

# Correlation between Co-Therapy of Efavirenz-Based ART and Pregnancy among HIV-Positive Women on Hormonal Contraceptive Implants at TASO Tororo-Uganda: A Retrospective Review

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## Abstract

**Background:** We examined the association between EFV and non-EFV based ART regimens and pregnancy outcomes among women who were on HCI in a peri-urban HIV clinic in Tororo, Uganda.

**Methods:** We reviewed and extracted routinely collected data from the TASO Tororo HIV clinic family planning register. All women >18 years of age and on ART who received HCI between January, 2012 and June, 2014 were included in the study.

**Results:** Of the 148 women reviewed 9 (6.1%) conceived. All women who conceived were on an EFV-based regimen, while none of the women on non-EFV based regimens conceived ( $p=0.0003$ ).

**Conclusion:** We observed a significant association ( $p=0.0003$ ) between HIV-positive HCI users on EFV-based ART regimens as compared to HIV-positive HCI users on non-EFV based ART regimens.

**Keywords:** Efavirenz; HIV; Pregnancy; Hormonal contraceptive implants

## Introduction

Hormonal implants is one of the very effective method of long acting but reversible family planning methods widely accessible in many sub-Saharan African(SSA) countries. It is estimated that up to 14% of women living with HIV in SSA use implants [1]. However, there are controversial findings about potential interactions between hormonal contraceptive implants (HCI) and antiretroviral therapy (ART) [2-4]. In Swaziland, 12.4% of women taking efavirenz (EFV)-based regimens while on levonorgestrel implant became pregnant, and EFV co-therapy were the only variable significantly correlated with pregnancy [1]. We examined the association between EFV and non-EFV based ART regimens and pregnancy outcomes among women who were on HCI in a peri-urban HIV clinic in Tororo, Uganda.

## Method

This study was conducted at The AIDS Support Organization (TASO Tororo branch) which cares for over 8000 HIV patients of whom, over 5000 are on ART. Using a retrospective observational study. We extracted family planning data from the Ministry of health family planning register at TASO Tororo HIV clinic. We included all women >18 years of age on ART who received HCI between January 2012 and June 2014. The primary outcome of interest was confirmed recorded pregnancy. The association between ART regimen and pregnancy outcome was assessed using fisher's exact statistics.

## Result

A total of 148 HCI users were identified, 62 (41.9%) on an EFV-based regimen and 86 (58.1%) on a non EFV-based regimen. The median age of the women was 34 years (IQR 22-48); mean weight was 58.0kgs (IQR 28-95); and median duration on ART was 22.7 months (IQR 17-37). Of the 148 women identified during the review period, 9 (6.1%) conceived and the median duration between HCI placement and confirmed pregnancy was 23 months (1QR 16-29). All women who

| Variables                 | EFV-based regimen | Non-EFV based regimen | P-value |
|---------------------------|-------------------|-----------------------|---------|
| Total                     | 62 (42%)          | 86 (58%)              | 0.734   |
| Age (years)               | 34 (IQR 22-48)    | 33.9 (22-46)          | 0.435   |
| Weight (Kilograms)        | 58 (IQR 28-95)    | 57.8 (29-94)          | 0.540   |
| Duration on ART ( months) | 33.3 (IQR 17-86)  | 30.3 (IQR 16-70)      | 0.889   |

Table 1: Characteristics of the study population.

conceived were on an EFV-based regimen, while none of the women on non-EFV based regimens conceived ( $p=0.0003$ ) (Table 1).

## Discussion

We observed a significant association ( $p=0.0003$ ) between HIV-positive HCI users on EFV-based ART regimens as compared to HIV-positive HCI users on non-EFV based ART regimens. This association is similar to findings in Uganda and Swaziland [1,2]. In Swaziland, a retrospective chart review found 15 (12.4%) pregnancies of the 121 patients on efavirenz based regimen compared to 208 women on nevirapine based regimen and 18 women on boosted protease inhibitor regimen [4]. Most of the pregnancies occurred on average 16 months after implants insertion suggesting a more rapid than expected decrease in levonorgestrel, which is expected to protect from pregnancy up to 5 years after insertion. In Uganda, one study showed that efavirenz

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Received February 15, 2018; Accepted February 21, 2018; Published February 28, 2018

**Citation:** Okoboi S, Eunice A, Oceng R, Etukoit B (2018) Correlation between Co-Therapy of Efavirenz-Based ART and Pregnancy among HIV-Positive Women on Hormonal Contraceptive Implants at TASO Tororo-Uganda: A Retrospective Review. J AIDS Clin Res 9: 759. doi: [10.4172/2155-6113.1000759](https://doi.org/10.4172/2155-6113.1000759)

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reduces blood level of levonorgestrel and resulting to a higher contraceptive failure rate among women on both efavirenz based regimen and implants [3]. This strengthens the evidence that women on EFV-based regimens desiring contraception may need to be cautioned about a potential increased risk of pregnancy with use of HCl.

## Conclusion

Our study adds evidence that HIV-positive HCl users on EFV-based ART regimens are at risk of unwanted pregnancy. A more systematic national surveillance of pregnancy among women on both ART and hormonal contraception may help to confirm a correlation and inform potential guidance on hormonal contraceptive use among women on ART in Sub Saharan Africa.

## Acknowledgement

This project has been supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through Centers for Disease Control and Prevention (CDC) under the terms of Cooperative Agreement number 1U2GGH000880-01.

## Ethical Approval

This review was approved by TASO Research Ethics committee.

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