



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
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2011 Advisory #27: Health Department Releases New HIV Treatment Recommendations

December 1, 2011

DOHMH now recommends offering antiretroviral treatment to any person living with HIV, regardless of the person's CD4 cell count.

Dear Colleagues:

New York City Department of Health and Mental Hygiene (DOHMH) now recommends that healthcare providers offer antiretroviral therapy (ART) to any person living with HIV, regardless of the person's CD4 count.

DOHMH is making this new recommendation for two reasons: to benefit those living with HIV and to benefit their partners. Evidence and additional support for this recommendation include:

- Evidence indicates that ART benefits the health of persons with early HIV infection. One large, observational study demonstrated that patients who initiate ART when CD4 counts are higher than 500 cells/mm³ live longer than those who do not[1], and that untreated HIV infection may lead to a number of non-AIDS-defining illnesses. Currently available ART regimens are now more convenient and better-tolerated than older regimens. Half of the members of the United States Department of Health and Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents[2] support this approach, and the San Francisco Department of Public Health together with the San Francisco General Hospital made a similar recommendation in April 2010[3].
- Recent research has demonstrated that effective HIV treatment prevents HIV transmission. The HIV Prevention Trials Network Study 052 (HPTN 052) found ART to be 96% effective in reducing HIV transmission from an HIV-infected person to an HIV-uninfected partner[4]. This study confirms the large body of evidence from observational studies[5-7], statistical models[8,9], and mother-to-child transmission trials showing that ART can prevent new HIV infections from occurring.

Providers should work with patients to prepare them for the long-term commitment to take medication daily, including addressing potential barriers to adherence prior to initiation. When the decision to initiate treatment is made, ART should be prescribed and monitored by providers with experience in managing ART. Appropriate support should be made available to all who need it in order to maximize retention in care and treatment adherence to ensure successful treatment outcomes.

Additional information about this new recommendation is included in the attached “frequently asked questions” document. Also, please visit www.hivguidelines.org to access HIV clinical guidelines from New York State.

We acknowledge that implementing this recommendation may require changes in the practices of medical and social service providers. We ask that you follow this recommendation in your management of patients with HIV infection. In doing so, you will be improving the health of New Yorkers living with HIV and helping to eliminate new HIV infections in New York.

Sincerely,



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TF/nm

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Recommendation to Expand Antiretroviral Therapy – Frequently Asked Questions (FAQ)

The New York City Department of Health and Mental Hygiene (NYC DOHMH) now recommend that healthcare providers offer antiretroviral therapy (ART) to all people living with HIV regardless of their CD4 count. The recommendation is based on evidence that ART can improve the health of people living with HIV and that ART can prevent transmission of HIV from an HIV-infected person to an uninfected sexual partner.

We have prepared responses below to Frequently Asked Questions (FAQs) for providers about NYC DOHMH's new recommendation.

FAQ for all providers

1. What is the evidence supporting treatment for individuals at any CD4 cell count?

The evidence supports treatment for both individual and public health benefit.

Individual patient benefit:

Randomized controlled evidence supporting initiation of ART in patients with CD4 counts >500 cells/mm³ is not yet available. However, some (though not all) cohort studies have shown a benefit in patients with normal CD4 counts. The NA-ACCORD study, a “cohort of cohorts” incorporating data from 22 observational studies in the U.S. and Canada, showed that there was a mortality benefit for those who initiated ART at a CD4 count >500 cells/mm³ compared with those who initiated at CD4 counts below 500 cells/mm³[1]. Furthermore, in the recently published HIV Prevention Trials Network Study 052 (HPTN 052), there were lower rates of extrapulmonary tuberculosis in individuals who initiated ART earlier than in those who delayed treatment [2]. These studies, along with evidence that patients who initiate ART earlier are less likely to suffer a variety of HIV-related complications, including cardiovascular disease, certain cancers and deterioration of the immune system [3-5], support treatment of HIV-infected persons with ART, regardless of CD4 level. Two smaller cohort studies do not show benefit for those who initiate ART at CD4 >500 cells/mm³[6,7].

Public health benefit:

HPTN 052, a prospective clinical trial, found that treatment is highly efficacious (96%) in preventing sexual transmission of HIV, presumably by decreasing viral load to undetectable levels. In addition, numerous previous observational studies[8-10] and clinical trials in pregnant and postpartum women[11-13] support the public health benefit of treatment to prevent transmission. Studies in both heterosexual couples and pregnant women have shown that transmission occurs more frequently at high viral loads and less frequently at very low viral loads, demonstrating the relationship between viral load and transmission [14,15].

2. Are there any patients for whom initiating ART is not recommended?

Discussion of the benefits of ART should occur at the start of care for all HIV-infected patients, regardless of CD4 count, with the anticipation that ART will be initiated. Misconceptions about treatment initiation should be addressed, including any concerns that starting ART represents advanced HIV illness. Despite this, some patients may refuse ART. In addition, as with starting any new long-term medication, providers should assess patient readiness and carefully evaluate factors that might limit adherence. Those patients for whom a provider has considerable or proven concern about adherence and for whom arrangements cannot be made to facilitate or monitor initial adherence should not be started on ART. *As with all aspects of routine medical care, the provider should involve the patient in this decision-making process.*

1. Which providers should consider prescribing ART to their HIV-infected patients?

Due to the complexity of HIV disease and its treatment (particularly the number of specific toxicities and drug-drug interactions), ART should be prescribed by providers with experience managing these medications. Appropriate training and continuous education are also critical to ensure optimal outcomes. A provider directory of experienced HIV providers in New York State is available at:

http://www.health.ny.gov/diseases/aids/resources/provider_directory/voluntary_hiv_providers.pdf

2. What should be discussed with patients prior to initiation of ART?

As with all aspects of routine care, providers should involve the patient in the decision-making process regarding the initiation of ART. Providers should review the benefits and risks of treatment for each individual patient, including the most recent data on the benefits of early ART. The decision to initiate therapy continues to depend on many individual factors for each patient and currently requires a lifelong commitment by the patient.

The provider should assess the need for supportive services to assure the success of long-term ART, such as mental health and substance use treatment, and link patients to these services as appropriate. An ongoing plan for coordination of care among all service providers should be established and maintained.

3. How does the New York recommendation differ from the current national HIV treatment guidelines?

Two expert panels regularly update guidelines for HIV treatment in the United States: the Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents[16] and the International AIDS Society-USA ART Panel[17]. The most recent versions were released in October 2011 and July 2010, respectively. Currently, the NYSDOH AIDS Institute's clinical guidelines for initiating ART are under revision to reflect this new recommendation and the results from HPTN 052 (visit www.hivguidelines.org).

Currently, each expert panel recommends that HIV-infected persons with either CD4 <500 cells/mm³ or a history of an AIDS-defining illness receive ART. Also, regardless of CD4 count, both panels agree that ART should be initiated in patients with pregnancy, HIV-associated nephropathy (HIVAN), or hepatitis B virus (HBV), when treatment of HBV is indicated.

For patients with CD4 >500 cells/mm³, the panels have different recommendations on whom to treat.

- **The DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents** was evenly divided on ART initiation for patients with CD4 >500 cells/mm³: 50% of members favored starting ART; 50% of members viewed ART as optional[16]. They consider the choice to be something for patient and provider to discuss, carefully weighing individual factors in the context of mutual understanding.
- **The International AIDS Society–USA Panel** recommended that ART be considered in asymptomatic individuals with CD4 >500 cells/mm³ who meet at least one of the following criteria: HCV co-infection, symptomatic HIV disease, HIV-1 RNA >100,000 copies/mL, rapid decline in CD4 cell count (>100/μL per year), active or high risk for cardiovascular disease, symptomatic primary HIV infection, and higher risk for secondary HIV transmission[17].

4. Who will this change in recommendations affect?

The majority of people living with HIV already have an indication to initiate ART, either because their CD4 count is <500 cells/mm³ or because they meet other criteria described above. Among New York City residents newly diagnosed with HIV and reported to DOHMH for whom sufficient CD4 count data are available, approximately 70% have a first CD4 cell count <500 cells/mm³, meeting both the DHHS and

IAS-USA ART thresholds for ART treatment. NYC DOHMH now recommends that all other people living with HIV be offered ART, regardless of CD4 count.

5. What is the evidence base for treatment as prevention?

HPTN 052 was the first randomized clinical trial to show that ART could prevent HIV transmission in serodiscordant couples. However, previous observational studies from Africa[9], Canada[8], and San Francisco[10] also support this finding. Since 1994, mother-to-child HIV transmission has been greatly reduced due to provision of ART for HIV-infected pregnant women before delivery and immediate provision of ART to exposed infants[11].

Although HTPN 052 studied predominantly heterosexual, serodiscordant couples, the remarkable 96% efficacy of the approach, evidence from related studies, and the biologic plausibility that early treatment reduces sexual transmission of HIV support the recommendation to offer ART to all people living with HIV, not just those in heterosexual relationships.

6. What other relevant research is ongoing?

A major new prospective clinical trial, known as the Strategic Timing of Antiretroviral Treatment (START) trial, is evaluating whether asymptomatic HIV-infected persons have less risk of developing AIDS or other serious illness if they begin taking ART earlier in their illness[18]. Conducted in 30 countries, the START trial will enroll 4,000 HIV-infected persons with CD4>500 cells/mm³ into two arms: immediate ART vs. delayed ART (when CD4 falls below 350 cells/mm³). START will study the potential individual health benefits and risks of each approach. It is anticipated that this study will be fully enrolled by December 2012; results may be available as early as March 2015.

7. Who will pay for this expansion of ART?

It is anticipated that this intervention will continue to be covered by each patient's insurance and, for uninsured or underinsured individuals, by the AIDS Drug Assistance Program (ADAP) for eligible patients. It is also expected that expanded ART will be a cost-effective intervention for people living with HIV/AIDS in New York[19]. Although this expansion will result in the increased cost of more people receiving ART, these medication costs should be offset by fewer hospitalizations and less HIV transmission.

8. How will this recommendation affect antiretroviral resistance in New York State?

Although there is concern about resistance, the incidence and prevalence of HIV drug resistance is stable or decreasing in countries, such as the United States and Canada, where optimal treatment is readily available, ART use is tailored to the results of resistance testing, and treatment is closely monitored with frequent viral load measurement [20]. Expanding ART in this context is not expected to substantively change this.

NYC DOHMH's HIV/AIDS surveillance program continuously monitors population-level HIV drug resistance patterns. From 2006 to 2009, primary HIV drug-resistance levels have remained around 10% with no disparities by transmission category, age, or race-ethnicity. The NYSDOH has seen similar levels of drug resistance statewide. Careful monitoring of resistance will continue.

9. How will the impact of this recommendation be evaluated?

NYSDOH and NYC DOHMH will work together to continuously collect and analyze data about New Yorkers with new or already established HIV infection. Evaluation of the new recommendation will include assessing trends in: (a) population-level viral load assessments ("community viral load"); (b) the proportion of persons with newly diagnosed HIV infection who have undetectable viral loads within 6-12 months after diagnosis; (c) primary HIV drug resistance; and (d) the incidence of new HIV diagnoses.

10. Should different ART regimens be prescribed for those with CD4 counts >500 cells/mm³?

No. Practitioners should select from among the same regimens used to treat anyone with HIV. The following links provide more detailed information about specific regimens to consider.

DHHS

<http://www.aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf>

IAS-USA

<http://jama.ama-assn.org/cgi/reprint/304/3/321.pdf>

HIV/AIDS Drug Information (NIH)

<http://www.aidsinfo.nih.gov/drugsNew/Default.aspx?MenuItem=Drugs>

HIV/AIDS Clinical Trials Information (NIH)

<http://aidsinfo.nih.gov/ClinicalTrials/Default.aspx?MenuItem=ClinicalTrials>

CDC

<http://www.cdc.gov/hiv/topics/treatment/resources.htm>

NYS Department of Health HIV Clinical Guidelines

<http://www.hivguidelines.org/>

11. What about pregnant patients?

The NYC DOHMH and NYSDOH continue to recommend initiation of ART for all HIV-infected pregnant women to optimize maternal health, decrease the risk of HIV transmission to the fetus, and prevent transmission to sexual partners. Prenatal care providers should collaborate with experienced HIV care providers to determine the optimal ART regimen. The benefits of continuing ART beyond the duration of the pregnancy should also be discussed.

12. What about an HIV-infected person with high CD4 count and no symptoms who is in a stable relationship with a partner who is also infected with HIV?

HIV-infected persons with CD4 counts >500 cells/mm³ and no clinical symptoms who are in a relationship with an HIV-infected partner should be offered ART to reduce their risk of developing HIV-related complications. ART will also reduce the risk of transmission to any new partners.

13. Does this change the recommendations about the use of PrEP?

No. Based on the strength of current evidence, serodiscordant couples should not, at this time, rely on PrEP to prevent HIV transmission. Rather, serodiscordant couples should use barrier precautions (e.g., condoms), and the HIV-infected partner should receive ART, regardless of CD4 count or clinical symptoms.

A recent randomized clinical trial, the Chemoprophylaxis for HIV Prevention in Men study (iPrEx), showed that daily, oral tenofovir/emtricitabine (“Truvada”) was safe and effective in preventing HIV infection among uninfected but exposed men who have sex with men (MSM)[21]. Immediately after the release of the iPrEX study results, which showed modest efficacy (44%) in protecting against infection, CDC [provided detailed interim guidance](#) about pre-exposure prophylaxis (PrEP)[22], recommending that PrEP be considered only for MSM (the population enrolled in the original iPrEX clinical trial) and only after the exclusion of acute HIV infection and the adoption of other non-pharmacologic risk reduction measures.

Preliminary results of subsequent studies in African heterosexual couples (TDF-2 and Partners PrEP), released in July 2011, support the use of PrEP in men and women[23,24]. Recently, another trial, the FEM-PrEP Study, was stopped early by the Data Safety and Monitoring Board (DSMB) because it was judged highly unlikely that the study would demonstrate PrEP effectiveness in enrolled women[25]. To date, none of these subsequent PrEP studies have been published in peer-reviewed journals, and CDC has not yet made recommendations based on them.

Note to providers regarding partner notification: NYS Public Health Law Article 21 (Chapter 163 of the Laws of 1998) requires that medical providers talk with HIV-infected patients about their options for informing sexual and needle-sharing partners who they may have been exposed to HIV. The NYSDOH and NYC DOHMH can assist in notifying partners. NYC providers can call Contact Notification Assistance Program (CNAP) at: (212) 693-1419 or 311 or can fill out a Provider Report Form. For more information on provider reporting, go to: http://www.nyc.gov/html/doh/html/dires/hcpreporting_how.shtml.

For areas outside of NYC, each NYS county has a Partner Services staff dedicated to providing health care providers with technical assistance and partner notification services. Contact information for Partner Services can be found at: http://www.health.ny.gov/diseases/communicable/std/partner_services/info_for_providers.htm

More information on Public Health Laws and Regulations can be found at <http://www.health.ny.gov/diseases/aids/regulations/>

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**Recommendation to Expand Antiretroviral Therapy to All Persons Living with HIV
Patient Frequently Asked Questions (FAQ)
December 1, 2011**

Background

The New York City Department of Health and Mental Hygiene (NYC DOHMH) is strongly encouraging all people living with HIV to begin taking antiretroviral therapy (ART, sometimes referred to as “HAART” or as “ARV”). There is increasing evidence that ART can improve the health of people living with HIV. There is also new evidence that ART can help prevent spread of HIV from an HIV-infected person to their uninfected partners.

Below are responses to Frequently Asked Questions (FAQs) for patients about this new recommendation. If you have questions about your individual health and treatment, please consult with your health care provider.

General FAQs

1. Why are the state and city health departments making this new recommendation that everyone living with HIV should start ART?

The new recommendation is based on recent scientific information showing that ART can help patients living with HIV better maintain good health. Starting treatment as early as possible can also lower your risk of transmitting HIV infection to your sexual partners.

2. In the past, my provider told me that since my CD4 count was above 500 I could delay starting treatment. Should I start treatment now even if I feel healthy and my CD4 count is over 500?

Studies are now showing that starting ART can help HIV-infected people live longer and healthier lives. This includes people with good immune systems (>500 CD4 cells/mm³) and no symptoms. People with good immune systems who started treatment have better outcomes than those who delayed treatment.

The recently published HIV Prevention Trials Network Study 052 (HPTN 052) documented that an HIV-infected person with good immune function and no symptoms could still transmit HIV infection to his or her sexual partner. However, HIV-infected men and women could reduce their risk of transmitting the virus to their sexual partners by taking ART every day and using condoms. In fact, ART reduced the likelihood of infection in the uninfected partner up to 96%. These new data give the strongest evidence to date that the spread of HIV can be decreased by encouraging everyone living with HIV to start ART in consultation with their health provider, even infected persons with good immune systems and no symptoms.

3. Do I have to start treatment?

No. If you are not ready to make the commitment to take ART, including taking the correct dose at the correct time exactly as prescribed. Discuss any concerns you may have with your health care provider. The final decision of when to start treatment is up to you.

4. Does this mean I will get side effects, like lipodystrophy and diabetes, sooner?

In the last several years, new medications have been introduced with fewer side effects and lower rates of complications. Recent data suggest that your overall health will be better preserved by taking ART, as explained above.

5. What if I have a reaction to ART?

It is important to see your provider if you develop any problems while taking ART. Your provider will help you manage any side effects and can also discuss alternative treatments if necessary.

6. Will ART eventually stop working if I start it sooner?

No. Research suggests that the treatment will continue to be effective if you take ART exactly as prescribed. Missing doses or starting and stopping treatment is the most common reason for the treatment to stop working because it allows the virus to re-grow when the levels of medication are low in the blood; resistance can develop when levels of medication are low.

FAQ about ART and Prevention of Transmission to Others

7. Why would taking ART help prevent transmission of HIV to my sexual partners?

After 1-2 months of taking ART, most people living with HIV will have a decreased amount of virus in their blood, meaning their viral load has gone down. One goal of ART is to reduce your viral load to undetectable levels (meaning that the amount of HIV in your blood is present but too low to be detected by the viral load test). When the amount of virus in your blood is undetectable or very low, there is also less virus in your other body fluids (for example, semen or vaginal fluid), reducing the risk of infection to your sexual partner. The important study mentioned earlier, called HPTN 052, showed that people with HIV who are on ART and use condoms were much less likely to pass the virus to their sexual partners.

8. Can a person with HIV who has an undetectable viral load pass HIV to someone else?

Yes, although it is not likely to occur. A viral load test measures the amount of HIV in a person's blood. An undetectable viral load means that the amount of HIV in your blood is present but too low to be detected by the viral load test. It does not mean that there is no HIV in other body fluids (for example, semen or vaginal fluid). A person who has a low or undetectable viral load can pass HIV to someone else, although the risk is definitely much lower than if he or she had a high viral load. It is also important to bear in mind that a low viral load in the past doesn't necessarily mean a low viral load right now. Risk reduction measures, like using condoms and not sharing needles, should still be taken.

9. Does taking ART mean I don't have to use condoms anymore?

No. You and your partner should still use condoms during sex. Condoms refer to male latex condoms, male polyurethane condoms, and FC2 condoms (also known as "female" or "insertive" condoms). Condoms decrease your risk of HIV and other sexually transmitted infections, including syphilis, gonorrhea, and chlamydia.

10. I am not sexually active. Do I still need to take ART?

The most important reason to start ART is to help improve your health. It is recommended that you take ART whether you are currently in a relationship or not. Taking ART will help protect any future partner(s) from getting HIV.

11. I am infected, but my sexual partner is not. Should my partner take ART too?

No. Your partner should only take ART if your partner has HIV infection. If you take ART and use condoms every time you have sex, your uninfected partner will have a very low risk of acquiring HIV. Some important studies are currently evaluating whether HIV-negative people might benefit from taking ART before an anticipated sexual exposure. This method is called "pre-exposure prophylaxis" or "PrEP." Many studies suggest that PrEP reduces the risk of acquiring HIV, but it does not completely eliminate the

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risk. ART is not currently FDA-approved for use in this way (as “PrEP”). If one of you has HIV infection and the other does not, you should follow the approach demonstrated by the HPTN 052 trial described earlier: use condoms with every sexual encounter and have the HIV-infected person take ART exactly as prescribed by their provider.

12. Since treatment of HIV can help prevent spread, can I just take ART right before I have sex and not all the time?

No. The medication does not work immediately and starting and stopping ART will very likely have a negative long term effect on your health. You need to have a specific level of medication in your blood for 1-2 months before the amount of HIV decreases to a level where transmission becomes less likely.

13. I have an uninfected child at home. Should I take ART to prevent transmission to him or her?

You cannot transmit HIV to your child or to anyone else through casual contact. HIV is not spread through shaking hands, hugging, or casual kissing. HIV is not spread by sharing objects such as toilet seats, water fountains, and eating utensils. You should take ART to maintain your health so that you can live a long life to be there for your children as they grow.

14. Where can I find an HIV provider?

For New York City services, call 311 or visit nyc.gov and search ‘HIV/AIDS.’ The NYSDOH AIDS Institute *Voluntary HIV Care Provider Directory* is a public directory that provides contact information for HIV care providers licensed in New York State. All providers included in the directory agreed to be listed. Providers in this directory are categorized by geographic region, and organized by adult, pediatric and adolescent patient populations. You can also find medical providers as well as other services in the AIDS Institute *Regional Directory of HIV/AIDS Service Programs*. To find these directories and other useful information for people living with HIV/AIDS throughout New York State, please visit the NYSDOH website at: <http://www.health.ny.gov/diseases/aids/resources/index.htm>.

15. I’m HIV-positive but not in care? What should I do?

All people living with HIV can benefit from getting into care. There are resources to help you get health care even if you don’t have health insurance. You may qualify for Medicaid or the NYSDOH HIV Uninsured Care Program which provides access to free health care for residents who are HIV-infected but uninsured or underinsured. The program is open Monday - Friday, 8:00AM - 5:00PM and can be reached at: **In State** - (800) 542-2437; **Out of State** - (518) 459-1641; **TDD** - (518) 459-0121. In addition, please see the resource directories listed under question 14.