# Hard to Swallow

The morning after morning after morning after pill

March 1, 1998 By Mubarak Dahir

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It was the “end of AIDS” summer of 1996, a season of falling viral loads and rising infections, three-drug “cocktails” and “morning-after” pills, hope and despair. For Bill Washington, a 31-year-old New Yorker whose lover had just left, it was the summer he learned how easy it is for someone handsome and heartbroken to lose his way in other men’s desire. By Labor Day, he’d hit bottom -- in a seedy hotel room with a man he’d met on a phone-sex line. His host had described himself as a hot top who liked to party, but he turned out to be a psycho on speed. The evening’s entertainment included alcohol, cocaine, ecstasy and crystal meth. “To say I wasn’t using my best judgment would be an understatement,” Washington (not his real name) says. “I was very vulnerable.”

The sex got rough. Washington struggled and half-struggled, confused by what he wanted and what he feared. Then, to Washington’s astonishment, the man blurted out that the only thing keeping them from becoming a couple was that he had HIV but Washington didn’t, and the only way to change that was for him to infect Washington. Washington fought to get free from the man’s hold, but the man suddenly had a knife. Beyond panic, Washington surrendered. The man penetrated Washington without a condom. After three or four minutes, Washington began struggling again, and this time pushed the man off. But too late -- his partner had already come inside him.

Once home, Washington immediately left a message on the answering machine of his ex-lover, an HIV positive man on Crixivan, AZT and d4T. Two hours later, at his ex’s urging, he swallowed his first dose of the drugs. “He got me the drugs from his own stash,” Washington says. “If it hadn’t been for him, I wouldn’t have known who to call or what to do. There was no clinic giving out these drugs that I knew of.”

Now, a year and a half later, six post-exposure prevention (PEP) centers have sprung up nationwide, and scientists, safe-sex professionals, doctors and activists remain bitterly divided about the growing use of treatment as prevention. The practice itself -- offering antiviral therapy to try to block infection -- isn’t new. AZT has long been available not only to medical professionals at risk of infection through needle-stick or other occupational exposures, but also to pregnant women at risk of transmitting the virus to their unborn. Still, it was only after protease combos made undetectable viral loads routine that the discussion of -- if not demand for -- PEP for people exposed to HIV through rape, unsafe sex or dirty needles accelerated. Then the press popularized

it as the “morning-after pill,” and prevention workers panicked. In fact, PEP is only nominally like the two-shot menstruation inducer. The treatment typically consists of two nucleosides (and, sometimes, a protease inhibitor) taken within 72 hours of exposure, and it provides a four-week crash course in such aspects of drug hell as dosing (ranging from one Comvivir, or AZT/3TC, twice a day to as many as 11 pills throughout the day if you add nelfinavir), side effects (fatigue, headaches, nausea, vomiting and diarrhea), cost ($600 to $1,300) and the remote risk of multidrug-resistant virus.

There is general agreement that in theory PEP should work. Yet its actual effectiveness is ultimately unprovable: The successes -- those who test negative after taking it -- may never have had virus in their blood in the first place. Supporters make their case for PEP as a viable, albeit last-resort, tool of HIV prevention mainly based on a Centers for Disease Control and Prevention (CDC) study (released in 1995 and updated last fall) claiming that hospital workers who took AZT after needle-stick exposures had a 79 percent (more recently upped to 81 percent) reduced risk of infection than those who didn’t. That this study has two significant shortcomings -- enrollment was small, and the results were derived from statistical inference rather than a placebo control group -- everyone agrees. What is debated is whether, and to what extent, the study supports PEP’s widespread application. Last July, at a CDC-sponsored meeting of treatment and prevention experts, physicians, rape-survivor advocates, drug-treatment professionals and others, critics disputed the 79 percent figure as probably inflated. Most notably, Dr. Alfred Saah, a researcher at the Merck lab that designed Crixivan (the PEP protease of choice), said, “There is not a 79 percent reduction in infections,” and warned that offering PEP on the basis of that stat might establish a nonexistent standard of care. (Since announcement of the CDC update, Saah’s doubts about PEP’s effectiveness for occupational -- but not sexual -- exposures have softened. “But I’m afraid we’re going to create an expectation that encourages high-risk behavior,” he says.)

Theoretically, according to Dr. Alastair McLeod at the Center for Excellence for HIV/AIDS in Vancouver, British Columbia, the chances of infection from a single exposure are “minimal,” whether through unprotected intercourse (one in 1,000) or needle-stick (three in 1,000). “In straightforward, clear-cut incidents, the same statistics of chance and biology should apply.” But in practice, as anyone afflicted with morning-after panic knows, calculating the chances of infection is an exercise in futility. “Outside of a health care setting, assessing actual risk and exposure is extremely difficult,” McLeod says. “Particularly when you’re talking about sex. Who the hell knows in those cases?”

Dr. David Ostrow, director of the AIM (Awareness Intervention for Men) project at Howard Brown Health Center in Chicago, goes further. “There are too many differences between occupational and sexual exposure to recommend this treatment on the basis of the CDC studies,” he says. “The time between exposure and treatment tends to be different. The dose of HIV delivered is different. And how it is delivered to the body is different -- one is into the blood, the other is through the body’s cells. We just don’t have enough evidence.”

Advocates concede that PEP has a distinct shot-in-the-dark aspect. “Certainly, our picture of this is not complete,” admits Dr. Steve Boswell, executive director of Boston’s Fenway Community Health

Center, which began offering PEP in March 1996. “But what we know about the biology of the virus, and about these drugs, suggests early intervention works.” Boswell says the key in applying PEP is “assessing an individual’s exposure level, then weighing the risk of contracting HIV against taking toxic drugs. It’s not a precise science. There’s no magic threshold to say this patient is a good candidate, and that patient is not. It’s a precarious balancing act.”

Boswell walks this tightrope at the Fenway clinic, where he sees as many as 12 PEP-seekers a month: After counseling, about half opt to take the therapy, and half of that number complete the four-week regimen, including the battery of blood tests (pretreatment viral load and HIV-antibody tests; weekly viral load tests; and HIV antibody tests three and six months after PEP). Fenway has yet to see a repeat visitor, an effect Boswell attributes to the success of the entire intervention. “It takes a lot of work to determine if someone is a good candidate for PEP,” Dr. Boswell says. “It’s not like we just give out three bottles of drugs and tell the person to come back for an HIV test in three months.”

David Asher was a good candidate. The 34-year-old university professor met with Boswell in September, two days (“39 hours”) post-exposure. A clear-cut case of “the condom broke,” Asher’s situation illustrates the torturous decisionmaking surrounding PEP: Even when all factors are known, every answer seems to raise only more questions. Since his friend and sex partner, Allan Snyder (neither man’s name is real), is positive, Asher had good reason to believe HIV had entered his bloodstream. He spent two-plus hours with Boswell and left the clinic with a 10-day supply of AZT/3TC/Crixivan; he talked to his sister (a doctor), Snyder’s doctors and a close friend. Still, he was miles from making up his mind. “I wanted time to reflect on all the information I’d just been given,” Asher says. “Will this really work? What if I’m really OK, and I end up taking a month of poisonous pills for nothing?” To complicate matters, can PEP cause resistance and affect his ability to take future antivirals if he becomes positive? And what if his virus is already resistant to this combination? “My life was turned upside down, and I had to make this big decision,” Asher says. Alone in his apartment, staring at the three bottles of hope, uncertainty and fear lined up on the coffee table and waiting for 11 pm, the time he’d set for his first dose, Asher made his decision. “I took the Crixivan,” he recalls, “and sat there wondering about side effects, ’How long until the parade of horrors begins?’” But Asher was one of the lucky few -- he had only mild side effects. The same was not true for Bill Washington or Judy Jensen, a 55-year-old Brooklyn needle-exchange volunteer pricked by a dirty needle in March 1997. As any veteran PWA pill popper could have predicted, the awful side effects altered their lives for the four weeks each took the pills. Still, they stayed the course.

The “morning-after pill” misnomer, with its magic-bullet fantasy, is every prevention advocate’s nightmare. Since the early ’90s, when the “second wave” of infections hit the gay community, safe-sex workers have cast desperately about for new prevention approaches. The last thing they needed was what the protease revolution delivered: The hope or hype of HIV’s “eradication,” of “noninfectious” infected men, of the uninfected young coming to view AIDS as treatable, or “no big deal.” At the first “morning-after” headlines, preventionists leapt into damage-control mode, fearing that this last-chance intervention would be seized on as a quick fix for unsafe sex.

“Talking about PEP as a form of prevention is getting away from the condom code,” says Richard Elovich, director of HIV prevention at Gay Men’s Health Crisis in New York City. “We should do nothing that gives men the idea not to use condoms, but that’s exactly what’s happening.” Even if PEP proves a potent infection blocker, Elovich questions its capacity to protect those most at risk: “Research shows when people don’t use a condom, it’s not a onetime thing. It usually happens again and again. So just giving these people pills is not solving their problem.”

At a time when targeted, psychological safe-sex messages are in the works -- but increased funds are not -- a thousand-dollar pill payout per person strikes many as less than cost-effective. “It’s not putting the money where the most people will be helped,” says Kevin Conare, executive director of Action AIDS in Philadelphia. Given the medical evidence to date, he says, “It’s giving more money -- and drugs -- to people who are less likely to be in an immediate health danger. But I’d rather see that money go into research and AIDS education.”

Yet even among prevention workers, opinion about PEP is split. Chris Bartlett, who directs SafeGuards, a safe-sex program in Philadelphia aimed at young gay men, says that years of survey data show that “there will always be a percentage of the population who engage in risky behavior. For whatever reasons, our messages don’t reach them.” But PEP may reach even these people. The pills are only one part of a proper PEP program, says Dr. Margaret Chesney, a codirector of the Center for AIDS Prevention Studies (CAPS) at San Francisco General Hospital, which launched the nation’s largest PEP clinic in October 1997, complete with three locations and a 24-hour hotline. “In addition to the therapy, people should be given hours and hours of counseling to help them think about their experience, what it means and how they can keep from repeating it.”

That’s how it worked for Bill Washington -- even without a clinic’s counseling. “The experience was horrific,” he says. "But it forced me to face why I was doing drugs and putting myself in bad situations.

A policy to withhold PEP in order to avoid legitimating unsafe sex, or to deny it to “repeat offenders” -- most likely gay men and needle drug-users, the epidemic’s time-honored “guilty” victims who “choose” their exposures -- strikes most experts as immoral. But some activists charge that such a practice has long been in place, albeit implicitly. “If health-care workers have had access to PEP treatment for years, why did it take until 1997 to offer it to people for sexual exposures?” is a question ACT UP/Golden Gate’s Don Howard has been asked so many times that he has a sound-bite ready. “Immaculate infections,” he says. “What’s implicit in all this is that occupational exposures are innocent and sexual exposures are guilty.” As Alastair McLeod notes, it is “generally accepted as advisable” to offer PEP to health care workers, police and firefighters and in cases of sexual assault. “The big debate is whether it is reasonable to offer it to people who have unsafe sex and IV drug users,” he says. “It’s not the science that’s the big hurdle to the wide acceptance of PEP programs. It’s the politics.”

Nothing illustrates these politics better than the fact that emergency rooms and clinics have rushed to offer PEP to survivors of rape, while hospitals, clinics and many physicians have foot-

dragged in treating gay men who have unsafe sex. “We hand out a five-day starter pack,” says Dr. Sue Comay, a medical consultant for the Sexual Assault Service of the British Columbia Women’s Hospital, in Vancouver, which began offering PEP in October 1996. While Comay believes that hers was the first rape crisis center in North America to establish an official PEP protocol, “I know it’s being dealt with the same way in many other centers” in Canada and the United States, she says. “It’s not yet the standard of care in the same way it is with hospital workers,” she admits, “but it will be by the end of the year.” In the first year PEP was available at Comay’s clinic, 28 women started on the treatment, but only two completed the regimen (neither has tested positive).

Comay concedes that in most rape cases, the victim is just as ignorant of her rapist’s HIV status -- and so, the likelihood of exposure -- as someone who has an unsafe one-night stand with a stranger. But she believes that the two risks yield different PEP policies. “The difference,” she says, “is that the one case is the result of a consensual act, while the rape is the result of a crime.”

Widely held if rarely articulated, this “not for unsafe sex” sentiment has advocates like Howard seeing red. “No one should be denied access to this treatment,” he says. “Moralizing has no place in this discussion.” Dr. Larry Bruni, who not only offers PEP to patients at his Washington, DC practice but even advertises it in an ad in the gay weekly *The Washington Blade*, agrees. “I’m outraged at the notion underlying who doctors are giving this treatment to and who they are withholding it from,” he says. “It’s nothing less than saying ’good’ people get access to medication and ’bad’ people don’t.”

Although Don Howard frets that Bruni’s ads might broadcast PEP as an alternative to condoms, Bruni says he is trying to make a quite different point. “I thought it would shame other [doctors] into talking about it.” Ads and all, last year only 12 patients came to him seeking PEP after unsafe sex, and only three of the 12 elected to go on the regimen (none has tested positive). “More than anything else, what people need is a place to bring their worries and fears when they’re in a state of panic about HIV,” he says.

This summer it will be two years since the “morning-after pill” promise and peril began. Even if the CDC is eventually recommends expanding PEP’s use beyond occupational exposures, some observers say, easy access through clinics is no certainty. The case of the PEP clinic at St. Vincent’s Hospital’s AIDS Center in New York City is instructive. According to director Dr. Gabriel Torres, the center -- a stone’s throw from the Lesbian and Gay Community Center -- began offering PEP last June, but only to survivors of sexual assault. “There was a strong movement -- and the political will -- for getting PEP to these people. I haven’t seen anyone advocating like that for gay men,” the openly gay Torres says. “For myself, I think most sexual exposures are more dangerous than occupational ones, so I believe it’s my ethical responsibility as a doctor to offer the treatment to anyone with a significant exposure. But I know other doctors who don’t.”

Yet whether it is seen as an ethical obligation or an economic opportunity, PEP’s time has come. And as current combination therapy is improved, resistance to PEP is likely to diminish. Meantime, ambitious studies are underway at the UCSF/San Francisco General and Fenway clinics to answer the elusive question: Does PEP encourage unsafe sex? Yet because there will be no control group

(no one will be turned away), researchers may never finally know whether this toxic barrage prevents infection.

But other answers exist. As of late 1997, when the PEP trio last checked in, Bill Washington, Judy Jensen and David Asher had all tested negative. Their evaluation is similar: The experience was terrifying, the drugs were terrible, but faced with the same needle-prick or rape or broken condom, each would choose PEP again. Even though they'll never really know if it worked. "If I seroconvert, at least I'll know I did everything I could to try to prevent infection," says Asher. "If I stay negative, the answer to that question doesn't really matter."

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