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Modest Advances in Hep C Treatment Come at a Hefty Price

by Dave Gilden

With the long awaited FDA approval last fall of Hoffmann-La Roche's products Pegasys and Copegus, Schering-Plough is suddenly facing competition for the hepatitis C market. In January, Roche heightened the rivalry by launching Copegus, its formulation of the standard drug ribavirin, for 43% less than Schering's price for its ribavirin brand, Rebetrol.

Price competition among prescription brand-name drugs is very unusual. How real is it in this case? Both companies are offering a modestly more effective version of interferon alfa and ribavirin for treating persons with chronic infection with hepatitis C virus (HCV). And the bill for even Roche's hepatitis C therapy is enormous. It has doubled since 1998 and is now more than twice the price of HIV therapy.

Pegasys and the two-year-old Schering product, Peg-Intron, are pegylated versions of interferon alfa, which has been the backbone of HCV treatment since 1991. Interferon alfa enhances cells' internal defenses against invading viruses and stimulates antiviral immunity. Pegylation involves joining interferon alfa to polyethylene glycol. This amalgamation stabilizes interferon in the body, allowing for higher average blood levels and once-weekly dosing.

When Schering introduced Peg-Intron two years ago, it charged a premium price — more than double that of its standard interferon, which was approved in 1992. Interferon alfa is usually taken with ribavirin, which alters cellular metabolism. Ribavirin further adds to the cost. The current price of Peg-Intron plus Schering's ribavirin is about $3,500 a month. Therapy lasts up to 12 months, so the total cost can exceed $40,000.

Price Backlash

During community meetings over the past three years, Roche promised to price responsibly. Activists felt betrayed when Roche introduced Pegasys at a price of $1,500 per month, almost exactly the same as Peg-Intron. Pegasys offered no relief to cash-strapped state AIDS Drug Assistance Programs and Medicaids, which are now cutting coverage to millions of people.

A national protest letter signed by 97 organizations and individuals complained: "Earlier on, many advisory board members, activists and HCV coalition members

Pegylated vs. Standard Interferon: Sustained Virologic Response*

	No. of Volunteers†	Overall Response	Genotype 1	Genotype 2 or 3
Schering-Plough Trial				
Standard interferon alfa 2b (Intron A) + ribavirin 800 mg/day	505	47%	33%	79%
Peg-Intron 1.5 MIU/wk for 4 weeks, then 0.5 MU/wk, both + ribavirin 1,000-1,200 mg/day	514	47%	34%	80%
Peg-Intron 1.5 MIU/wk + ribavirin 1,000-1,200 mg/day	511	54%	42%	82%
Roche Trial				
Intron A + ribavirin 1,000-1,200 mg/day	444	44%	36%	61%
Pegasys 180 mcg/wk	224	29%	21%	45%
Pegasys 180 mcg/wk + ribavirin 1,000-1,200 mg/day	453	56%	46%	76%

*Sustained virologic response is defined as undetectable HCV viral load (less than 200 copies/mL) 24 weeks after ending 48 weeks of therapy.

†Trial participants had mild-to-moderate liver disease. They were all HIV-negative and HCV treatment-naive.

Response in persons with high viral load genotype 1 HCV:

From the Schering Peg-Intron package insert: In the trial above, HCV patients with both poor prognostic factors (genotype 1 and high viral load) had a response rate of 30% (78 out of 256 trial participants) with Peg-Intron/ribavirin compared with a response rate of 29% (71/247) with Intron A/ribavirin.

From the Roche Pegasys package insert: Treatment response to Pegasys/ribavirin is lower in patients with genotype 1 high viral load HCV compared with genotype 1 low viral load (43% vs. 56%, respectively).

worked with the FDA to clear the path for regulatory approval of Pegasys, stressing the need for competition because of the incredible price charged by Schering. Most of all, we warned Hoffmann-La Roche not to use the Schering price as a standard of reference, but rather make its pricing decision on a higher moral and ethical plane… We expected a lower price for Pegasys and got one even higher than anyone imagined." (This letter was circulated by Project Inform in San Francisco.)

Referring to the ribavirin price break, Roche marketing official Jesus Leal said, "I couldn't have done this without the community support." The 43% saving over Schering leaves Roche's ribavirin costing around $6.50 per capsule at the retail level. Patients take four to six capsules per day, depending on their weight. The mathematics is formidable, and the 12-month combined retail cost for Roche's two products amounts to over $30,000.

Brian Klein, of the Hepatitis C Action and Advocacy Coalition (HAAC) in San Francisco, was partially mollified. "Roche did come in significantly better than I expected. I would have expected that generics would come in at that price. I thought they would have charged about 25% less than Schering because Schering pays royalties on ribavirin. This price will put pressure on the generics whenever they are finally allowed onto the market."

The Generic Players

Aside from Roche and Schering, ribavirin is also available from Fisher's SPS, a compounding pharmacy in Pittsburgh. Fisher's custom packs its own ribavirin capsules from the bulk drug purchased in China. Fisher's price — $1.50 per capsule — is much lower than the big companies. Klein claims that "it only costs ten cents per capsule for the [Chinese] bulk drug."

There is plenty of room for price competition on ribavirin, and generic drug companies geared up to market it after its patent expired last June. Schering has blocked these moves with lawsuits. FDA approval of generic ribavirin has also been delayed by a technical dispute over the wording of the official package insert.

Roche sidestepped much of the legal blockade by developing a new brand-name ribavirin, whose approval entailed new clinical trials. Of course, these excess development costs add to the final price. The generic companies, on the other hand, are only required to prove that their product is chemically equivalent to the brand-name drug. They don't have to engage in special clinical trials. The generic companies will probably charge about a fifth less than Roche, which has set the new benchmark.

Patients Drop Out as the Healthcare System Flounders

The introduction of pegylated interferon was heralded as a great advance, but clinical trials found only small improvements in the response to therapy (see table). Particularly disappointing were the responses in people with high viral load genotype 1 HCV. A majority of Americans with hepatitis C have stubborn infections of this sort.

Patients' actual experience is much worse than the trial data indicate. Hepatology clinics in Boston and Cleveland recently reported that about 70% of referred patients are found ineligible for treatment because medical or psychological factors make them unlikely to endure its rigors. Eligible patients face a long list of side effects even with pegylated interferon. These include fatigue, flulike symptoms, muscle aches, gastrointestinal upset, diabetes, vision loss, rashes, anemia, low white blood cell counts, kidney damage, agitation and depression. The frequent ribavirin-induced anemia is managed with Procrit, an

injectable red blood cell growth factor. Procrit adds another $7,500 to $15,000 to the yearly cost of treatment.

Other steps to make therapy tolerable include Neupogen for low white blood cell counts, insulin-sensitizing drugs for diabetes, SSRIs for depression and many lab tests. A patient's out-of-pocket costs can amount to as much as $1,000 per month, said Ken Fornataro, Director of the AIDS Treatment Data Network in New York. Many hepatitis C patients stop therapy in the third month. "They kind of hit a wall at 12 weeks," he said, "they actually have more toxicities than ever while having a harder time dealing with the care system." The 12-week point is the time for initial evaluation of the therapy's effectiveness. If viral load has declined dramatically, treatment continues, but the doctors now turn their attention to newer patients who are struggling to cope with starting therapy. Continuing patients lose the priority they once had. They have to wait for appointments or even to talk to healthcare providers.

"It all has to do with cost of staff, resources and efficiency of referrals to specialists," said Fornataro. "At 12 weeks, patients decide that therapy isn't working for them. Stopping appeals more than the promise of a sustained virologic response."

The cost of hepatitis C treatment is like a tidal wave cutting through the doctor's office. It carries away all the funding available from private insurers and public health agencies, leaving little for ongoing case management.

The New Ribavirins

Three safer alternatives to ribavirin are on the way, promising to ease the burden of HCV therapy. Vertex Pharmaceuticals' VX-497, like ribavirin, inhibits the cellular enzyme IMPDH. VX-497 is now in phase II trials. Also in the works are levovirin, a mirror image of the ribavirin molecule and viramindine, a ribavirin prodrug preferentially absorbed by liver cells. These should hit the market in two or three years. The current price of ribavirin will not have a long-term impact on hepatitis C treatment, except that it establishes a floor for the new drugs. Their developers will charge a premium over ribavirin based on the drugs' attractive features.

Pegylated interferon will remain the expensive mainstay of hepatitis C therapy for many years to come. True antiviral drugs, analogous to the ones for HIV, will not arrive until late in the decade. These are still in early stages of development, and it is hard to speculate on their role, much less their price. There is a good chance that they will require help from the older drugs to stop HCV. Triple combinations of interferon alfa, a ribavirin-like drug and an antiviral are likely. If the current pricing trends do not change, the new antivirals will represent a huge additional expense even as prices continue to rise for the older drugs.

The cost of therapy for HCV may double again by the end of the decade. In principle, treatment will be more effective than ever, but the medical system will find it still more difficult to provide adequate care.

Female Barrier Contraceptive Finds New Role in HIV

by Kristen Kresge

"People started calling me the diaphragm lady," remarked Nancy Padian, Director of International Programs at the University of California, San Francisco's AIDS Research Institute. Padian spent much of the last eight years on a spirited quest to study diaphragms' power to prevent HIV transmission. With tens of millions in new funding for trials, she is no longer so easily dismissed.

Women for decades have carried around rubber diaphragms in their handbags as a convenient and unobtrusive barrier method of birth control. This old mainstay may now have a promising new role in the global fight against HIV. Vaccine researchers may view this as a reversion to the Stone Age, but Padian finds it intriguing. "The fact that you have an approved device that might be preventive … it's sort of elegantly simple," she said.

A properly fitted standard diaphragm costs about $25, and an experimental one-size-fits-all version will cut the price dramatically. Once positioned over a woman's cervix, the diaphragm can comfortably remain in place for an entire day and protect during repeated sexual acts. A diaphragm can also be used without sexual interruptions or the partner's knowledge. This becomes especially useful among sex workers in Africa and other regions where women are paid less if a protective device is used.

Padian hopes that the diaphragm will reduce HIV infection rates by 30% or more, the same goal sought for the first HIV vaccines, which are years away from practi-

cal use. Even this low rate of protection could have a major impact on HIV's spread.

Padian considers the female condom, the only other attempt at creating barrier HIV protection for women as highly disappointing. This barrier device fails as a good alternative to the male condom because it requires cooperation from the woman's partner. Female condoms are also quite expensive for women in developing countries because they cannot be reused. Besides, how much protection the female condom provides amount protection they provide is still unknown.

Opening Up the Funding Gates

Funding agencies initially dismissed the idea that women would be willing to use a diaphragm, even if proven effective in preventing HIV transmission. Finally, CONRAD, a small contraception research agency based at the Eastern Virginia Medical School, supported Padian's pilot study in Zimbabwe to measure women's willingness to use the diaphragm. In that country, HIV infects an estimated 34% of adults aged 15 to 49. Padian presented this study's results at the XIV International AIDS Conference last summer in Barcelona.

Zimbabwean women first took part in a two-month program to encourage and teach male condom use. Those still unable to convince their partners to regularly employ condoms were enrolled in the diaphragm acceptability phase. Padian found that 98% of the 156 women in this study were willing to use the diaphragm as an alternative method, knowing that its effectiveness against HIV remains undetermined. Only 1% of the women in the study had ever used a diaphragm before.

That preliminary study paid off. At the end of the summer, Padian's proposed diaphragm efficacy trial in southern Africa received $28 million in funding from the Bill & Melinda Gates Foundation. One reason that the Gates Foundation grew interested in the diaphragm's benefits was its own focus on preventing the spread of the disease. The foundation released a report at the International AIDS Conference this summer detailing a comprehensive plan to prevent 29 million HIV infections by 2010. Padian received the bulk of the funds made available to investigate available technologies.

Padian, who is a major recipient of National Institutes of Health funding for other projects, could never obtain government backing for diaphragm research. "The simplistic approach to an AIDS problem is not looked at with great enthusiasm," said AIDS pioneer Dr. Jay Levy, a colleague of Padian's at the University of California, San Francisco. "It was too simple for the NIH to sponsor. The Gates Foundation listened and agreed to give it its day in court."

The study itself is hardly simple. Collecting enough data to analyze the diaphragm's influence on HIV transmission will take at least four years. Padian's trial will follow 4,500 women at two sites in South Africa and one in Zimbabwe. It will last four years, with participants randomized to either the control group or the diaphragm group. Both groups will receive safe sex/condom counseling to satisfy ethical concerns.

Since the condom is the most effective prevention tool available, Padian does not want the diaphragm perceived as its replacement. "I don't think we're looking for just one prevention device," said Padian. The ethically necessary safe sex counseling, which promotes condom use even as the diaphragm is tested, will complicate and further retard the data analysis.

A nettlesome analytical issue will arise if members of the trial's control group utilize condoms more often than the diaphragm group. This will weaken diaphragms' observed effect. Then too, the study must rely on information provided by the participants to determine the results, which decreases its analytical precision. Some women may report using a diaphragm when they did not or some may use a condom and a diaphragm together without mentioning this dual use.

"There are many things that make these trials difficult to show what they're trying to show, even if they work," said Thomas Moench, the Medical Director of the microbicide research firm ReProtect in Baltimore. "You could have 40 or 50 percent prevention with the diaphragm and the study wouldn't show it."

The Original Science

The cervix has long been identified as a focal point for sexually transmitted disease. Although they can shift during sex and leave the cervix exposed, diaphragms usually block fluids from ever reaching the cervix or the upper genital tract. Researchers have found that diaphragms offer strong protection against chlamydia and gonorrhea, which may be due to the associated spermicide as well as to the physical barrier that diaphragms provide.

The concept of employing diaphragms against AIDS was an extension of these observations. Jay Levy first proposed the idea back in 1989. Levy's laboratory was studying the transmission of HIV from men to women. He found that a woman's cervix, and not her vagina, is probably the most susceptible location for infection during heterosexual transmission.

He also found that a main source of infection was not free-floating virus in semen, but seminal cells already infected by HIV. For these HIV-infected cells to infect the woman, Levy knew they had to come into contact with immune cells.

Cervical tissue is full of immune cells, much more so than vaginal tissue. Levy observed that it was also easy for the HIV-infected cells to reach the cervical immune cells because the cervix has a very fragile and thin lining. Also, contractions that occur during sex cause fluids to be drawn up into the uterus and upper genital track, another vulnerable region.

It makes sense that the majority of women with HIV contract the virus through the cervix, and the diaphragm's ability to block the cervix should offer protection. "I'm fairly certain there will be an effect," Levy predicted.

Levy called the cervix the "hot spot" for transmission of HIV, but it is not the only place where infection can occur. Thomas Moench pointed out that female monkeys can still contract HIV even if they have had complete hysterectomies.

"Transmission can occur across the vagina, but the vagina is kind of like skin — it's made of many layers of cells. The cervix is very fragile. It's most susceptible," said Moench.

Bolstering the Diaphragm

No one expects the diaphragm to be as protective as the condom. Condoms are the most proven method available for protection against HIV and AIDS, with an efficacy rate estimated by several studies to be 90% to 95%. Getting people to incorporate them into their sex lives has been the big problem.

Moench says that in the United States, condom use occurs in less than 15% of heterosexual sex. It is dramatically lower in countries where infection rates are higher. The Joint United Nations Programme on HIV/AIDS claims that condom use is below 5% in hard-hit Botswana, where 40% of all adults aged 15 to 49 are infected with HIV.

"This epidemic would be over if we didn't have problems with condom acceptability. Condoms are the best thing we've got," said Moench. "But we need a method women can control themselves."

Moench worries that many people will trade in the safer condom for the more convenient diaphragm if the trial results are good, a trend that he refers to as "condom migration." Conversely, he wonders whether the public will dismiss the diaphragm entirely if the desired protective effect is not evident. This could have an unwelcome impact on microbicide research.

He foresees combining microbicides and diaphragms as the ultimate protection strategy for women. But because a female-controlled device is urgently needed, Padian does not want to wait until a microbicide receives approval.

"It's proven difficult to get at this in a way that's satisfying to everyone," Moench remarked. "One is more likely to work [diaphragm with microbicide] and one is simpler [just diaphragm]. But it could be years until a microbicide is approved. That's driving them to want to explore the diaphragm by itself."

Moench agreed that diaphragms are a sound option for women who cannot convince their partners to regularly use condoms. "You don't have to be going after 100% efficacy. A partially effective strategy, used widely, could be tremendously beneficial."

As Padian works out the final design of the study, both she and Levy remain confident that the diaphragm will show significant protection against HIV. "I think it will work. We're hoping for a 30% to 40% effect, but we may do even better," said Levy.

Cuba Fights AIDS its own Way

by Anne-christine d'Adesky

Located a half's-hour drive from Havana, the sanatorium at Santiago de las Vegas is the biggest and oldest AIDS center of the 17 on the island. The main facility is hidden behind a walled entrance in an architectural hybrid of heavy Soviet-style institution and Alpine ski resort set in the humid tropics. Across the highway, smatterings of low Florida-style bungalows serve as laboratories and medical wards and house some 450 patients.

From 1986 to 1993, Santiago de las Vegas epitomized the country's much criticized quarantine that kept people with HIV apart from the general public. Forced quarantine ended in 1993, but the government retains an aggressive public health approach to controlling HIV. The sanatorium model reflects an emphasis on preventive care over acute care and on early diagnosis and quick treatment of infectious diseases like tuberculosis. Cuban officials take pride in the sanatoriums, crediting them with keeping HIV prevalence under 0.1% of adults between 15 and 49 years old. That is one of the lowest incidences in the world and ten to 60 fold below that of Cuba's Caribbean neighbors. By official count,

Cuba has about 3,200 cases of HIV, almost entirely in gay and bisexual men.

Like TB, HIV is viewed by the state as a medical condition for which an individual bears social responsibility. Individuals who test positive for HIV are required to spend at least three months in an AIDS sanatorium where they take a training course in living with HIV and protecting others from exposure. As part of the sanatorium model's 1993 reform, they also have the option of attending the training on an outpatient basis. Today, 48% of Cuba's HIV population live in the sanatoriums. The rest live outside and receive care at a few specialty centers.

A key criterion for living outside the sanatoriums is disclosure of one's sexual partners and providing the health authorities with "confidence" that one is sexually responsible. The health authorities actively pursue contact tracing and HIV testing of sexual partners, strategies borrowed from the TB program. There is also mandatory HIV testing of pregnant women, soldiers and blood donors, but anonymous testing is available for the general public. Last year, over a million HIV tests were done in Cuba, out of a population of 11 million. Condom use has doubled in a few years. These are distributed in bars, clubs and pharmacies but are in limited supply.

Before 2001, some patients were getting dual therapy through foreign donors, and drug availability was problematic. Around 900 people now receive a triple generic cocktail of two nucleoside analogs and the protease inhibitor indinavir. Two new medicines in other classes will soon be attainable. The government has started training the specialists who treat AIDS patients and other health professionals as well, but budget restrictions have hampered this effort.

"We have made a lot of progress, despite not having all the resources we need," said Dr. Jorge Perez, head of the national HIV treatment program and director of the Pedro Kouri Institute of Tropical Medicine (IPK) in Havana, an infectious disease hospital and the main center for AIDS research. The IPK serves as the central clearinghouse for all Cubans receiving anti-HIV drugs, which it distributes to their clinics.

"Free and Easy Access"

"One of the characteristics of the health system is that it is free and has easy access. Everyone is entitled to the same level of care," explained Dr. Perez. "Even though I am a specialist and in charge here, a patient from anywhere can decide to come and see me."

Like other health officials, Dr. Perez cited the U.S. trade blockade of Cuba as a critical factor that has affected the AIDS program and contributes to the chronic shortage of medicine, food and other necessities.

"It's true we are hurt by economic problems and our patients have suffered from a lack of medicine," said Perez. "The lack of money is a constant problem for everybody. But now that we are producing our own drugs, things have started to change."

The IPK is located outside the capital and is compared to the National Institutes of Health in the U.S. because it combines frontline clinical research with treatment. In reality it is a small, dimly lit place in need of a paint job. HIV patients praise the free medical care it provides, which includes both medicine and diagnostic tests. HIV patients have their CD4 counts assayed every three months, and those on treatment also get viral load tests. They return to IPK for monthly follow-up visits and are monitored at home by a family doctor.

Of the 900 people on anti-HIV therapy, 72% are men, and 28% women. One hundred thirty who have received drugs since 1996 require salvage therapy regimens. They rely on donated drugs. Perez will not begin someone on a salvage regimen unless he has a guaranteed six months' supply of the drugs. Still there are gaps in the supply.

For the majority, anti-HIV drugs are seen as a godsend. After 18 months, Dr. Perez reported, "Most of the people on therapy are doing very well." His one-year follow-up data shows that almost all had undetectable viral levels, higher CD4 counts and improved weight gain. After three months of therapy, 74% who began with CD4 counts below 200 jumped to over 200, then climbed progressively to over 350 after a year. Those who began with CD4 counts around 350 went up to 500 within three months, "and very easily," the doctor added. As of December, 50 people were waiting to get their first anti-HIV medications but not because the drugs are lacking, Perez explained. It takes four to eight weeks to meet with referring doctors and complete the paperwork.

Cuba has a uniquely decentralized, family-centered healthcare structure that relies on a local team of a family doctor, nurse, and social worker assigned to care for 120 people in a given community. Local health officials report up the ladder to regional and national authorities. "At each level, there are people invested in how the patient is doing," explained Dr. Perez. That includes the pharmacists at IPK who track every pill given out and the psychiatrist who evaluates how patients are coping.

Adherence to dosing schedules remains a daily challenge. Perez has had patients who stopped taking their medicine without telling anyone and even died. HIV treatment is supervised for those hospitalized at the IPK and at the sanatoriums but not for those living at home. The family doctor or social worker is supposed to follow up, but in reality,

"Many people don't like their families to know they have HIV. It's difficult to send a nurse in - it's an ethical issue," he said.

The biggest challenge is caring for patients with advanced AIDS. Treating their HIV does not help them much, Perez observed. In 2000, 141 people with AIDS died. In 2001, when triple therapy commenced, the number dropped to 116. The mortality rate is now 7%. Most new HIV cases are diagnosed early, within six months to a year of exposure, so AIDS itself should now be avoidable.

Life inside the Sanatoriums

Dr. Perez took over the reins at the Santiago de las Vegas sanatorium in 1989 and is lauded as the person responsible for opening up the system. "They have very good living conditions there," he said, adding that many living in the sanatoriums are poor, previously unemployed or lack family support to live as well outside. "They have a house, air conditioner, color TV, 100% of their salary and a diet very high in calories and rich in protein. No one else has so much," he noted, smiling.

That said, he was still shocked back in 1993 when only 10% of residents opted to leave the sanatorium when offered the chance. "It was not discrimination; it was fear," he explained. "Those were the years of the really bad 'Special Period' when people were hungry." Others point out that since most residents are gay or bisexual men, the sanatoriums provide a more tolerant social environment, allowing gay couples to live together, for example. Some residents have lived there since 1996.

According to sanatorium officials, residents can freely come and go and get daily visits from relatives and friends. It is a major change from 1989. "When there was no treatment, it was hard for the patients and for the persons caring for them to confront [the absence of medical options]," said a staff psychologist there. "This was a very difficult situation."

Of the 1,000-plus people who have passed through the sanatorium since it opened, 380 now live there. A medical and social support staff of 300 attends to them. Between 1998 and 2000, there were 22 outpatient groups.

To an outside visitor, the sanatorium feels like an army base, set apart from civilian life in a self-sufficient world with a basketball court, a garden and other facilities. Residents live as couples or four to a small house, their rooms resembling college dorms with basic furniture, including the air conditioners Perez mentioned. At one house, four gay men gathered on a porch amidst the heat on a humid afternoon. They greeted a visitor politely but warily, aware that a staff psychiatrist was present. Yes, they replied, they receive superior medical care compared with outside hospitals, and they eat well. Yes, friends and family may visit them. All of them received a special stipend for working on the premises. Sanatorium residents are entitled to receive 100% of their former salary. Persons with HIV outside the system get 50%.

Many residents require treatment for their HIV, they confirmed. Two of the men were managing their drugs without much difficulty. One had experienced some initial side effects. A younger man was preparing to begin treatment. He was unsure of what medicine he would take or how it worked. All expressed a desire to know more about new developments in AIDS and to have more contact with HIV-positive persons outside Cuba.

How free were they to leave? They were free to go if they were healthy, had completed the HIV training course and were enrolled for social services, said the psychiatrist. "If they have health problems and they want to go, they can, but we don't recommend it," he added. "Or if they've started triple therapy, we suggest they stay a while to see if there are any adverse reactions."

What about the issue of "sexual responsibility" — the standard by which people are judged eligible to leave? "Here we view the idea of a person being responsible for the health of another as a very relative term," explained the psychiatrist. "We say that person has a right to a higher quality of life and social rights. But they must modify their behavior to care for themselves and others. If you meet someone who has psychological issues, who has no family to support them, or if they are a person who has infected several people because they have no conscience, then we have to make a plan for that person. For them, it can take longer." The program works, he argued. "Out of the thousand-odd people who have stayed here, or as outpatients, very few have infected others."

The Unofficial Story

That is the official story. Away from the eyes and ears of health officials, Cubans living outside the sanatoriums offer a different picture. "I have always disagreed with this decision by the state," Cheo (not his real name) remarked about the sanatorium system. Forty-one years old and bisexual, he was diagnosed with HIV in 1993, just as Perez was reforming the sanatorium system. An HIV test was done without his knowledge after he went to a hospital for what doctors thought was glandular cancer. "For me, it was obligatory to be in the sanatorium; there was no other option. But I didn't want to go," he related. "For two years, they tried to pressure me, saying I had to go and learn to live with HIV, that there was good food, etc. But I said my parents supported me very well. I didn't want to be separated from them."

Cheo says he received regular visits from health officials and was threatened with arrest, as were his parents. He pleaded his case with higher officials and was allowed to take a training course in a Havana center. He gets treatment at the IPK. But for years, he said, "I had no support because I had no friends with HIV, and my family was ignorant about it. I thought I would die right away."

In Cheo's view, life at the sanatoriums "is not a normal life, because it is very controlled. It is all about illness." People may get quality medical care, but they remain socially isolated. "If they could afford to, most would live outside," he believes. "How can you call something a choice if you don't have another option?"

He isn't alone in complaining about the lack of privacy or consent for Cubans living with HIV. In interviews, several individuals complained of the paternalistic nature of the AIDS program, and of the prevailing stigma and isolation they suffer. "There is a lack of freedom here in Cuba, and when you have HIV, it's that much harder," explained Cheo. "You are seen as a threat to society by the authorities. These views are changing, but people still think that way."

The same is true for gay people, who are more socially accepted, but live publicly closeted lives. There are no openly gay clubs or spaces, he explained, just informal parties. And though the cruising scene in Havana is active, Cheo says the police regularly show up at 2 a.m. to shoo gay people away from the Malecon, Havana's famous seaside boardwalk. "It's not like it was ten years ago, but it's not easy to be gay here," he concluded. "You have to watch yourself."

The law makes it hard for people with HIV to organize or get support outside of state-run organizations, though "mutual aid" groups have been permitted to form since 1997. "We exist, but we aren't legalized," said Cheo, who added that informal groups cannot legally fundraise or apply for government funds. In Havana, around 60 people attend a support group at the Montserrat church, the largest of its kind. The church provides a safe haven, Cheo claimed, because "the government isn't allowed to enter that terrain."

Cheo is especially critical of the policy of contact tracing. "It's supposed to be a decision of the person to disclose, to take charge of their situation and inform the people they've had relationships with," he explained. "But the thing is, the authorities need to know and there is a lot of pressure to tell them. If you don't say, and if they take you to the sanatorium, they won't release you because they won't have confidence in you."

Another critic, Manuel (again not his real name), said that gay people who test positive are asked to name their sexual partners of the previous five years. "Some people are afraid to name more than five persons because they will be labeled promiscuous," he noted, "but if you name too few, they'll say you are not disclosing."

Critics contend that there is a gap between official AIDS policy and discriminatory routine practices. "There is no privacy," said Manuel. "The minute you are diagnosed, everyone seems to know. The state can't protect you." Although a new labor law forbids the firing of HIV-positive individuals, both men have friends who've lost their jobs after being diagnosed. They know friends who have had unsafe sex with positive partners but won't get tested, out of fear of being sent to a sanatorium and losing their jobs. "A lot of people are in hiding or denial, " added Cheo, who feels official HIV statistics are too low.

Despite their complaints, these critics don't hold AIDS officials accountable for the problems of the system. "Dr. Perez doesn't make the rules. Nor do the people who work at the sanatorium," said Manuel matter-of-factly. "They can't speak out any more than we can. If they did, they'd be risking their jobs. A lot of people are doing what they can to help us. We appreciate that."

By highlighting Cuba's AIDS successes and struggles, officials hope foreign donors will respond. By speaking out, their critics are looking to HIV-positive groups for support. The Cubans urgently need more medicine (especially NNRTIs and OI drugs) as well as food and other basic necessities. Doctors and patients who lack access to the Internet seek the latest AIDS information. In a rare note of agreement, critics and officials alike feel that a change of U.S. policy toward Cuba and an end to the trade embargo would dramatically alter the economic and medical picture.

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