



Summary of BHIVA guidelines HIV treatment for pregnant women: HIV treatment

BHIVA (the British HIV Association) is an organisation that represents healthcare professionals working in HIV in the UK. Its **guidelines** set out the medical and other care people living with HIV can expect to receive in the UK. You can find out more about the process used to develop the guidelines here: **How BHIVA guidelines are developed**.

BHIVA's *Guidelines for the management of HIV infection in pregnant women 2012* set out evidence-based clinical practice for treating and managing HIV infection in women who are already pregnant. These guidelines also specify the treatment and care of the newborn baby in relation to preventing HIV transmission. HIV clinic staff, following recommendations in these guidelines, will be providing the best possible treatment and care to their patients, taking into account individuals' situations as well as what is known about the most effective treatments during pregnancy. Your doctor should discuss your treatment options with you.

- This symbol identifies a strong BHIVA recommendation for treatment or care.
- This symbol identifies treatment or care that BHIVA suggests is appropriate: a recommendation with weaker evidence or some conditions attached.

identifies a 'good practice point' – a recommendation drawn from everyday clinical experience rather than research-based evidence.

HIV can pass from a mother with HIV to her child:

- During pregnancy the foetus is infected by HIV crossing the placenta.
- During childbirth the baby is infected by HIV in the mother's cervical secretions or blood.
- During breastfeeding the baby is infected by HIV in the mother's breast milk (or blood).

When HIV treatment is used during pregnancy, it protects your health as well as playing an important role in preventing HIV being passed on from you to your baby during pregnancy and birth.

In the UK, because of high standards of care (as set out in the BHIVA guidelines), the risk of mother-to-child transmission is very low. For women who have been diagnosed and who receive the right advice, treatment and care, the risk is below 1%. For women who are on effective HIV treatment and who have an <u>undetectable viral load</u>, risk of transmission to their baby is 0.1%, or one in a thousand.

This factsheet summarises the recommendations relating to HIV treatment during pregnancy and after a baby is born. You can find out about BHIVA recommendations on the safest way for your baby to be delivered in *Factsheet 6: HIV treatment for pregnant women: Mode of delivery*, and find information about care and support before and after your baby is born in *Factsheet 7: HIV treatment for pregnant women: Antenatal and postnatal care*. There is information on HIV treatment during pregnancy for women who also have hepatitis B or hepatitis C in *Factsheet 8: HIV treatment for pregnant women: HIV treatment, hepatitis and pregnancy*.

The aim of HIV treatment

The aim of HIV treatment is to reduce the amount of HIV in the body to a very low level, below the point most viral load tests can find HIV in a blood sample (usually below 50 'copies' of HIV in a millilitre of blood). This is called an undetectable viral load. While you are pregnant, decisions on your care will sometimes be informed by your viral load, and whether or not it is undetectable.

If you are not on HIV treatment when you become pregnant, and *don't* need treatment for your own health

Even if you don't yet need treatment for your own health, taking HIV treatment during your pregnancy is the most important thing you can do to avoid passing HIV on to your baby.

- The guidelines recommend that **all** women should have started HIV treatment by week 24 of their pregnancy.
- If you have a viral load of more than 30,000 copies/ml, it is recommended that you start HIV treatment at 13 weeks (at the start of the second 'trimester' of your pregnancy, weeks 13 to 28).
- **O** If your viral load is over 100,000 copies/ml, you and your doctor may discuss you starting HIV treatment earlier than 13 weeks.

What anti-HIV drugs will be used?

- The two anti-HIV drugs used most often in pregnancy are <u>AZT</u> (zidovudine, *Retrovir*) and <u>3TC</u> (lamivudine, *Epivir*). There is good evidence of their effectiveness.
- Alternative suitable drug combinations for use during pregnancy are:
 - —<u>tenofovir</u> (*Viread*) plus <u>FTC</u> (emtricitabine, *Emtriva*)

or

-abacavir (Ziagen) plus 3TC.

These drugs will usually be used in combination with a protease inhibitor.

- Your short course of HIV treatment used to prevent mother-to-baby transmission should contain a drug from the <u>protease inhibitor</u> class, unless there are medical reasons why this class of drug isn't suitable for you. If your viral load is less than 100,000 copies/ml, taking a combination of AZT, 3TC and abacavir may be another option.
- You may be able to take just one anti-HIV drug, AZT (zidovudine, *Retrovir*), if:
- —you are planning to have your baby by caesarean section and
- —you have a viral load of less than 10,000 copies/ml and
 - -your CD4 cell count is over 350.

This is called AZT or zidovudine monotherapy.

More information from NAM

Find out more about BHIVA guidelines on childbirth in Factsheet 6: HIV treatment for pregnant women: Modes of delivery.

Anti-HIV drugs are grouped into types, or 'classes'. In most cases, HIV treatment will consist of three drugs taken in combination. Find out more about the drugs and classes in NAM's booklet, <u>Anti-HIV drugs</u> or by using the interactive tool <u>My drugs chart</u>.

If you are not on HIV treatment when you become pregnant, and do need treatment for your own health

BHIVA's guidelines on *Treatment of HIV-1 positive adults* with antiretroviral therapy (2012) recommend that people generally start HIV treatment when their CD4 cell count is around 350. (Find out more about these guidelines in Factsheets 1 to 4 on HIV treatment for adults.)

• If you need to start HIV treatment for your own health, start as soon as possible.

There are many health benefits to starting HIV treatment as soon as possible if you need it for your own health. In addition, it gives you more time to achieve an undetectable viral load, which greatly reduces the risk of HIV being passed on to your baby.

• If you have had any sort of AIDS-related illness, such as an opportunistic infection, start HIV treatment straight away.

Around half of all pregnant women will have morning sickness – nausea (feeling sick) and vomiting (being sick) – in the first trimester of their pregnancy. If you are less than 12 weeks pregnant, and your need for treatment is based only on having a CD4 cell count of about 350, you and your doctor may discuss waiting to start HIV treatment until you are 13 or 14 weeks pregnant, when morning sickness generally stops. This is because some anti-HIV drugs can also make you feel sick during the first few weeks of treatment.

What anti-HIV drugs will be used?

Anyone who starts HIV treatment for the first time should have a <u>resistance</u> test. The results will help your doctor choose the most suitable anti-HIV drugs for you.

- The guidelines recommend a drug regimen containing <u>efavirenz</u> (Sustiva), or <u>nevirapine</u> (Viramune), or a drug from the <u>protease inhibitor</u> class, unless there are medical reasons why one of these drugs isn't suitable. You should only take nevirapine if your CD4 cell count is under 250.
- This drug will be combined with two others. The two anti-HIV drugs used most often in pregnancy are AZT (zidovudine, *Retrovir*) and 3TC (lamivudine, *Epivir*). There is good evidence of their effectiveness. Other suitable drug combinations for use during pregnancy are:
 - —<u>tenofovir</u> (*Viread*) plus <u>FTC</u> (emtricitabine, *Emtriva*)

or

-abacavir (Ziagen) plus 3TC.

The guidelines explain there is no need to alter the doses or timing of anti-HIV drugs during pregnancy. (The only exception to this is the anti-HIV drug darunavir (*Prezista*), generally taken once a day, which should be taken twice a day during pregnancy.)

O In some situations, it may be helpful for you to have 'therapeutic drug monitoring' during the last three months of your pregnancy. This process looks at the levels of different drugs in your blood. It can be useful during pregnancy, when women undergo a lot of physical changes that can affect how drugs act in the body. For example, some women need to take an increased dose of some protease inhibitors in the last trimester of pregnancy.

If you are already on HIV treatment when you become pregnant

• If you are on effective HIV treatment, keep taking the same anti-HIV drugs during pregnancy.

This remains the recommendation if you are taking <u>efavirenz</u> (Sustiva, also in Atripla). Previous guidelines recommended that women on efavirenz should change to another drug, as it was thought there may be a connection between efavirenz and birth defects. The latest evidence doesn't support this advice, so the 2012 guidelines say you can continue to take efavirenz if it is working for you.

There are two reasons why you might be advised to change treatment. These only apply to a very few people:

- If you are taking protease inhibitor (PI) monotherapy; that is, just taking one anti-HIV drug, from the PI class. In this case, one or more anti-HIV drugs will be added to your HIV treatment, so your combination includes some drugs that cross the placenta and protect your baby from HIV.
- You should not take a combination of d4T (stavudine, Zerit) and ddl (didanosine, Videx) while you are pregnant. This is because these drugs are linked to a serious side-effect called lactic acidosis. However, these drugs are now rarely used in the UK.

If you are diagnosed with HIV when you are more than 28 weeks pregnant

- Start HIV treatment straight away.
- If you have a very high viral load (more than 100,000 copies/ml), start a treatment combination containing three or four drugs, including <u>raltegravir</u> (*Isentress*). This is because raltegravir seems to be particularly effective at reducing viral load quickly.
- If you are diagnosed when you are already in labour, you should be given a single dose of <u>nevirapine</u> (*Viramune*) immediately. Also start treatment with a fixed dose of <u>AZT</u> (zidovudine, *Retrovir*) with <u>3TC</u> (lamivudine, *Epivir*, called *Combivir* when combined with AZT) together with <u>raltegravir</u>.
- You should be given AZT intravenously (through a drip) throughout your labour and delivery.
- **O** If you have gone into labour prematurely (before the full term of your pregnancy), another drug, <u>tenofovir</u> (*Viread*), should be added to your treatment combination. If your baby is born very prematurely, she or he may not be able to absorb HIV treatment for the first few days after she or he is born. The double dose of tenofovir provides extra protection for your baby.

If you also have hepatitis B or hepatitis C

Having hepatitis B or hepatitis C as well as HIV can make managing treatment and care during pregnancy more complex. The guidelines emphasise the importance of your antenatal care team working closely with your hepatitis doctor to ensure the best possible treatment and care are given.

Your healthcare team will use the guidelines on adult treatment (mentioned above) to determine whether you need HIV treatment for your own health. Otherwise, you should start treatment to prevent mother-to-baby transmission as outlined above.

Find out more about the guidelines' recommendations on HIV and hepatitis treatment and care during pregnancy in Factsheet 8: HIV treatment for pregnant women: HIV treatment, hepatitis and pregnancy.

If your viral load doesn't become undetectable by the time your baby is due to be born

At 36 weeks of pregnancy, you and your doctors will be able to make a final decision on the type of delivery to plan for you and your baby. Whether or not you have an undetectable viral load will be an important factor in that decision. Ideally, your viral load will be undetectable at 36 weeks.

- If you have started HIV treatment during pregnancy, and you don't have an undetectable viral load by the time you are 36 weeks pregnant, your doctor should:
 - —talk to you about how you are coping with taking your HIV treatment (adherence).
 - —do a <u>resistance</u> test to see if your HIV is resistant to the anti-HIV drugs you are taking.
 - consider whether you would benefit from therapeutic drug monitoring (TDM).
 - consider changing your HIV treatment if there is another combination that would be more effective.
 - consider adding another anti-HIV drug to your treatment combination.

These actions will increase your chance of reducing your viral load to an undetectable level by the time your baby is due to be born.

Stopping HIV treatment after your baby is born

• If you had a CD4 cell count over 350 at the time you started treatment during pregnancy, you can stop HIV treatment after you have given birth.

The way this should be managed is covered in BHIVA's guidelines on <u>Treatment of HIV-1 positive adults with</u> <u>antiretroviral therapy (2012)</u>. Find out about this in <u>Factsheet</u> 4: HIV treatment for adults: Stopping treatment.

The exceptions to this may be:

- if you also have hepatitis B or C and your CD4 cell count is between 350 and 500.
- **O** if your CD4 cell count is between 350 and 500 and you would prefer to stay on treatment.
- **O** if you would like to continue <u>treatment to reduce the risk</u> of HIV transmission.

Continuing HIV treatment after your baby is born

If you started HIV treatment during pregnancy, stay on treatment after your baby is born if:

- you have had an AIDS-defining illness.
- you had a CD4 cell count of less than 350 when you started treatment.
- you had a CD4 cell count between 350 and 500 when you started treatment and you also have hepatitis B or hepatitis
 C. (Find more information in <u>Factsheet 8: HIV treatment for pregnant women: HIV treatment, hepatitis and pregnancy.</u>)

O you would like to continue <u>treatment to reduce the risk of</u> HIV transmission.

These recommendations are the same as those made by BHIVA for all adults with HIV.

• There is some evidence there may be health benefits to starting HIV treatment with a CD4 cell count of about 500. Some research has shown that women may do better if they stay on treatment after they have had a baby, even with a CD4 cell count over 350, although other studies have found no advantage. Although the evidence is not completely clear, if you started HIV treatment during pregnancy with a CD4 cell count of between 350 and 500, you can stay on it after your baby is born, if you would prefer to do so.

HIV treatment for your baby

For the best chance of preventing HIV, your baby will need to take HIV treatment for a short period after he or she is born. This is sometimes called infant post-exposure prophylaxis, or infant PEP.

- If your viral load was undetectable when you were 36 weeks pregnant or when you gave birth **or** you had a planned caesarean section and were on AZT monotherapy, your baby should be given AZT monotherapy. This means he or she will take this single anti-HIV drug, usually twice a day, for four weeks. He or she should start this treatment within four hours of being born.
- If you did not have an undetectable viral load at 36 weeks of pregnancy or when you gave birth, your baby should be started on HIV treatment quickly, at least within four hours of being born. The recommended treatment in this situation is a three-drug combination. Your baby will take HIV treatment as infant PEP for four weeks.
- If you have not been on HIV treatment at all during your pregnancy, and your baby is less than three days old (72 hours), your baby should be started on HIV treatment immediately. The recommended treatment in this situation is a three-drug combination. Your baby will take this treatment as infant PEP for four weeks.

Not all anti-HIV drugs available are considered suitable for use in babies. Which anti-HIV drugs are used in a three-drug combination can also depend on any treatment you have been on (because your baby will have been exposed to those drugs in the womb). Doctors will use the evidence outlined in the guidelines to help them choose the best combination for your baby.

- If the first HIV test your baby has suggests they may have HIV or
- if your viral load was more than 1000 copies/ml at 36 weeks of pregnancy or when your baby was born,

your baby should be given antibiotic treatment to stop him or her developing PCP, a type of pneumonia. This treatment is often referred to as PCP prophylaxis.

Find out more about other care your baby will receive in Factsheet 7: HIV treatment for pregnant women: Antenatal and postnatal care.

Commissioned by:
British HIV Association (BHIVA)
Secretariat: Mediscript Ltd
1 Mountview Court
310 Friern Barnet Lane
London N20 0LD

Telephone: +44 (0)20 8369 5380
Website: www.bhiva.org
Email: bhiva@bhiva.org

Registered charity number: 1056354

This patient-friendly version is based on information contained in the BHIVA guidelines *Treatment of HIV-1* positive adults with antiretroviral therapy (2012), 13 (Suppl. 2), 1–85, which were produced using the NICE-accredited process.

The full version of the guidelines is available to download from the BHIVA website at: www.bhiva.org/ TreatmentofHIV1_2012.aspx

NAM Publications

77a Tradescant Road London SW8 1XJ, UK Telephone: +44 20 3242 0820

Website: www.aidsmap.com Email: info@nam.org.uk

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NAM's information is intended to support, rather than replace, consultation with a healthcare professional. Talk to your doctor or another member of your healthcare team for advice tailored to your situation.

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