Combined drug therapy to treat TB and HIV significantly improves survival

February 25 2010

Initiating antiretroviral therapy (ART) during tuberculosis therapy significantly reduced mortality rates by 56 percent in a randomized clinical trial of 642 patients co-infected with HIV and tuberculosis. The study, which provides further impetus for the integration of TB and HIV services, lays to rest the controversy on whether co-infected patients should initiate ART during or after TB treatment. Findings are published in the February 25th issue of The *New England Journal of Medicine*.

Tuberculosis is the most common opportunistic disease and the most frequent cause of death in patients with HIV infection in developing countries, and the number of patients with co-infection continues to grow rapidly.

"Despite World Health Organization(WHO) guidelines supporting concomitant treatment of the two diseases and urging more aggressive management initiation of antiretroviral therapy, treatment often has been deferred until completion of tuberculosis therapy because of concern about potential drug interactions, overlapping side effects, a high pill burden, and programmatic challenges," said Salim S. Abdool Karim, MD, PhD, professor of clinical epidemiology at Columbia University's Mailman School of Public Health, pro vice-chancellor (research) at the University of KwaZulu-Natal in Durban, South Africa, and principal investigator of the study.

The new study, called the Starting Antiretroviral Therapy at Three Points in Tuberculosis (SAPiT), was designed to determine the optimal time to

initiate antiretroviral therapy in patients with HIV and tuberculosis co-infection who were receiving tuberculosis therapy. The trial was conducted at the eThekwini HIV-tuberculosis clinic, operated by the Centre for the AIDS Programme of Research in South Africa (CAPRISA) in Durban, South Africa.

Of the 642 patients in the trial, 429 were in the combined integrated-therapy groups who initiated ART during TB treatment as compared with the 213 patients in the sequential-therapy group who initiated ART only after TB treatment was completed. Only patients with TB and HIV infection with a CD4+ cell count of less than 500 cells per cubic millimeter were included in the study.

All patients received standard tuberculosis therapy and a once-daily antiretroviral regimen.

Based on the results of this study, the World Health Organization guidelines for treatment of TB and HIV co-infection were revised in late 2009. On World AIDS Day in 2009, President Zuma of South Africa announced the new policy, to provide ART to all TB patients with HIV infection and CD4 counts below 350 cells per cubic millimeter.

"Our findings provide compelling evidence of the benefit of initiating antiretroviral therapy during tuberculosis therapy in patients with HIV co-infection, and also support recommendations by the WHO and others for the integration of tuberculosis and HIV care," notes Dr. Karim.

Provided by Columbia University's Mailman School of Public Health