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Early H.I.V. Therapy Sharply Curbs Transmission

By **DONALD G. McNEIL Jr.**

People infected with the virus that causes **AIDS** are far less likely to infect their sexual partners if they are put on treatment immediately instead of waiting until their immune systems begin to deteriorate, according to preliminary results from a large clinical trial released Thursday.

Patients with **H.I.V.** were **96 percent less likely to pass on the infection** if they were taking antiretroviral drugs — a finding that is so overwhelming that it is likely to change the way American AIDS doctors treat patients and what treatment policies are adopted by the World Health Organization and other countries, said Dr. **Anthony S. Fauci**, head of the National Institute of Allergy and Infectious Diseases, which paid for the trial.

The data was so convincing that the trial, scheduled to last until 2015, is effectively being ended early.

There have been previous studies, notably among drug abusers in San Francisco and Vancouver, British Columbia, that concluded that starting patients on drugs immediately would stop them from infecting others.

Those studies led Unaid, the United Nations AIDS-fighting agency, to adopt “test and treat” as its goal last year; the policy encourages doctors to start people on treatment as soon as they test positive for H.I.V. However, this is the first evidence from a randomized clinical trial, the gold standard in medical research.

AIDS prevention specialists not connected to the trial were enthusiastic.

“These results are phenomenal,” said Thomas J. Coates, director of the global health program at the University of California, Los Angeles, and the founder of the Center for AIDS Prevention Studies in San Francisco. “It was a tough study to do, and I’m thrilled it came out this way.”

Dr. Julio Montaner, an AIDS specialist at the University of British Columbia whose work among Vancouver heroin addicts helped lead to the Unaid policy, called the result of 96 percent protection “as good as it gets.”

“This is consistent with what we’ve been saying and doing in British Columbia for close to a decade,” he said. “How much more evidence do we need before we implement what we know works?”

The \$73 million trial, known as HPTN 052, involved 1,763 couples in 13 cities on four continents. One member of each couple was infected with H.I.V.; the other was not. In half the couples, chosen at random, the infected partner was put on antiretroviral drugs as soon as he or she tested positive for the virus.

In the other half, the infected person started treatment only when his or her CD4 count — a measure of the immune system’s strength — dropped below 250 per cubic millimeter.

In 28 of the couples, the uninfected person became infected with the partner’s strain of the virus. Twenty-seven of those 28 infections took place in couples in which the partner who was infected first was not yet getting treatment.

On Thursday, Dr. Fauci and Dr. Myron Cohen, an AIDS specialist from the University of North Carolina at Chapel Hill and the study’s director, announced that the data collected since the study began in 2005 had been “unblinded” to an independent safety review panel, which is standard procedure in clinical trials. When the panel realized how much protection early treatment afforded, it recommended that drug regimens be offered to all participants. Although participants will still be followed, the trial is effectively over because it will no longer be a comparison between two groups on different regimens.

The results carry moral implications for doctors in the United States. Although medical associations like the Infectious Diseases Society of America advocate starting patients on AIDS drugs early, the decision is made by the doctor and patient. Some patients fear the reported side effects of AIDS drugs and want to delay taking the drugs until they get obviously sick or until their CD4 counts fall, and some doctors go along with that, Dr. Fauci said, especially as long as their patients’ CD4 counts remain above 350.

But that means the patient may infect others during the delay. Of the 27 people in the study who became infected while their partners were not yet taking the drugs, 17 had partners whose CD4 counts were still above 350.

Asked if it could now be considered immoral for a doctor to accede to a patient’s request to delay starting drugs, Dr. Fauci said: “I’m not going to go there. I’m not going to say it’s immoral. But there is more and more data showing the advantages of starting as early as you can.”

Dr. Coates of U.C.L.A. said he hoped that treatment delays would fade away because the newest

antiretroviral drugs had few side effects.

Although the evidence suggests that it would be good public health policy to lower infection rates by starting everyone on drugs as soon as they are infected, that is impossible in much of the world. For lack of money, clinics in Africa are turning away patients who are not just infected but close to death. And in some American states where money provided by the Ryan White Care Act has run out, poor uninsured people are on waiting lists.

Although the trial was relatively large, there are some limitations on interpreting the data.

More than 90 percent of the couples in the trial, who lived in Botswana, Brazil, India, Kenya, Malawi, South Africa, Thailand, the United States and Zimbabwe, were heterosexual.

“We would have liked to have a substantial number of men as potential study subjects, but they just weren’t interested,” Dr. Cohen said.

Although common sense suggests the results would be similar in the contexts of homosexual sex and sex between people who are not couples, strictly speaking, the results apply only to the type of people studied, Dr. Fauci said.