

AIDS Treatment News
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A Word from John James on this Special Issue on Treatment and Survival

This issue of AIDS Treatment News brings together some of the most important information on the effect of modern HIV treatment on improved survival. Some cautions:

1. Almost all doctors today agree that not everyone infected with HIV needs to take antiretroviral or other drugs. But everyone with HIV does need medical monitoring and care -- and access to treatment when and if it is appropriate for them.
2. Just because studies described below found that those with treatment had a fraction of the death rate of those without does not necessarily mean that your chance of survival will be correspondingly increased by antiretrovirals. The reduced death rates reflect the benefit of treatment for those who needed it most.

This article is part of our series to counter misinformation about AIDS treatment and prevention. Fringe groups are aggressively promoting such ideas as that HIV is harmless (or does not exist) in ways that encourage people to ignore medical and infection-control advice, risking their own health and the health of others. They are telling people that AIDS drugs are worthless poisons, prescribed because of a vast mistake or corruption, and suggesting that people with HIV or AIDS reject most or all medical care for that condition.

These bizarre theories -- sometimes presented with dozens of hundreds of misused references or snippets from legitimate scientific articles -- have led some people with HIV to stop all medical care based on one-size-fits-all conspiracy theories, regardless of their individual medical condition. Some of the believers are highly intelligent, and properly skeptical of mainstream authority; some have sincerely tried to investigate both sides of the controversy. Often they have found mainstream professionals too busy to talk with them, and not interested in explaining their work to the public -- while medical cultists, flush with mystery money but with no responsibilities for actual AIDS research or patient care, have spent years learning how to slickly package their arguments, complete with celebrity endorsements.

The following article, and others in this series, focus on bringing together findings of recognized scientists and explaining them for those who are not medical specialists. All of the articles will be available on our Web site (<http://www.aidsnews.org>).

-- John S. James, AIDS Treatment News

AIDS Treatment Improves Survival: Answering the "AIDS Denialists" by Bruce Mirken

Introduction

A sharp decline in AIDS deaths in the United States, Canada, Europe, and Australia began in 1996, coinciding with the widespread adoption of what has become known as "highly active antiretroviral therapy" (sometimes abbreviated "HAART"). These combination treatments have received much of the credit for the plunging death rate.

But AIDS denialists have disputed this claim, branding it a "myth." The denialists—who prefer to call themselves "AIDS dissidents"—not only reject the evidence that HIV causes AIDS, most even reject the idea that the term "AIDS" describes a unique medical condition. The denialists include a handful of scientists who had substantial credentials but have done little or no research with actual AIDS patients. Although members of this movement don't agree completely, most reject virtually all accepted HIV/AIDS medical treatment, as well as the use of condoms and safer sex to prevent AIDS.

Debate about the impact of anti-HIV drugs long precedes the advent of HAART. In 1992 this writer asked the late Michael Callen, an early AIDS activist and persistent skeptic about HIV, what would convince him that HIV caused AIDS. His immediate answer: "If antiretroviral drugs actually made people better." Callen, who unequivocally accepted the fact that AIDS was something new and deadly even as he doubted HIV's role in it, saw the minimal impact of the drugs available at the time—AZT, ddI and ddC, generally used as monotherapy (single drug treatment)—as corroborating his belief that HIV was not the cause.

While factions in the denialist camp disagree about what actually makes people with AIDS sick, there is nearly universal agreement in the movement that anti-HIV drugs are useless or worse. HIV is irrelevant, they argue, so the drugs provide nothing but toxicity.

"Die Offs" and "Shocking Statistics"

When a steady stream of reports of improved health and decreasing death rates started to flood the media in 1996 and 1997, denialists like AZT: Poison by Prescription author John Lauritsen dismissed them as so much smoke and mirrors. In a March 1997 talk he attributed the apparent good news to the "psychological effect" of people with AIDS being "expected to have a Lazarus recovery" and to "the selective reporting of anecdotes."⁽¹⁾ He predicted that this house of cards would soon collapse, declaring, "I expect within the next half year or year we'll see a perfectly hideous crash, a die-off."

But the die-off failed to materialize. The Centers for Disease Control and Prevention continued to log declines in AIDS deaths in 1997, 1998 and -- tentatively, as reporting may still be incomplete -- 1999.(2, 3)

As it has become indisputable that the drop in AIDS deaths is real, other explanations have been put forth. In her book, *What If Everything You Thought You Knew About AIDS Was Wrong?*, Christine Maggiore suggests that "a more likely explanation for decreased deaths would be the change in the official AIDS definition adopted in 1993, which allows HIV positives with no symptoms or illness to be diagnosed with AIDS. Since 1993, more than half of all newly diagnosed AIDS cases are counted among people who are not sick."

The logic behind this statement is unclear. If, as Maggiore argues, CD4 cell counts do not correlate with health or illness, then the 1993 addition of a CD4 count below 200 as an AIDS-defining condition has qualified some perfectly healthy people for an AIDS diagnosis. But giving otherwise healthy people an AIDS diagnosis would not necessarily affect either the number of people who had AIDS based on the old criteria or their survival prospects. If, as some charge, the drugs actually cause AIDS, it might even increase the number of AIDS deaths by encouraging healthy people to go on toxic regimens.

In her book and on the Web site of *Alive and Well AIDS Alternatives*, Maggiore makes a second argument: "AIDS deaths began to decline in 1994, two years before the new 'AIDS cocktails' were made available for general use," and so shouldn't be credited with a trend that had already started.(4, 5)

In fact, according to the U.S. Centers for Disease Control and Prevention (CDC), U.S. AIDS deaths rose from 45,271 in 1993 to 49,677 in 1994 and 49,992 in 1995. AIDS deaths dropped to 36,930 in 1996, 20,945 in 1997 and 16,432 in 1998, the lowest number since 1986.(3)

A variation on this argument -- that the decline in AIDS deaths began well before the advent of HAART -- was put forth by Celia Farber in the March, 2000 issue of *Gear*. She quotes David Pasquarelli, of the group that calls itself ACT UP San Francisco, writing that his organization "recently unearthed a 1997 study by San Francisco Health Department director Dr. Mitch Katz which exposes a shocking statistic which would appear to dispel the claim that the cocktails have caused AIDS deaths to plummet. Using stored blood samples and computer analyses, the study, published in the *Journal of AIDS and Human Retrovirology*, concluded that new HIV-antibody positive diagnoses peaked in 1982 in San Francisco -- two years before AIDS even had a name." She notes that the study estimated new HIV infections in San Francisco at 500 per year from 1987 on, adding that "Katz has since confirmed the group interpreted his data correctly."(6)

The study projected that reduced rates of HIV transmission would lead to fewer AIDS cases a decade later. But in announcing this "shocking" fact Farber never explains why she and Pasquarelli seem to fully accept estimates based on an assumption both have emphatically rejected: that HIV causes AIDS.(7) This also may be the only time ACT UP San Francisco has agreed with Katz, whom it accused of "genocide" in 1997 for studying

post-exposure prophylaxis,(8) and more recently branded "a lying AIDS industry clown who pulls bogus HIV increases out of a hat in order to secure funding."(9)

Farber's claim that Katz accepts ACT UP San Francisco's interpretation of his data is mistaken. The key conclusion, that reduced HIV transmission in the 1980s foreshadowed fewer AIDS cases in the 1990s, is stated explicitly in the article and requires no interpretation. Katz firmly disputes the claim that HAART has had no effect.

The numbers of actual and projected AIDS cases -- not mentioned in Farber's article -- appear to back him up. Katz and colleagues, assuming that treatment would only be as effective as AZT monotherapy and adjusting for distortions caused by the 1993 change in the CDC AIDS definition, projected that the drop would level out beginning in 1995 with 1,283 new AIDS cases that year, 1,200 in 1996, 1,122 in 1997 and 1,115 in 1998.(7) But 1995 saw 1,743 AIDS cases, 40 percent above the projection. In 1996, the year protease-based combinations became the standard of care, new cases plunged to 1,178. They kept dropping to 899 in 1997 and 713 in 1998-more than a third below projected levels. "That," says Katz, "is the treatment effect."(10)

What the Cohort Studies Say

Still, the basic issue put forth by Farber, Pasquarelli and Maggiore needs to be answered: If some unknown factor or factors unrelated to treatment reduced the number of AIDS patients, HAART could be receiving undeserved credit for the drop in deaths. On the other hand, if it can be shown that HAART has substantially improved patients' survival it is at least partly responsible for the good news.

The critical question, then, is: Is there evidence that HAART has improved the survival of HIV/AIDS patients? According to a leading denialist, University of California chemist David Rasnick, "It may come as a surprise that there is not even one study in the vast scientific, medical literature that shows that . . . a group of HIV-positive adults or children who take the anti-HIV drugs live longer or better quality lives than a similar group of adults or children who are HIV-positive and do not take the drugs."(11)

In fact there is an abundance of such evidence. Some, from clinical trials, has been discussed in detail in medical articles and at conferences. But clinical trials, conducted on limited numbers of patients for a relatively short time, with care often provided by physicians with more HIV expertise than average doctors, might not reflect what happens to most patients.

Real-world information on the impact of HAART in daily practice comes from what are known as cohort studies, which follow the experiences of specific groups of patients over extended periods of time. A number of large, prospective cohorts, specifically set up to track both the natural course of HIV infection and the effects of treatment and behavioral factors, have now reported results covering the pre- and post-HAART eras. Additionally,

a number of individual hospitals and clinics have reported on the impact of HAART on their patients.

The results from these cohorts, covering tens of thousands of patients from a wide range of locations and backgrounds, have been astonishingly consistent despite differing methodologies: When HAART is introduced, opportunistic infections and deaths drop. Patients on anti-HIV therapy do better than those on no therapy, and those on regimens involving more drugs do better than those on fewer. Most of these analyses, by focusing on deaths among patients already diagnosed with AIDS, are not affected by any overall reduction in the number of AIDS cases, whether due to reduced HIV transmission or some unknown factor.

One of the world's largest AIDS cohorts is the CDC's Adult/Adolescent Spectrum of Disease Project. The ASD project began in 1990 and has enrolled over 49,000 participants at 93 hospitals and clinics in nine cities. As of January 1998, 19,565 had an AIDS diagnosis by the 1993 definition.

During that period 9,280 deaths were recorded, and researcher Amy McNaghten and colleagues included in their analysis all except 188 deaths caused by murder, suicide or drug overdose. Average survival time after diagnosis increased in the later years of the study, coinciding with a shift from monotherapy (a single antiretroviral, such as AZT alone, or ddI alone) to two-drug regimens, and later to three-drug HAART combinations. All anti-HIV regimens improved survival compared to no treatment, with more intensive regimens producing greater improvement. Patients on three-drug combinations had a 1.6 times lower risk of death than those on dual therapy and a 2.5 times lower risk of death than those on monotherapy.(12)

The ASD researchers later reported that incidence of AIDS- defining opportunistic infections in the whole study population of over 49,000 patients plummeted when HAART came into common use in 1996. Strikingly, 46 percent of PCP cases after 1996 occurred in people who had never been in HIV/AIDS care.(13)

One of the most-cited reports came from the HIV Outpatient Study, which has followed over 3,500 patients in eight U.S. cities since 1992. Researchers analyzed data for all who had ever had a CD4 count below 100 (considered most vulnerable for opportunistic infections or death) from 1994 through June, 1997. Use of protease-inhibitor-containing regimens among these 1,255 patients went from two percent in mid-1995 to 82 percent by June, 1997.

Mortality (deaths per 100 person-years) remained roughly constant in 1994 and 1995, then dropped abruptly in the second quarter of 1996 and continued dropping. To determine the effect of treatment, investigators classified patients by type of therapy: no antiretrovirals, nucleoside analogue monotherapy, nucleoside combination therapy, and combination therapy including a protease inhibitor. Patients on no anti-HIV treatment were 1.5 times as likely to die as those on monotherapy, 2.9 times as likely to die as those taking combination nucleosides and 4.5 times as likely to die as those on protease inhibitor combinations. The risk of serious opportunistic infections was reduced in a nearly identical pattern.(14)

Strikingly similar results were reported by the EuroSIDA cohort, a prospective observational cohort that began recruiting patients from across Europe in May 1994. In November 1998 researchers reported on all 4,270 patients enrolled who were over age 16 and had a CD4 count below 500. Through March 1998, 1,215 had died.

As in the HIV Outpatient Study, the death rate was analyzed by treatment category. The results, published in *The Lancet*, are broken down into six-month periods, and the correlation between more intensive regimens and fewer deaths is consistent and dramatic. The lowest death rate recorded in any period for patients on no treatment was 50.3 per 100 person-years, while for those on one antiretroviral the death rate never rose above 22.3 per 100 person-years. On two drugs deaths never rose above 7.9 per 100 person years and on three or more drugs the highest rate recorded was 3.9 per 100 person-years. In other words, the lowest death rate for patients on no anti-HIV drugs was 13 times the highest death rate recorded for those on three or more. The researchers further noted that "in any given 6-month period, the death rate among patients taking protease inhibitors was much lower than among those not taking protease inhibitors."(15)

The EuroSIDA researchers also examined opportunistic infection incidence for HAART and non-HAART patients. Patients with CD4 counts below 200 were over three times as likely to have an opportunistic infection if they weren't on HAART.(16)

Several other large European cohorts have reported similar results, including the Swiss HIV Cohort,(17) the Italian HIV Seroconverter Study(18) and the Italian Register for HIV Infection in Children.(19)

Local Studies with All HIV/AIDS Patients

Certain localities have been able to assemble cohorts that reach essentially the entire population seeking care for HIV- or AIDS-related illness. For example, since 1986 the Canadian province of British Columbia has distributed anti-HIV drugs at no cost through a centralized system under specific guidelines, making tracking and analysis relatively simple.

In order to compare the real-world results of dual-nucleoside combinations vs. three-drug regimens including either a protease inhibitor or a non-nucleoside reverse transcriptase inhibitor, researchers at the British Columbia Centre for Excellence in HIV/AIDS studied all HIV-positive patients in the system who began anti-HIV treatment from October 1, 1994 through December 31, 1996. In a multivariate analysis (using statistical methods to adjust for a variety of differences between patients), those on two drugs were over three times as likely to die as those on three.(20)

San Francisco has an AIDS surveillance system that captures basic data for approximately 95 percent of the city's AIDS patients, and this data is particularly interesting in light of Farber's allegations. Unlike the study Farber cites, which used a complex collection of computer models and projections to estimate HIV infection rates

and AIDS cases, this "active surveillance" system assembles data on actual patients from health care facilities, death certificates and other sources. An analysis of this information was published earlier this year in the American Journal of Epidemiology, with a year's worth of additional follow-up presented at the International AIDS Conference in Durban, South Africa (July 9-14, 2000).

The first report found that survival after an AIDS diagnosis improved dramatically for those diagnosed in 1995 and 1996 compared to earlier periods. Researchers then analyzed all deaths among San Franciscans diagnosed with AIDS from 1993 through 1996 for whom treatment and CD4 data was available, finding that any antiretroviral treatment, before or after an AIDS diagnosis, significantly reduced the risk of death. When protease inhibitors were included the risk of death was cut by 75 percent compared to no treatment. The analysis included deaths from all causes, so any deaths from drug toxicities were included.(21) The research team's Durban presentation extended the findings through 1997 and again found that "antiretroviral therapy, especially combined with a protease inhibitor, strongly predicts improved survival."(22)

A number of other presentations at Durban reported a similar association between HAART and reduced rates of death and illness. Dr. Gary Reiter of the River Valley HIV Clinic in Holyoke, Massachusetts presented an analysis of HIV patients seen at his clinic and another Holyoke facility from March 31, 1997 to December 31, 1999.

177 of 300 patients were on HAART, defined as any regimen that maintained HIV suppression below 25 copies. According to Reiter, baseline characteristics of HAART and non-HAART patients were similar, except that those not on therapy generally went untreated because of psychosocial instability, mental illness and/or substance abuse. 20 of 23 deaths were in the 123 non-HAART patients. None of the three HAART deaths were due to AIDS-related infections, but one was from a drug side effect: ddI-related pancreatitis.(22, 23)

Reiter, who began his career in San Francisco at the start of the AIDS epidemic, commented, "Those of us who've been involved with the epidemic since '81 know that antiretroviral therapy works. I had hundreds and hundreds of patients die in San Francisco (1981 to 1985) and then western Massachusetts (1987 to 1995) until we got effective therapy. We are coming up on four years now of no AIDS deaths in treated individuals."(24)

Even early skeptics about some of the mainstream ideas have seen the value of anti-HIV treatment. Joseph Sonnabend, M.D., who treated some of the first AIDS patients about 20 years ago and whose early articles are still quoted on some denialist Web sites, now says, "the antiviral therapies available since about 1996 can be life saving in people with more advanced disease, and HIV clearly plays a central role in this disease."

The "Drug-AIDS" Hypothesis

It is worth noting that some in the denialist camp not only claim that anti-HIV treatment is worthless, but that it actually causes AIDS. The most well known of such theorists is University of California Berkeley molecular biologist Peter Duesberg, who has proposed that AIDS in the U.S. and Europe is caused entirely by recreational drugs and antiretroviral medications, especially AZT.(25, 26) Many in the denialist movement who do not fully embrace Duesberg's hypothesis agree that anti-HIV drugs play a role in causing AIDS. Maggiore, for example, accuses AZT of killing HIV patients and suggests that all of the nucleoside analogues may constitute "AIDS by prescription."(27) Pasquarelli recently asserted that "the ONLY people dying are those who take poisonous AIDS drugs."(28) (emphasis in original)

Such theories are difficult to sustain in light of the data cited above, and the broader picture backs up the studies. During the period in which AIDS deaths dropped by two thirds, sales of the drugs condemned as "toxic DNA chain terminators" skyrocketed. Sales of Glaxo's antiretrovirals, led by AZT and 3TC, quadrupled between 1995 and 1999.(29) Bristol-Myers Squibb, the other leading maker of nucleoside drugs, also reported large sales increases.(30)

Since Duesberg's "drug-AIDS hypothesis" pins much of the blame on recreational drugs, it is plausible that a massive decline in recreational drug use might have overcome the exponential growth in use of allegedly murderous antiretrovirals, but the opposite appears to have happened. The government's major instrument for measuring rates of drug use, the National Household Survey on Drug Abuse, charted an almost unbroken rise in the use of illegal drugs during the 1990s. The survey noted substantial increases in use of many of the specific drugs Duesberg implicates in AIDS, including heroin, cocaine and inhalants.(31) While information on drug use by gay men, still disproportionately affected by AIDS, is less complete, there has been much discussion in the gay press and in popular books about increasingly heavy drug use in certain segments of the gay community, particularly the co-called "party circuit." At least one study has reported significant increases in both numbers of drug users and severity of drug use among young gay men from 1994 to 1997.(32)

Might it be that this increase in use of anti-HIV and recreational drugs hasn't had enough time to do damage? While theoretically possible, such a proposition would directly contradict the arguments Duesberg made throughout the 1990s. In making an epidemiological case for drugs as the cause of AIDS, he cited evidence that drug use -- as indicated by increases in drug-related arrests and hospital emergency room admissions -- had risen in tandem with AIDS cases during the 1980s.(25, 26) He has also argued that Kimberly Bergalis, famous for allegedly being infected with HIV by her dentist, was killed by AZT in just two years.(33)

The arguments that once seemed to bolster the drug-AIDS hypothesis now severely undercut it. And the evidence overwhelmingly demonstrates that HAART has played a large role in reducing AIDS deaths in the last several years.

This does not mean that antiretroviral drugs are benign or that their toxicities are not serious. Indeed, this and other HIV/AIDS publications have noted a growing movement away from the so-called "hit early and hard" approach precisely because the drugs now in

use may well be too toxic for most patients to use indefinitely. There is much work to be done, both to develop new, safer treatments and to make better use of the ones we have.

Indeed, one of the tragedies of the denialist movement is that it has distracted attention from these issues. By forcing researchers and activists to take time and energy defending what has already been proven, it has diverted effort from critical questions regarding what sort of research is needed and how to speed the development of better, less toxic therapies.

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