## High Prevalence and Long Duration of Nervous System and Psychiatric Adverse Drug Reactions in Ugandan Patients Taking Efavirenz 600mg Daily

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## Abstract.

Efavirenz-related nervous system or psychiatric adverse drug reactions (ADRs) are conventionally reported to resolve soon after initiation, with incidence of dizziness at 8.5% in large clinical trials. Patients of black ethnicity are genetically at greater risk of elevated efavirenz exposure, which has been linked to nervous systemtoxicity. Patients and methods: The current data derive from a prospective longitudinal observational study of adult HIV-positive outpatients taking current antiretrovirals, at three diverse clinics in central Uganda. As part of an interview about medicine use, patients were asked by trained pharmacy techniciansto detail current side effects and to rate their severity on a simple visual analogue scale (1–10). Details of thereported ADRs were verified by case note review. Severity and causality of ADRs were rated by the study teamusing validated tools. Results: A total of 300 patients taking efavirenz were analysed. Of these, 108(36%, 95% CI 30.6%–41.7%) were affected by persisting nervous system/psychiatric ADRs (median duration 22months). Dizziness affected 27.3 %(95% CI 22.4%-32.8%) of patients taking efavirenz. Severity of the ADRs was rated by patients at 5/10 in 76 (58.5%) cases. In 95 (86%) cases, there was no recordof the ADRs in the clinical notes. Strategies are needed to identify and prioritize patients urgently with persisting efavirenz neurotoxicity for a switch to newer regimens as they become available.

**Key Words:** High Prevalence, Long Duration, Nervous System, Psychiatric Adverse Drug Reactions, Ugandan Patients