

# Incidence of virological failure and major regimen change of initial combination antiretroviral therapy in Latin America and the Caribbean: an observational cohort study

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## Resumen

**Background** Access to combination antiretroviral therapy (ART) is expanding in Latin America (Mexico, Central America, and South America) and the Caribbean. We assessed the incidence of and factors associated with regimen failure and regimen change of initial ART in this region.

**Methods** This observational cohort study included antiretroviral-naive adults starting ART from 2000 to 2014 at sites in seven countries throughout Latin America and the Caribbean. Primary outcomes were time from ART initiation until virological failure, major regimen modification, and a composite endpoint of the first of virological failure or major regimen modification. Cumulative incidence of the primary outcomes was estimated with death considered a competing event.

**Findings** 14 027 patients starting ART were followed up for a median of 3.9 years (2.0-6.5): 8374 (60%) men, median age 37 years (IQR 30-44), median CD4 count 156 cells per mu L (61-253), median plasma HIV RNA 5.0 log 10 copies per mL (4.4-5.4), and 3567 (28%) had clinical AIDS. 1719 (12%) patients had virological failure and 1955 (14%) had a major regimen change. Excluding the site in Haiti, which did not regularly measure HIV RNA, cumulative incidence of virological failure was 7.8% (95% CI 7.2-8.5) 1 year after ART initiation, 19.2% (18.2-20.2) at 3 years, and 25.8% (24.6-27.0) at 5 years; cumulative incidence of major regimen change was 5.9% (5.3-6.4) at 1 year, 12.7% (11.9-13.5) at 3 years, and 18.2% (17.2-19.2) at 5 years. Incidence of major regimen change at the site in Haiti was 10.7% (95% CI 9.7-11.6) at 5 years. Virological failure was associated with younger age (adjusted hazard ratio [HR] 2.03, 95% CI 1.68-2.44, for 20 years vs 40 years), infection through injection drug use (vs infection through heterosexual sex; 1.60, 1.02-2.52), and initiation in earlier calendar years (1.28, 1.13-1.46, for 2002 vs 2006), but was not significantly associated with boosted protease inhibitor-based regimens (vs non-nucleoside reverse

transcriptase inhibitor; 1.17, 1.00-1.36).

Interpretation Incidence of virological failure in Latin America and the Caribbean was generally lower than that reported in North America or Europe. Our results suggest the need to design strategies to reduce failure and major regimen change in young patients and those with a history of injection drug use.

## Palabras clave

### KeyWords

**Plus:**[METAANALYSIS](#); [PROGRESSION](#); [MORTALITY](#); [INFECTION](#); [SETTINGS](#); [GENDER](#); [TIME](#); [RNA](#)

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