

HATiP

HIV & AIDS Treatment in Practice

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Highlights from CROI 2009

This edition of HATIP is devoted to news headlines from last week's Sixteenth Conference on Retroviruses and Opportunistic Infections, held in Montréal, Canada. We published comprehensive news coverage from this conference at aidsmap.com.

CROI is one of the major HIV-related scientific meetings of the year, and many of the most important presentations at this year's conference were of research conducted in Africa and Asia that will be directly relevant to the care of people with HIV and prevention of HIV infection in those settings.

This bulletin divided into five sections, each highlighting the major studies presented in those areas at the conference. Of particular note are the following:

- Opportunistic infection management and prophylaxis: a large randomised study demonstrated that prophylaxis with fluconazole reduced the risk of cryptococcal meningitis in people with advanced HIV disease, while another study showed that use of the steroid prednisone improved the outcomes of people with TB-related immune reconstitution inflammatory syndrome (IRIS).
- Antiretroviral treatment reduced the risk of HIV transmission within HIV-discordant partnerships in two separate studies in Uganda, Rwanda and Zambia.
- The first evidence of microbicide effectiveness, from the HPTN 035 study, showing that PRO2000 reduced the risk of HIV infection by around 30%. Results of another major study, due to finish by the end of 2009, are awaited in order to confirm this result.
- Late treatment initiation in resource-limited settings continues to confer an increased risk of death for years afterwards, due to the prolonged period individuals spend with very low CD4 counts.
- Antiretroviral treatment for mothers during the breastfeeding period reduces the risk of HIV after a 14 week course of prophylaxis for the infant is stopped – but only in mothers with a CD4 count below 250 cells/mm³. Is infant prophylaxis the better tool for preventing transmission during breastfeeding? Some experts at CROI said yes, but others would prefer to give ART to mothers.

All the summaries link to news reports published at aidsmap.com. You can view all symposia and oral research presentations from the conference online at the conference website <http://www.retroconference.org/2009> (although we have not tested the feasibility of doing this over a dial-up internet connection and would note that even over a high-speed broadband connection it can take several minutes for presentations to load). You can also browse the conference programme online and view pdf versions of the vast majority of posters presented.

Opportunistic infections: prophylaxis and management

Ugandan study supports the use of fluconazole to prevent cryptococcal meningitis

Oral fluconazole prophylaxis safely prevents invasive cryptococcal disease in people with advanced HIV, according to a randomised, double-blind, placebo-controlled trial conducted in over 1500

participants in rural Uganda, and presented on Monday at the Sixteenth Conference on Retrovirus and Opportunistic Infections (CROI) in Montreal. Prophylaxis was effective in people who were waiting to receive antiretroviral therapy (ART) and in those who had recently started ART, but who had not yet had a significant improvement in their immune status. It also significantly reduced the incidence of other serious fungal infections like oesophageal candidiasis.

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Corticosteroid therapy improves outcomes in people with TB-IRIS in trial

A four-week course of the anti-inflammatory corticosteroid, prednisone, improves outcomes when given to people who develop tuberculosis (TB)-immune reconstitution inflammatory syndrome (TB-IRIS) after starting antiretroviral therapy (ART) - without causing an excess of steroid side-effects or other infections, according to a randomised placebo-controlled trial conducted in Cape Town, and presented on Monday at the Sixteenth Conference on Retroviruses and Opportunistic Infections in Montreal.

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More treatment failure in people on TB treatment who start once daily nevirapine-based ART than efavirenz-based ART

People on TB treatment who started a once-daily antiretroviral therapy (ART) regimen of nevirapine/ddl/3TC were significantly more likely to fail ART than those who started on a once-daily regimen of efavirenz/ddl/3TC, according to a randomised prospective study from Chennai, India. In fact, the nevirapine arm performed so poorly that the study's Data Safety and Monitoring Board (DSMB) ended accrual to that study arm and closed the study ahead of schedule.

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Prevention technologies

Antiretroviral treatment lowers rates of HIV transmission in heterosexual couples in Africa

Antiretroviral treatment is associated with a lower risk of heterosexual HIV transmission in African serodiscordant couples, according to findings from Uganda, Rwanda and Zambia, presented on Monday at the Sixteenth Conference on Retroviruses and Opportunistic Infections.

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HIV sporadically detectable in semen of men with undetectable plasma viral loads

At the Sixteenth Conference on Retroviruses and Opportunistic Infections in Montreal on Monday morning, two back-to-back oral presentations affirmed that HIV is indeed often detectable in semen despite undetectable viral loads in blood plasma. The two studies found measurable HIV RNA ("viral shedding") in 3% to 14% of seminal fluid samples taken from study participants with undetectable plasma viral loads.

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Seminal HIV: cell-free virus, not infected cells, leads to transmission between men

At the Sixteenth Conference on Retroviruses and Opportunistic Infections in Montreal on Monday morning, David Butler of the University of California San Diego presented data on four cases of

male-to-male sexual transmission, showing that cell-free virus in semen – not proviral DNA in infected cells – was the means of transmission in all four cases.

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PrEP could work even if taken several days in advance

A study using tenofovir and FTC (*Truvada*) to prevent rectal SHIV infection in monkeys – so-called pre-exposure prophylaxis (PrEP) – has shown that it is as effective for the medication to be given up to three days before exposure as it is one day before. Even giving *Truvada* a full week before exposure resulted in a considerable reduction in the risk of infection.

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Microbicide reduces HIV infections by 30% in first success for field

Campaigners were celebrating the results of a trial of a microbicide to prevent HIV that has produced a positive result, the first one to do so. The results of the HPTN 035 were announced at the Sixteenth Conference on Retroviruses and Opportunistic Infections in Montreal today.

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High-dose tenofovir microbicide completely protects monkeys

An animal study has found that a single dose of a microbicide gel containing tenofovir and FTC completely protected six out of six monkeys given a twice-weekly vaginal challenge of a combined human/monkey virus called SHIV. No monkeys were infected after 20 challenges with the virus whereas monkeys not given the microbicide were infected after an average of four challenges.

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HIV testing and prevention

Men becoming visible: more light shed on men who have sex with men in Africa and India

The majority of men who have sex with men (MSM) in three different African countries and in Tamil Nadu State in India also have sex with women, according to two presentations and a poster at the CROI Conference in Montreal.

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HIV testing in Kenya on the rise, but four out of five Kenyans with HIV still unaware of their status

HIV prevalence in Kenyan adults has remained relatively steady since 2003, at around 7%, according to a major national study presented to the Sixteenth Conference on Retroviruses and Opportunistic Infections (CROI) on Wednesday. However, less than one in five HIV-positive adults were aware of their HIV status, and over half had never been tested for HIV at all.

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Ugandan studies identify benefits of home-based HIV counselling and testing approaches

Findings from two Ugandan studies suggest that home-based HIV counselling and testing may augment traditional HIV counselling and testing services in important ways in some settings, both by increasing acceptance and uptake of HIV testing, but also by impacting attitudes toward HIV at a population level. The results of both studies were presented to the Sixteenth Conference on Retroviruses and Opportunistic Infections (CROI) on Wednesday by Sundeep Gupta of the Centres for Disease Control, Uganda, on behalf of the investigating teams.

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HIV incidence high and unchanged in rural South African community over five-year period

Longitudinal surveillance of a poor rural community in Kwazulu-Natal, South Africa, indicates that HIV incidence remained high from 2003 through 2007, despite prevention activities in the region, with almost half of all new infections occurring in people who had already received one negative test result through local voluntary testing and counselling services.

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Antiretroviral therapy

When to start HIV treatment: cohort studies disagree on how early

Two major analyses of the risk of death or AIDS-related illness in people who started treatment at different CD4 counts have produced conflicting evidence about the benefit of starting treatment substantially earlier than current guidelines recommend, the Sixteenth Conference on Retroviruses and Opportunistic Infections heard on Monday.

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HIV infection has similar impact on hardening of arteries as smoking, diabetes

HIV infection independently increases the severity of atherosclerosis as much as traditional cardiovascular risk factors such as smoking and diabetes, researchers reported on Wednesday at the Sixteenth Conference on Retroviruses and Opportunistic Infections in Montreal.

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Rosiglitazone improves fat loss and insulin resistance in people with lipodystrophy

The diabetes drug rosiglitazone (*Avandia*) improved limb lipodystrophy in HIV-positive people taking antiretroviral therapy, researchers reported Wednesday at the Sixteenth Conference on Retroviruses and Opportunistic Infections in Montréal. However the researchers did not study the drug's effect on facial fat loss.

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Diabetes, high blood pressure and smoking raise risk of death for all people with HIV

A number of modifiable or preventable medical conditions can nearly double the risk of death in people with HIV, a large cohort study has found, and can double the risk of death due to specific causes. Colette Smith of University College Medical School, London, presented the latest analysis of the D:A:D study to the Sixteenth Conference on Retroviruses and Opportunistic Infections in Montreal on Wednesday.

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Certain protease inhibitors and abacavir linked to heart attacks in two large cohort studies

The latest follow-up data from two large cohort studies, presented on Monday at the Sixteenth Conference on Retroviruses and Opportunistic Infections in Montreal, adds further evidence that specific protease inhibitors (PIs) and nucleos(t)ide reverse transcriptase inhibitors (N(t)RTIs) are associated with a higher risk of cardiovascular problems in people with HIV.

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Treatment switches on basis of CD4 declines often unnecessary, Uganda research shows

Switching people to second-line antiretroviral treatment on the basis of CD4 declines, without information from viral load tests, could result in a large numbers of unnecessary switches to more expensive second-line regimens in resource-limited settings, a study in Uganda has found.

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Disadvantage of late treatment start in Africa may persist for years, studies find

Starting antiretroviral therapy earlier, before the development of symptoms, is the most likely way to reduce the high death rates after treatment initiation seen in people with HIV in resource-limited settings, two large cohort analyses show. The studies also show that the major disadvantage of starting treatment late - an increased risk of death - may persist for some years, burdening already overstretched health systems with illness that could be avoided by earlier treatment.

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Double-dose lopinavir/ritonavir provides insufficient lopinavir exposure in children on rifampicin-based TB treatment

Doubling the dose of lopinavir/ritonavir (*Kaletra*) in children with HIV on rifampicin-based TB treatment fails to provide adequate lopinavir concentrations according to a drug interaction study presented this week at the Sixteenth Conference on Retrovirus and Opportunistic Infections in Montréal

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PMTCT and maternal health

ART use in mothers with low CD4 cell counts reduces breastfeeding transmission fivefold: Malawi

The use of antiretroviral therapy (ART) by breastfeeding mothers greatly reduced the risk of HIV transmission to their infants after a 14-week course of infant HIV prophylaxis was stopped, according to a study performed in Malawi and presented to the Sixteenth Conference on Retroviruses and Opportunistic Infections (CROI) on Tuesday. However, ART use did not significantly reduce transmission risk in mothers with CD4 cell counts above 250 cells/mm³.

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Breastfeeding in HIV-positive mothers in Botswana did not affect mortality

A controlled, randomised, prospective trial of 1200 HIV-positive mothers in Botswana found no differences in mortality between those who breastfed and those who formula fed. A trend toward faster declines in CD4 cell count began to emerge several years after cessation of breastfeeding, but this was not statistically significant and its significance is unknown.

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Maternal resistance to nevirapine following single dose reduced by AZT/ddI or one month's ART

Two Thai studies have provided further evidence that short courses of more than one antiretroviral drug after delivery almost eliminate the risk of nevirapine resistance in mothers when it is used to prevent mother-to-child transmission, thus preserving nevirapine as an option for maternal treatment when eventually needed.

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Kaletra superior to nevirapine-based ART for women already exposed to single-dose nevirapine

An antiretroviral regimen based on the boosted protease inhibitor lopinavir/ritonavir (*Kaletra*, or *Aluvia*) was significantly more effective than a nevirapine-containing regimen in mothers previously exposed to single-dose nevirapine, according to results from the randomised OCTANE study presented on Tuesday at the Sixteenth Conference on Retroviruses and Opportunistic Infections in Montreal.

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Nearly half of new infant HIV infections in Botswana may result from mothers infected during pregnancy or after delivery

In discussions of mother-to-child transmission of HIV, the assumption is often made that the mothers themselves were already HIV-positive at or before the time of becoming pregnant. This assumption was challenged at a Tuesday morning session on mother and child health issues at the Sixteenth Conference on Retroviruses and Opportunistic Infections in Montreal. Presenter Lydia Lu of the Centers for Disease Control, on behalf of a US/Botswana research team, estimated that over 40% of infants who acquired HIV via mother-to-child transmission (MTCT) in 2007 may have been born to mothers who became HIV-infected during pregnancy or in their first post-partum year, when they were likely to be breastfeeding.

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Hormonal contraception does not affect HIV progression in large international cohort

Previous analyses, including a cohort study in Kenya and secondary results from a randomised controlled trial in Zambia, have suggested that hormonal contraception may accelerate HIV disease progression in women not yet on antiretroviral treatment (ART). However, an analysis of a cohort of over 4500 women across multiple sites in Africa and elsewhere found no evidence that hormonal contraception affects mortality or disease progression. Elizabeth Stringer of the University of Alabama at Birmingham reported the findings to the Sixteenth Conference on Retroviruses and Opportunistic Infections last week on behalf of a research team from Zambia and the US.

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about HATiP

A regular electronic newsletter for health care workers and community-based organisations on HIV treatment in resource-limited settings.

The newsletter is edited by Theo Smart (Cape Town) and Keith Alcorn, NAM's Senior Editor (London).

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