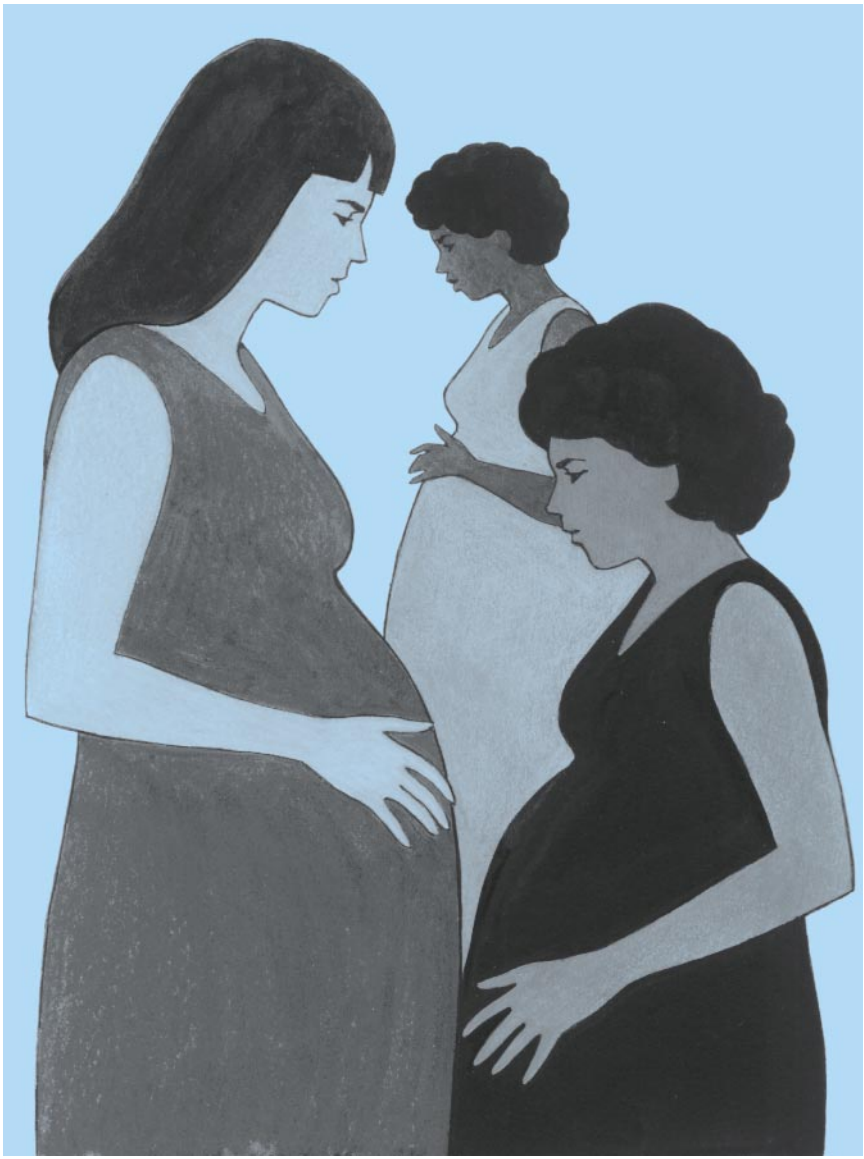
# What Women Need to Know:

## The HIV Treatment Guidelines for Pregnant Women



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The Guidelines referred to in this booklet are: Centers for Disease Control and Prevention (CDC). Public Health Service Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant Women Infected with HIV-1 for Maternal Health and for Reducing Perinatal HIV-1 Transmission in the United States. *MMWR* 1998; 47 (No. RR-2).

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# What Women Need to Know:

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## What are the Guidelines and who are they for?

These are guidelines for doctors and other healthcare providers in the United States. They suggest how to use antiretroviral drugs (anti-HIV medicines) in pregnancy to improve a woman's health and to reduce the chance that the virus will pass from mother to baby (called perinatal transmission).

## Why are the Guidelines important?

They give healthcare providers new information on what we know about the safe use of antiretroviral medicines (for both mother and baby) in pregnancy. The Guidelines include what we know about mother-to-baby HIV transmission and ways to reduce it.

Today there are many new advances in treating HIV. Doctors and other healthcare providers who care for pregnant women with HIV infection need to consider this new information. Women need to be informed too.



## What have we learned about HIV in pregnancy and in infants?

- Most transmission of HIV from mother to baby happens near or during delivery.
- HIV-positive mothers should not breast-feed. There is an increased risk that the baby will become infected with the virus through drinking breast milk.

  *In the United States, infant formula is available for babies.*
- Women who take a medicine called AZT (ZDV) during pregnancy can lower the risk of perinatal transmission. (This medicine is also called zidovudine or Retrovir®.)

  *In a large research study of women with HIV, 1 of 4 babies whose mothers did not take AZT (ZDV) were HIV-infected.*

  *However, only 1 in 12 babies whose mothers did take AZT (ZDV) were HIV-infected.*
- Because of this information, many women in the United States are making the choice to take AZT (ZDV) in pregnancy.
- Fewer babies are getting the virus when their mothers have taken AZT (ZDV).

## What is new about HIV/AIDS medicines that HIV-positive women need to know?

- Many powerful new anti-HIV medicines are now available.
- We know a lot about the HIV virus and how to use medicines to fight it.





- We have learned how to use medicines together to fight the virus. This is called "combination therapy."

  *It is sometimes called the "cocktail" or "HAART."*
- Antiretroviral medicines are used together (2 or more drugs) to treat HIV infection.
- A pregnant woman who does not need these medicines for her own health can take AZT (ZDV) to reduce the chance that her baby will get the virus.
- We have new tests to measure the virus and to see how the medicines are working. These are called viral load or HIV-RNA tests. (They are also called "RNA.") They measure how much of the virus is in the blood at any time.

## What are the recommendations for starting antiretroviral therapy (medicines) for adults and older adolescents with HIV infection?

The recommendations depend on whether someone has symptoms of HIV infection and what his or her CD4 T cells (immune system cells) and viral load levels are.

- Antiretroviral medicines are **recommended** if the person is "symptomatic," or has symptoms of HIV.

  *These symptoms can be any of the conditions of AIDS, or others such as thrush, infections, or unexplained fevers. For women, the symptoms can be recurrent vaginal infections.*

  *If you have symptoms, the medicines are recommended no matter what your CD4 T cell number and viral load are.*

- Antiretroviral medicines should be **offered** to a person whose CD4 T cell number is less than 500, OR whose viral load is higher than 10,000–20,000 (depending on the viral load test) even if he or she has no symptoms from HIV.
- **Watch and wait** for a person who has no symptoms from HIV, whose CD4 T cells are more than 500, and whose viral load is less than 10,000–20,000 (depending on viral load test).

  *Some HIV experts would offer antiretroviral medicines to all persons with HIV infection.*
- It is important that the person is willing to take the medicines.
- It is very important to take every dose of these medicines.
- Missing doses may cause the medicines to stop working for the person.
- Deciding to take these medicines is a big commitment.

## What do we know about viral load in pregnancy?

- We know that HIV infection gets worse when a person's viral load is high.
- It is important for doctors to measure viral load at least every 3–4 months during pregnancy.
- Viral load should also be measured every 3–4 weeks after starting new antiretroviral medicines. This is to see how they are working.





- Scientists have not yet found all the answers about viral load and mother-to-baby transmission.

  *We need to learn more about viral load in pregnancy.*

  *In most research studies, babies were more likely to get the virus if their mothers had a high viral load.*

  *But some babies got HIV even when their mothers had low or "undetectable" levels. (These are levels so low that they cannot be measured on the tests.)*

## Why are antiretroviral medicines needed in pregnancy?

Antiretroviral medicines may be needed for two reasons:

- They help the woman's health by fighting the virus.
- They help to reduce the risk of the virus passing from the mother to her baby.

## What do the Guidelines say about antiretroviral medicines in pregnancy?

- Pregnancy is **not** a good reason to withhold antiretroviral medicines from a woman with HIV infection.
- Antiretroviral therapies that work well for women should be offered to pregnant women. Of course, the choice of which medicines to use depends on how safe they are and how they act with other medicines.
- Talk to your healthcare provider about the right medicines for you.



## What do the Guidelines mean for me?

- If you are pregnant, you should have the best medicines that work against the virus. They should be the ones that cause no side effects or very few side effects for you and your baby.
- Your healthcare provider should give you all the information there is. This means what we know and what we don't know about these medicines in pregnancy.
- He or she should tell you what good may come of taking these medicines and what are the risks to you and your baby.
- Remember: The choice to take antiretroviral medicines during pregnancy is yours.
- Talk to your healthcare provider.

*Get the facts and advice on what's best for you and your baby.*

## Why does pregnancy need special considerations?

- Some medicines taken by pregnant women go from the mother's blood system to the baby. This means two people are taking medicine—you and your baby.
- Pregnancy can mean that your body uses medicines differently.

*In pregnancy, you may need more or less of a medicine for it to work. How your body gets rid of medicines may be different.*





- Medicines may affect how your baby grows or develops. If they are taken early in pregnancy when the baby's organs are being formed, problems may happen.
- All of this may depend on the medicine, your dose, and how far along your pregnancy is.

## What does it mean that a medicine is "safe" to take during pregnancy?

- No medicine is completely safe.
- For pregnant women, the best medicines are those that do a lot of good with no side effects, or only a few mild ones.
- The best medicines do not harm either a pregnant woman or her baby.
- Medicines need to be safe both short-term and long-term.

*"Short-term" means a problem may happen during pregnancy—for example, a miscarriage. Or a problem might show up right after delivery. The mother or baby may develop a condition such as anemia (low red blood cell count). This usually goes away or can be treated.*

*"Long-term" means a drug causes something to happen in the future. An example of this is cancer. Many years ago, some teenage girls developed cancer. Researchers found that the girls' mothers had taken certain medicines during pregnancy.*

*A baby may not grow or develop well during the pregnancy.*

*A baby may have a birth defect that shows up at birth or later.*

- It is important to know that problems can happen even if no medicines were taken in pregnancy.



## How do we know any medicines are safe?

- Medicines are tested for safety in the laboratory before being given to people.
- The next step is to study what happens when people (volunteers) take the medicines. These research studies are called clinical trials.

## Have all the antiretroviral drugs been studied in pregnancy?

- No.
- We know the most about AZT (ZDV). This medicine has been studied for safety in pregnant women since 1991.
- 3TC (Epivir®) and nevirapine (Viramune®) have been studied in small numbers of pregnant women.
- Most of the other antiretroviral medicines are now being studied in pregnant women or in newborns.

  *This means we are not sure how much of these medicines to give, or how pregnancy will affect the medicines.*

  *We do not know how safe such medicines may be for the fetus and infant.*

  *At present, women who need these medicines for their own health are taking the same doses given to non-pregnant HIV patients.*
- Because answers about these medicines in pregnancy are so important, you may be asked to participate in a clinical trial.
- This research may be studying how anti-HIV medicines affect pregnant women or their babies.





## What do we know about AZT (ZDV)?

- AZT (ZDV) was the medicine given in a research study called ACTG 076. (ACTG stands for AIDS Clinical Trials Group.)

  *So far, it has been found to be safe for women and infants.*

  *Some pregnant women had nausea and an upset stomach as side effects from AZT (ZDV).*

  *Some infants whose mothers took AZT (ZDV) were anemic (had a low red blood cell count) at birth. The anemia went away. No special treatment was needed.*

## Why are the children from this study being followed up on for so many years?

- We want to be sure that there are no long-term effects of the medicine in these children.
- In some research done on pregnant animals that were given AZT (ZDV), the babies developed cancer of the vagina and other parts of the body. However, the doses of AZT (ZDV) given to the animals were much higher than those taken by pregnant women. Cancer was not seen in animals whose mothers were given normal doses of AZT (ZDV).



## What does research in animals mean for pregnant women and their babies?

- We don't know.
- Sometimes, bad results in animals never happen in humans. Other times, people have side effects that animals did not.

## In the 076 study, how are uninfected children doing whose mothers were given AZT (ZDV)?

- The children are now 4–6 years old.
- They are growing and developing the same as children of mothers who did not take AZT (ZDV).
- Their immune systems are no different from the children whose mothers did not take AZT (ZDV).
- None of the children have developed cancer.
- These children will need to be watched by their healthcare providers for a long time.
- All infants whose mothers took antiretroviral medicines before their birth will need watching.

## Does AZT (ZDV) work to protect babies whose mothers have more advanced HIV infection?

- We have learned that AZT (ZDV) works even for women who are sicker with HIV. It has worked well for women with low CD4 T cell numbers.

  *This means that AZT (ZDV) should be offered to all HIV-positive pregnant women. We know it works to reduce the chance that the virus will pass from the mother to her baby.*





## What do we know about the medicines called protease inhibitors in pregnancy?

- Research on these medicines in pregnant women and their infants has just started.
- We have no conclusive information yet about drug dose and safety in pregnancy for any of the protease inhibitors. This work is going on now.
- Because answers are so important, almost all the approved antiretroviral medicines are now being studied in pregnant women.

## What do the Guidelines recommend about health care for pregnant women who have HIV infection?

- During pregnancy, you, your OB/GYN, your HIV specialist, and your pediatrician should work together.
- Your HIV infection should be carefully evaluated. You need to know how your immune system is doing. This means knowing your CD4 T cell number and your viral load.
- What medicines you take or have taken is important information.
- Your baby's gestational age is important. This means how far along your pregnancy is.
- Based on this information, your healthcare provider can tell you what medicines are recommended to treat your HIV infection.

- Ask your healthcare provider what research has been done on each of these antiretroviral medicines.
- Also ask your healthcare provider to tell you about AZT (ZDV) and how it reduces the chance of passing the virus to your baby.

  *If you have HIV, are not already taking AZT (ZDV), and are pregnant, you need to think about taking it to decrease the chance of passing the virus to your baby.*

## Taking Antiretroviral Medicines in Pregnancy

### What if I have not taken any of these medicines before?

- Your doctor will evaluate your health and how HIV is affecting you.
- The AZT (ZDV) regimen will be recommended to you. This is to reduce the chance of passing the virus to your baby.

  *This means you will need to take AZT (ZDV) pills by mouth during your pregnancy.*

  *It will be given to you by IV (intravenously, or into your vein) during your labor and delivery.*

  *Your baby will take the medicine by mouth in syrup form for 6 weeks after birth.*
- If you need other antiretroviral medicines for your health, your doctor will discuss these with you.

  *You will need medicine if your CD4 T cell number is low and your viral load is high.*





### What if I am in the first 3 months of pregnancy?

- In the first 3 months of pregnancy, your baby's organs (heart, kidneys, and others) are being formed. We do not know what these medicines may do at this time.
- You may want to wait to start these medicines until after your first 3 months.
- Your doctor should talk to you about the benefits and risks of waiting to start your antiretroviral medicines.

### What if I am already taking the combination therapy (the "cocktail" or "HAART"), and I just found out I am pregnant?

- What to do depends on how far along your pregnancy is.
- The Guidelines recommend that if you are past the first 3 months you should continue your medicines.
- If AZT (ZDV) is not one of your "cocktail" or group of medicines, it should be added or switched with one that is the same type or belongs to the same family. These are medicines that work against the virus the same way. Examples of these are AZT (ZDV), ddI (also called Videx®), and 3TC.

  *During delivery, you should be given AZT (ZDV) by IV (into your vein) .*

  *Your baby should take AZT (ZDV) syrup for 6 weeks after birth.*



## What if I am in the first 3 months and I am taking antiretroviral medicines?

- Your healthcare provider should counsel you on the benefits and possible risks of taking these medicines during this time.
- We really don't know enough about these medicines to say what will happen to your baby.

- If your viral load is high, your healthcare provider may advise you that you should continue to take the medicines. Your baby will be watched carefully.
- If you and your doctor decide to stop the medicines, they need to be stopped all at the same time. This will help keep the virus from becoming resistant.

*They can be started again all at the same time, after the third month.*

## Why do the medicines need to be stopped at the same time or started all at the same time?

- We have learned that the best way to fight the virus is to give more than one antiretroviral medicine. Each one works against the virus in a different way.

  *They work together to decrease the amount of virus to the lowest possible level. This is important.*
- One or two drugs sometimes give the virus a chance to resist, or get around, the medicine.
- If medicines are stopped one by one, the same thing may happen.





## What might happen to me if I stop taking the medicines for 3 months to protect my baby?

- Your viral load will go up. How risky this is depends on how high your level is. This may mean that your HIV might get worse. Your immune system might get more damaged by the virus. This would not be good for you or your baby.
- This is why you need to talk it over with your doctor or your healthcare provider.

## Decisions about taking antiretroviral drugs in pregnancy are hard.

- For your doctor, this means knowing what medicines are best for you and your baby and when to use them.
- It also means giving you information and advice, and accepting your decision.
- For you, this means deciding which medicines you will take, if any, during your pregnancy.
- Taking antiretroviral medicines is a big commitment at any time, especially during pregnancy. Talk it over with your healthcare provider. Together you can decide what's best for you.

## What is recommended for HIV-infected women in labor who have taken no antiretroviral drugs?

- Scientists believe that most mother-to-baby HIV transmission happens near or at the time of birth.
- It may be possible to reduce the chance that a baby will get the virus through the birth process.



- AZT (ZDV) given as an IV medicine (into your vein) is recommended during labor and delivery.
- The baby also needs to take AZT (ZDV) for 6 weeks after birth.
- The new mother should have her health and HIV infection evaluated, if this was not done during the pregnancy. The results should include her viral load and her immune system. This will show if she needs to start antiretroviral therapy for her own health.

## What is recommended for infants whose mothers have HIV but have taken no antiretroviral drugs in pregnancy or delivery?

- Six weeks of AZT (ZDV) is recommended for infants. Treatment should start as soon as possible after birth and no later than 12–24 hours after birth.

## What health care should I have after my baby is born?

- Discuss this with your healthcare provider.
- You may need to go back to your previous antiretroviral medicines.
- You may need to start on combination therapy.
- You may need to stop AZT (ZDV) if it was started only to prevent perinatal (mother-to-baby) transmission.





## What follow-up care should my baby get?

In addition to routine well baby care, your baby needs some special things:

- Your baby will be tested for HIV infection in a few days or weeks after he or she is born.
- Tests can usually show that a baby is HIV-infected or not by a few months of age.
- Your baby should take AZT (ZDV) until he or she is 6 weeks old.
- At 6 weeks, your baby should start on an antibiotic (Bactrim™ or Septra®) to prevent serious pneumonia, which babies with HIV can get.
- Your baby needs to get care from a pediatric HIV specialist for at least the first 6 months of life.
- Even though your baby may look well, keep all the appointments with the pediatric HIV specialist. It is important to have all the testing to find out whether or not your baby has HIV infection.

## Since the treatment for HIV is always changing, what is the most important thing to remember?

- See your healthcare provider regularly.
- At every visit, review your medicines with your healthcare provider to make sure they are the right ones for you.

## Important Phone Numbers

Doctor _____

Nurse _____

Case Manager _____

Pharmacy _____

Pediatric HIV Doctor _____

### You Can Find Out More: Resource Information

**HIV/AIDS Treatment Information Service:**
1-800-448-0440 (English and Spanish)
1-888-480-3739 (TTY/TDD)
Internet: www.hivatis.org

**AIDS Clinical Trials Information Service:**
1-800-TRIALS-A (1-800-874-2572)
(English and Spanish)
1-888-480-3739 (TTY/TDD)
Internet: www.hivatis.org

**National HIV/AIDS Hot Line (CDC):**
1-800-342-2437





### Glossary of words used in this booklet

**ACTG 076 (also called AIDS Clinical Trials Group #076):** a research study of perinatal HIV transmission. The study found that mother-to-baby HIV transmission was reduced from 25% to 8% when mothers took AZT (ZDV) during pregnancy and their infants took AZT (ZDV) for 6 weeks after birth.

**anemia:** a condition caused by too few red blood cells or too little hemoglobin, a protein in the red blood cells.

**antiretroviral drugs (also called "antiretoviral therapy"):** anti-HIV medicines that prevent the virus from reproducing or replicating (making more copies of itself).

**AZT (also called ZDV, zidovudine, or Retrovir):** an anti-HIV medicine that was taken by pregnant women in the ACTG 076 research study.

**CD4 T cells (also called T cells or helper cells):** the cells of the immune system that are attacked by HIV. People who are infected by HIV often have too few CD4 T cells. CD4 T cells play an important role in the working of the immune system.

**combination therapy (also called the "cocktail" or "HAART"):** several different kinds of anti-HIV medicines taken at the same time to keep the HIV virus from reproducing or replicating (making more copies of itself). These medicines each work against a different part of the virus when it is replicating.

## Glossary of words used in this booklet

**HAART: H**ighly **A**ctive **A**nti**R**etroviral **T**herapy: a combination of anti-HIV medicines that work well against the HIV virus.

**HIV-RNA test (also called viral load test or just "RNA"):** a blood test that measures the amount of HIV virus in a person's blood plasma (a part of blood).

**perinatal transmission:** transmission of the HIV virus from an infected woman to her baby during pregnancy or at the time of birth.

**resistance (also called viral resistance):** a virus's ability to change its structure, or mutate, so that the same medicine no longer works against it.

**side effect:** a secondary and usually unwanted effect of a medicine or therapy.

**viral load test (also called HIV-RNA test or just "RNA"):** a blood test to measure the amount of HIV virus in a person's blood plasma (a part of blood).





## NOTES AND QUESTIONS

The National Pediatric & Family HIV Resource Center (NPHRC) offers a range of services to healthcare professionals caring for children, youth, and families affected by HIV infection. NPHRC provides consultation, technical assistance, and training, and produces a variety of professional curricula and family education materials. For more information on NPHRC's programs and services, contact: NPHRC at 1-800-362-0071 from 9:00 a.m. to 5:00 p.m. EST.