaccine development. Over half a million people have chosen to wear The Bracelet. What about you? Available at: The Body Shop; Kenneth Cole; Virgin Megastore; Ben Bridge Jewelers and other fine retailers. Or visit us at WWW.UNTIL.ORG or call 1-800-88-UNTIL to order.



Purchasing a UTAC bracelet contributes directly to the International Association of Physicians in AIDS Care (IAPAC) and its mission to improve access to quality treatment for all people living with HIV/AIDS. A full 25 percent of the price of each bracelet goes directly to IAPAC programming. Please be sure to mention IAPAC when shopping at www.until.org.