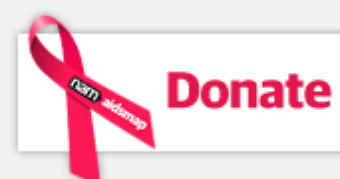




Wednesday 28 October 2015

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New EACS guidelines recommend antiretroviral treatment for all



Panel presenting the treatment guidelines at EACS 2015. Photo by Liz Highleyman, [hivandhepatitis.com](#)

The new [European AIDS Clinical Society \(EACS\) HIV clinical guidelines](#), released last week at the [15th European AIDS Conference](#), bring Europe into line with the rest of the world by recommending HIV treatment upon diagnosis for everyone living with HIV.

[The guidelines recommend tenofovir and emtricitabine \(*Truvada*\) or abacavir/lamivudine \(*Kivexa*\) as the backbone for first-line antiretroviral therapy.](#)

They recommend six first-line regimens. Four use integrase inhibitors as their third drug (*Truvada* plus dolutegravir, *Truvada* plus raltegravir, the combination pill *Triumeq* (which is *Kivexa* plus dolutegravir), and the combination pill *Stribild* (which is *Truvada* plus boosted elvitegravir). They also recommend the NNRTI-based *Complera/Eviplera* pill, which is *Truvada* plus rilpivirine, and the PI-based regimen of *Truvada* plus ritonavir-boosted darunavir.

Other changes in the new guidelines include a positive recommendation for [pre-exposure prophylaxis \(PrEP\)](#), which brings them into line with the US, [World Health Organization \(WHO\)](#) and British HIV Association (BHIVA) recommendations. PrEP is “recommended” for “men who have sex with men and transgender individuals, who are inconsistent in their use of condoms with casual partners or with HIV-positive partners who are not on treatment,” and “may be considered” for “heterosexual men and women who are inconsistent in their use of condoms and are likely to have HIV-positive partners who are not on treatment.”

The guidelines emphasise that PrEP is a medical intervention that may have side-effects, does not protect against other sexually transmitted infections, “may not provide full protection against acquiring HIV” and should be prescribed and supervised by a doctor experienced in sexual health.

The guidelines recommend that PrEP can be prescribed as a daily or intermittent regimen, in the latter case taken as it was in the Ipergay study (a double dose in the 24 hours before sex then one dose each on the two following days after sex).

EACS has also changed its recommendations for *post-exposure* prophylaxis (PEP). The guidelines no longer recommend PEP if the source partner is HIV-positive with an undetectable viral load, a change that finally brings them into line with BHIVA, and they recommend *Truvada* plus darunavir/ritonavir or raltegravir as regimens.

Related links

[Read this story in full on aidsmap.com](#)

[Download the European guidelines from the EACS website](#)

New formulation of tenofovir shows improved safety



Bart Rijnders, presenting at EACS 2015. Photo by Liz Highleyman, hivandhepatitis.com

Research presented at the 15th European AIDS Conference last week shows improved safety for a combination containing a new formulation of tenofovir, recently granted scientific approval for marketing in the European Union.

Gilead Sciences' tenofovir alafenamide (TAF) is a new pro-drug formulation that delivers the active agent to HIV-infected cells more efficiently than the current tenofovir disoproxil formulation (*Viread*, also in *Truvada*, *Atripla*, *Eviplera* and *Stribild*). Tenofovir is generally safe and well-tolerated but it can cause a small amount of bone loss soon after starting therapy and can lead to kidney problems in susceptible people.

A report on two phase III randomised trials of tenofovir alafenamide in combination with elvitegravir, cobicistat and emtricitabine showed that after 96 weeks, people who received TAF experienced smaller declines in bone mineral density and fewer cases of serious kidney toxicity, when compared to people who received the older formulation of tenofovir as part of the same combination. There was no difference in rates of virological suppression.

Another study presented at the conference found that people switching from atazanavir/ritonavir and tenofovir/emtricitabine to tenofovir alafenamide in combination with elvitegravir, cobicistat and emtricitabine experienced significant improvements in bone mineral density, and there was some evidence of an improvement in kidney function too.

Based on favourable study findings to date, Gilead has requested US and European regulatory approval of the elvitegravir/cobicistat/emtricitabine/TAF single-tablet regimen, which will be marketed as *Genvoya*. The scientific committee of the European Medicines Agency approved *Genvoya* in September and full marketing approval is expected within several months. The US Food and Drug Administration is scheduled to make a decision in November.

Risk of heart attack rises with length of HIV infection, regardless of age



Ten years after acquiring HIV, a person living with HIV has approximately twice the risk of heart attack compared to someone who has just acquired HIV, regardless of the age at which they seroconvert, and after taking into account the effects of ageing, [an analysis of 18,468 people living with HIV has shown](#).

The study was carried out by the CASCADE collaboration in [EuroCoord](#), and looked at eight cohorts in Europe and North America. It was designed to examine the contribution of HIV infection and immunosuppression, as distinct from antiretroviral treatment or known risk factors, to the risk of heart attack in people living with HIV. Long-term infection with HIV might raise the risk of heart attack by causing inflammation, but previous studies have not looked at whether the duration of HIV infection (how long someone has been living with HIV) had any effect on the risk of heart attack. Previous studies have shown that exposure to specific drugs – indinavir, lopinavir/ritonavir and current abacavir treatment – is associated with an increased risk of heart attack.

The study showed that the duration of HIV infection was one of the strongest predictors of heart attack, after controlling for age and type of antiretroviral treatment, and it did not matter whether a person had a fully suppressed viral load or very high viral load. Severe immune suppression did raise the risk however. Having a current CD4 cell count below 100 was associated with an approximate four-fold increase in risk compared with having a CD4 cell count above 100.

Alexandra Lyons of University College London, presenting the findings, concluded that guidelines for cardiovascular risk management in people living with HIV may need to consider duration of HIV infection as an independent risk factor, and that particular emphasis needs to be placed on addressing risk factors like diet, smoking and exercise in people who have been living with HIV for a long time, regardless of their age.

START sub-studies



Jennifer Hoy, presenting at EACS 2015. Photo by Liz Highleyman, [hivandhepatitis.com](#)

The START (Strategic Timing of Antiretroviral Treatment) trial was designed to address the question of when to start HIV treatment, especially for people who still have high CD4 counts. It randomised people with CD4 cell counts above 500 to immediate or deferred treatment.

Participants who started antiretroviral therapy (ART) soon after HIV diagnosis in the large START trial showed a greater decrease in bone density at the hip and spine compared to those who deferred treatment, researchers reported at a joint session of the [15th European AIDS Conference](#) and the [17th International Workshop on Co-morbidities and Adverse Drug Reactions in HIV](#). There was no significant difference in the likelihood of fractures, however, and two other START sub-studies saw no differences in lung function or neuropsychological performance between people randomised to immediate or deferred ART.

Starting antiretroviral treatment before the development of serious immune system damage greatly reduces the risk of HIV disease progression and death, but early treatment can potentially also have drawbacks including longer exposure to toxic drugs. Since tenofovir and protease inhibitors are associated with reduced bone mineral density, [START investigators looked at whether earlier treatment increased the risk of bone loss in a sub-study](#) of 193 people randomised to the early ART group and 204 in the deferred ART group.

Bone mineral density in the spine declined during the first year of treatment in the immediate treatment group and then stabilised. Total hip bone mineral density continued to decline over three years in both study arms, but the percentage loss was greater in the immediate compared to the deferred group. These differences were statistically significant.

There was no difference in the development of osteoporosis or fractures.

The only treatment factor significantly associated with bone mineral loss was protease inhibitor treatment.

Having a lower CD4 count was associated with greater bone loss at the spine, while longer time since HIV diagnosis was the major factor affecting hip bone loss.



Ken Kunisaki, presenting at EACS 2015. Photo by Liz Highleyman, [hivandhepatitis.com](#)

Related sub-studies from the START trial looked at [changes in lung function and neurocognitive function](#). The lung function study examined whether the risk of chronic obstructive pulmonary disease (COPD) increased as a result of earlier treatment. Observational studies have shown that people with HIV are at higher risk for COPD, but there are conflicting data about whether ART is associated with elevated risk.

The study found no difference in lung function decline between immediate and deferred treatment groups, either in smokers or non-smokers.

[The neurocognitive sub-study](#) addressed the question of whether early treatment might affect

neurocognitive performance – skills such as memory, concentration and the ability to process and act on information. There is some evidence from cohort studies of modest declines in neurocognitive performance that fall short of AIDS dementia in people with more advanced HIV infection, and it has been suggested that earlier treatment might prevent these changes.

The neurocognitive sub-study showed "no overall neurocognitive advantage (or disadvantage) for immediate ART initiation in asymptomatic treatment-naïve individuals with high CD4 counts," the researchers said. These findings suggest that there is both a "low incidence of ART-preventable neurocognitive impairment" in this population and a low incidence of neurocognitive decline while off treatment, as well as "no clear evidence of neurotoxicity".

Related links

[Read more about the bone mineral density sub-study on aidsmap.com](#)

[Read more about the lung function and neurocognitive function sub-studies on aidsmap.com](#)

Hepatitis C infection and mortality: does treatment cure everything?



Lars Peters, presenting at EACS 2015. Photo by Liz Highleyman, hivandhepatitis.com

Hepatitis C treatment that leads to sustained virological response (SVR) – generally regarded as a cure – was associated with a reduced risk of liver-related death and improved overall survival in an analysis of 3500 people with HIV and hepatitis C virus (HCV) co-infection, according to a presentation at the conference. A related study found that while some liver-related events are declining over time, liver cancer remains a risk for people with co-infection.

Prior research has shown that sustained response to hepatitis C treatment is associated with reduced mortality among HIV-negative people with HCV. The survival benefit of treatment for people with co-infection could be greater due to their accelerated fibrosis progression, or less because they are more likely to die of other 'competing' causes.

An analysis of 18 European cohorts of people with HIV and HCV co-infection by COHERE (Collaboration of Observational HIV Epidemiological Research in Europe), which looked at all people who had ever started interferon-based hepatitis C therapy and were followed for at least 96 weeks, found that people who responded to treatment were less likely to die of liver-related causes or other causes.

Another study, of four cohorts of treated and untreated people with co-infection, found that whereas non-cancer liver events had declined since 2003-4, the incidence of liver cancer has continued to rise by around 11% a year. Cirrhosis strongly predicted the development of liver cancer, raising the risk 13-fold.

Related links

[Read this news story in full on aidsmap.com](#)

BMS maturation inhibitor



Carey Hwang, presenting at EACS 2015. Photo by Liz Highleyman, hivandhepatitis.com

Bristol-Myers Squibb's next-generation maturation inhibitor BMS-955176 demonstrated good antiviral activity against HIV subtypes B and C in a short proof-of-concept study and appeared to be safe and well-tolerated, according to findings presented at the conference.

Effective antiretroviral therapy (ART) combines agents that target different steps of the HIV lifecycle, but none of the currently approved drugs interfere with viral assembly, maturation and release from host cells. Such drugs could offer an important treatment option for people who have HIV with extensive resistance to existing antiretroviral classes.

A phase 2a study presented at the conference showed that an experimental maturation inhibitor combined with atazanavir (without or without ritonavir boosting) reduced viral load to a similar extent as a combination of tenofovir/emtricitabine and atazanavir (without or without ritonavir boosting). In a dose-ranging monotherapy study also presented, short-term treatment with BMS-955176 was generally safe and well-tolerated, with no deaths, serious adverse events or study discontinuations due to adverse events. The most common side-effects were headaches and abnormal dreams. Hyperbilirubinemia associated with atazanavir was the most frequent side-effect in the combination therapy phase of the study.

Related links

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EACS 2017



The European AIDS Conference 2017 will take place in Milan, Italy, from October 25-28 2017. Keep up to date with the conference at the [16th European AIDS Conference website](#).

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NAM's coverage of the 15th European AIDS Conference has been made possible thanks to support from the European AIDS Clinical Society (EACS), Bristol-Myers Squibb, Gilead, Merck & Co., Inc., and ViiV Healthcare.



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