

# The study of HIV and antenatal care integration in pregnancy in Kenya: design, methods, and baseline results of a cluster-randomized controlled trial.

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## Abstract

### BACKGROUND:

Despite strong evidence for the effectiveness of anti-retroviral therapy for improving the health of women living with HIV and for the prevention of mother-to-child transmission (PMTCT), HIV persists as a major maternal and child health problem in sub-Saharan Africa. In most settings antenatal care (ANC) services and HIV treatment services are offered in separate clinics. Integrating these services may result in better uptake of services, reduction of the time to treatment initiation, better adherence, and reduction of stigma.

### METHODOLOGY/PRINCIPAL FINDINGS:

A prospective cluster randomized controlled trial design was used to evaluate the effects of integrating HIV treatment into ANC clinics at government health facilities in rural Kenya. Twelve facilities were randomized to provide either fully integrated services (ANC, PMTCT, and HIV treatment services all delivered in the ANC clinic) or non-integrated services (ANC clinics provided ANC and basic PMTCT services and referred clients to a separate HIV clinic for HIV treatment). During June 2009- March 2011, 1,172 HIV-positive pregnant women were enrolled in the study. The main study outcomes are rates of maternal enrollment in HIV care and treatment, infant HIV testing uptake, and HIV-free infant survival. Baseline results revealed that the intervention and control cohorts were similar with respect to socio-demographics, male partner HIV testing, sero-discordance of the couple, obstetric history, baseline CD4 count, and WHO Stage. Challenges faced while conducting this trial at low-resource rural health facilities included frequent staff turnover, stock-outs of essential supplies, transportation challenges, and changes in national guidelines.

### CONCLUSIONS/SIGNIFICANCE:

This is the first randomized trial of ANC and HIV service integration to be conducted in rural Africa. It is expected that the study will provide critical evidence regarding the implementation

and effectiveness of this service delivery strategy, with important implications for programs striving to eliminate vertical transmission of HIV and improve maternal health.