What Are Treatment Guidelines?

• Issued by variety of global and country-based agencies
  – Intended to help providers, people living with HIV make decisions about when to start, stop, change HIV medications
  – Written, regularly reviewed by HIV experts (researchers, healthcare providers, community activists, etc.)
  – Help providers and people living with HIV with guidelines to best manage and treat HIV

• Global HIV treatment guidelines are issued by the World Health Organization (WHO)

• US HIV treatment guidelines are issued by Department of Health and Human Services (DHHS)
When to Start Treatment?

Over the years, there has been lots of discussion about when to start treatment, especially for people living with HIV who are relatively healthy:

- High CD4 counts
- No signs of ill health

Guidelines have been changed a number of times. Earlier versions recommended people wait longer before starting HIV treatment:

- Due to concerns that side effects might be more harmful to people with higher CD4 counts than HIV itself

*We now understand that this is not true*
The START trial:

• **Definitely showed**: people living with HIV who start treatment early, while CD4 counts are still high, have a much lower risk of illness and death
  – Including people living with HIV who may have no outward signs of ill health
  – Taking HIV drugs earlier reduced likelihood of developing AIDS-related *and* non-AIDS related illnesses

• **Made clear**: benefits of starting early outweigh any potential risks

• Scientific experts and policy makers issued statement declaring all people living with HIV should have access to HIV treatment as soon as they’re diagnosed

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HIV treatment is recommended for all people living with HIV regardless of CD4 count

- HIV drugs can prevent both AIDS-related and non-AIDS-related illness in people living with HIV
- People living with HIV and on treatment are much less likely to transmit virus
  - People with undetectable viral loads have effectively no risk of transmitting HIV to their sexual partners
- HIV treatment should only be started when individual understands risks/benefits of treatment; is willing/able to commit to taking HIV drugs as prescribed
World Health Organization (WHO) recommends HIV drugs for all people living with HIV at any CD4 count

By October 2015, all internationally-written guidelines were in agreement for the first time since 2006. The DHHS, WHO, EACS (European AIDS Clinical Society), BHIVA (British HIV Association), and the IAS-USA (International AIDS Society USA) all recommend that HIV treatment be offered to all people living with HIV, regardless of their CD4 cell count.
Benefits of Starting Early

• Having a higher CD4 cell count and keeping it high
• Preventing further damage to the immune system
• Decreasing risk for HIV-related and non-HIV-related health problems
• Reducing your risk of transmitting HIV to others:
  – Sexual partners (risk is zero)
  – Babies (through perinatal transmission – also called vertical transmission)
  – This is known as Treatment as Prevention or TasP
Risks of Starting Late

• Severely weakened immune system
  – Can take longer to restore your immune system to full strength, and you to full health.
  – Recent studies have shown that delaying treatment can increase the chances that people living with HIV will develop AIDS and other serious illnesses

• Increased chance of immune reconstitution syndrome when you begin taking HIV drugs

• Transmitting HIV to others, including sexual partners and babies (if you become pregnant)
What to Start With?

• No HIV drug should ever be used by itself
• HIV drugs work in different ways to stop the virus at different points in its lifecycle
• HIV drugs are divided into classes as follows:
  – Nucleoside/nucleotide reverse transcriptase inhibitors ("nukes" or NRTIs)
  – Non-nucleoside reverse transcriptase inhibitors ("non-nukes" or NNRTIs)
  – Protease inhibitors (PIs)
  – Integrase inhibitors
  – Entry inhibitors (fusion inhibitors and chemokine receptor 5 [CCR5] antagonists)
  – Boosting agents
What to Start With?

• Guidelines for first HIV regimens include:
  – Integrase inhibitor + 2 NRTIs or, possibly ...
  – PI (boosted with a small dose of a second drug that makes the PI work better) or NNRTI + 2 NRTIs

• DHHS guidelines rank specific drug combinations as recommended or alternative
  – Recommended regimens may not be ideal for everyone
  – Drugs should be chosen based on specific needs, lifestyle, schedule, other medications, resistance test results, etc.
DHHS Recommended Initial Regimens

- Integrase inhibitor-based regimens
  - Biktarvy (bictegravir/tenofovir alafenamide/emtricitabine)
  - Triumeq (dolutegravir/abacavir/lamivudine), but only after testing for a genetic variation that could result in hypersensitivity to abacavir
  - Tivicay (dolutegravir) + Truvada (tenofovir disoproxil fumarate/emtricitabine) or Descovy (tenofovir alafenamide/emtricitabine)
DHHS Recommended Initial Regimens

- **Integrase inhibitor-based regimens**
  - Isentress (raltegravir) + Truvada (tenofovir disoproxil fumarate/emtricitabine) or Descovy (tenofovir alafenamide/emtricitabine)
  - Dovato (dolutegravir/lamivudine), except for people whose viral load before treatment is above 500,000 copies; people living with active hepatitis B (HBV); or those who have not been tested for resistance to these drugs, or tested for HBV)
WHO Recommended Regimens

• As of December 2018: World Health Organization (WHO) guidelines reviewed and updated to recommend HIV drug regimens containing Tivicay or Isentress for those starting HIV treatment for the first time, as well as those who have already taken an HIV drug regimen
  — This recommendation includes pregnant women, children, and those also being treated for tuberculosis
Regimens for Pregnant Women

- Due to recent revisions, Tivicay can now be an alternative drug for women who wish to become pregnant; preferred regimen for pregnant women.
- Women who are pregnant should not take medications that contain cobicistat (Tybost, found in several other HIV drugs) – levels of drug may drop too low to provide effective HIV treatment.
- Efavirenz (Sustiva, also found in Atripla and Symfi Lo) should only be used if other preferred regimens cannot be used, due to birth defects seen in monkey studies (not in people).
If one needs to make *changes in their regimen*:  
- DHHS recommends focusing on maintaining viral suppression without reducing future treatment options.  
- Reasons for changing one’s HIV drug regimen include:  
  - Side effects  
  - Viral load not controlled  
  - Simplifying the regimen  
  - Trouble with adherence  
- Once HIV treatment is begun, it should not be stopped without consulting a health care provider.
Resistance Tests

• DHHS guidelines recommend drug resistance testing for:
  – People who have just acquired HIV
  – People who have never been on HIV drugs and are planning to start
  – People on HIV drugs who see their viral load go up
  – People who recently started HIV drugs whose viral load is not coming down to undetectable
  – Pregnant women living with HIV
  – People whose viral loads are not well controlled using an Integrase inhibitor-based drug combination
    • Should receive genotype test for Integrase resistance
    • May also need regular genotype test

• Testing is not usually recommended for people who have stopped HIV drugs for four weeks or more

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• There is **much more information in the guidelines**, including:
  – Other possible drug regimens
  – What drugs not to take
  – What types of resistance tests to use
  – Information on pregnancy and women-specific treatment issues
  – Other aspects of HIV care and treatment
• Guidelines are always changing and based on the most up-to-date information from studies and clinical trials
• They are only general suggestions!
• To learn more, please read the full fact sheet on this topic:
  – HIV Treatment Guidelines
• For more fact sheets and to connect to our community of women living with HIV, visit:
  – www.thewellproject.org
  – www.facebook.com/thewellproject
  – www.twitter.com/thewellproject