Hormonal contraception and the risk of HIV acquisition among women in rural and urban communities in KwaZulu-Natal, South Africa

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BACKGROUND

- Worldwide, about 150 million women use hormonal contraception (HC).
- □ HC use is common in high HIV prevalence areas.
- In KwaZulu-Natal, HC use is highest among younger sexually active women aged 15 to 34 years.
- Many studies have investigated the association between HC and HIV with conflicting results.
- We aim to provide additional evidence, if any, to the current debate on the risk of HIV acquisition associated with HC use.

STUDY HYPOTHESIS

The use of hormonal contraception increases the risk of HIV acquisition in women.

STUDY DESIGN & POPULATION

- Observational analysis of HIV incidence among HC users in 2 prospective cohort studies conducted at 2 different time points in the same population:
 - HPTN 055: prospective cohort study conducted at potential phase 2/IIb microbicide trial sites (2003 -2005).
 - HPTN 035: multi-center Phase II/IIb safety and effectiveness study of the vaginal microbicides BufferGel and 0.5% PRO 2000/5 Gel (P) (2005-2008).
- □ Sites: Durban (urban) and Hlabisa (rural)
- Population: 1533 women aged 18 years and over, HIV negative at baseline
 - > 479 (HPTN 055)
 - > 1054 (HPTN 035)

STUDY OBJECTIVES

- To determine the incidence of HIV among HC users and non-HC users during follow up in HPTN 055 and HPTN 035.
- To assess if there were differences in HIV incidence in HC users between the two studies concluded at different time points in the same community.
- To investigate potential reasons for any observed association, including sexual risk behaviour (number of partners, condom use), acquisition of other STIs, etc.

DATA ANALYSIS PLAN

- Primary outcome measure: incidence of HIV-1 seroconversion.
 - > HIV incidence rate per 100 wy (Hlabisa and Durban): HPTN 055 - 5.5
 HPTN 035 - 7
- Contraception use was assessed at each quarterly visit
- □ Classification of contraception users:
 - HC users (injectables vs. oral pills)
 - Non-HC users (condoms, tubal ligation, IUCD)

DATA ANALYSIS PLAN

- Frequency distribution and percentages: baseline STI and BV diagnosis, demographic and behavioural characteristics of HC and non-HC users
- Time-dependent Cox proportional hazard regression models: assess the impact of contraceptive methods on risk of HIV- seroconversion.

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