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Session: **CS3**: Saturday May 2 – 15:00:17:00 – Antiretroviral Therapy and Resistence

Track:	Clinical Sciences
Subject:	Pharmacology, Pharmacokinetics and Pharmacoeconomics
Presentation Type:	Oral
Title of Abstract:	**Untimed Plasma Efavirenz Levels after Switching from Brand to Generic Formulations**
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Abstract

Background: In British Columbia, ARVs are distributed by the publicly-funded BC Centre for Excellence in HIV/AIDS Drug Treatment Program (DTP), using generic formulations when possible. A generic efavirenz-emtricitabine-tenofovir DF (EFV-FTC-TDF) combination pill became available in April 2018. To estimate bioequivalence of the generic product, we compared EFV untimed drug levels (UDL) in DTP participants switching from brand to generic EFV-FTC-TDF.

Methods: Archived plasma samples were identified for consenting DTP participants who switched to generic EFV-FTC-TDF. For each person, 3 pre-switch and 2-3 post-switch samples collected ≥1 month apart were selected. EFV dosing time was unknown (“untimed”) relative to plasma collection. EFV concentrations were determined using LC-MS/MS. Participants’ mean pre- and post-switch EFV levels were compared using the Wilcoxon signed-rank test. We also evaluated the number of participants with EFV levels in the range associated with decreased risks of virologic failure and central nervous system toxicity (1000-4000 ng/mL) before and after switch.

Results: EFV levels were measured in 261 pre-switch and 225 post-switch samples from 87 participants. Participants had a median 103 (Q1-Q3: 87-116) and 12.7 (Q1-Q3: 12-14) months of exposure to brand and generic EFV, respectively. The final brand sample was collected a median 97 (Q1-Q3: 78-109) days pre-switch, the first generic sample a median 123 (96-176) days post-switch. No significant differences were observed in participants’ mean EFV levels before (median 1968 ng/mL; Q1-Q3: 1534-2878 ng/mL) and after (median 1987 ng/mL; Q1-Q3: 1458-2800 ng/mL) switch (p=0.70). In total, 69 participants had mean EFV levels within the 1000-4000 ng/mL range while on brand drug, of which 65 (94%) remained within this range following switch.

Conclusion: No statistically significant differences in untimed EFV concentrations were observed in patients switching from brand to generic EFV combination pill. Given the long elimination half-life of EFV, UDL may be a convenient method to estimate bioequivalence