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Hormonal Contraception and STI risk: HPTN 035 South Africa

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Background

- ❑ Globally 340 million new STIs each year
- ❑ Family Planning and Antenatal clinic attendees: 49-90% have at least 1 STI.
- ❑ Untreated STIs – PID, cervicitis, infertility, increased risk of HIV.
- ❑ Oral and injectable HC may increase risk of NG and CT
- ❑ Hypothesized mechanisms: increased cervical ectopy, mucosal changes- increased susceptibility to specific STIs
- ❑ In SA, 60% of women (15-49 years) use a method of HC.

HPTN 035

- HPTN 035 was a phase II/IIb, four arm, multi-site, randomized, controlled trial that tested the safety and effectiveness of two vaginal microbicides between Feb 2005-Aug 2008.
- HIV negative, sexually active, non-pregnant women, 18-35 were recruited.
- 5888 screened; 3101 enrolled at 8 sites globally
- 2 SA sites Chatsworth (urban) and Hlabisa (rural) enrolled 704 and 350 participants respectively.
- Contraception use was not a protocol requirement.
- Methods offered at site and local clinic: DMPA, Net-en, Nordette and Triphasil. Chatsworth (48% IC; 11%OCP) and Hlabisa (42% IC; 5% OCP).

Hypothesis

- Oral and injectable contraception use increases the risk of cervical STIs

Objectives

- Primary objective:
To determine the association of oral and injectable HC with the acquisition of cervical STIs NG and CT
- Secondary objective:
To determine the association of oral and injectable HC with the acquisition of vaginal STIs, syphilis, TV and HSV2

Methods & Plan of Analysis

- Baseline demographics
- Primary endpoints and analysis: Acquisition of NG and CT infection. Urine SDA for NG and CT done at annually, exit and when clinically indicated.
- Secondary endpoints and analysis: Acquisition of syphilis (annual, exit), TV (quarterly, annual) and HSV2 (enrollment and exit).
- Primary exposure : HC use (OCP and IC)
- Follow-up contraception and condom use : behavioral assessment data collected quarterly. Assumed that same method used in 3 months between visits.

Significance of Analysis

- ❑ Significant interest in determining the association of HC use and HIV. Less recent data looking at association of HC use on incident STIs.
- ❑ An association between HC use and STI acquisition – potential mechanism for increased risk of HIV acquisition
- ❑ High STI and HIV prevalence and widespread use of HC in KZN – public health importance.

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