BACKGROUND

• Nigeria is the most populous African country with an estimated population of 152 million. The HIV prevalence in Nigeria is approximately 3.6%, based on 2007 estimates.1

• The Harvard PEPFAR / AIDS Prevention Initiative in Nigeria (APIN) program currently provides HIV treatment and care services at 36 sites across 9 Nigerian states. For the purposes of this study, ART (ARV) is defined as ARV therapy provided by the APIN program's electronic prescription database.

• Eligibility for ART in the program is consistent with the APIN treatment guidelines: CD4 ≤ 200 cells/mm³ or CD4 < 350, if asymptomatic.

• Standard first-line ART for treatment-naive patients enrolled in the program includes a NRTI backbone of zidovudine (AZT) or lamivudine (TDF) plus lamivudine (TDF) plus lamivudine (TDF) plus lamivudine (TDF) plus lamivudine (TDF) plus lamivudine (TDF) plus lamivudine (TDF) plus lamivudine (TDF) plus lamivudine (TDF) plus lamivudine (TDF).

• Of the nearly 50,000 adult patients currently on 12 ARV in our program, 16 ARV is defined as patients enrolled in the program who started ART from January 2006 to December 2007 and are still ART-naive and who received TDF/3TC/NVP or AZT/3TC/NVP at enrollment.

METHODS

• This retrospective cohort study includes ARV-naive patients enrolled in the Harvard PEPFAR / APIN program who initiated ART with AZT/3TC/NVP or TDF/3TC/NVP between January 2006 and December 2007. Patients were followed until December 31, 2009. Differences in baseline characteristics between patients initiating ART with TDF/3TC/NVP or AZT/3TC/NVP were compared using t-tests for continuous variables and chi-square tests for categorical variables. Characteristics associated with virologic failure by univariate analysis were entered into a multiple logistic regression analysis to evaluate their association with virologic failure. Significant results from this analysis are presented.

• In this large retrospective cohort analysis of HIV-1–infected, treatment-naive patients, study-defined VF was 1.8 times more likely to occur in patients receiving TDF/3TC/NVP compared to AZT/3TC/NVP after adjustment for covariates. (Table 3)

• These results are inconsistent with large prospective studies that have evaluated these NRTI backbones with EFV-based therapy and found TDF/3TC to be superior to AZT/3TC. This finding suggests that there may be a negative pharmacokinetic or pharmacodynamic interaction between this NRTI backbone and EFV.

• In addition to first-line regimen, other independent predictors of VF in multivariate analysis include medication adherence < 95%, younger age, and indicators of HIV disease severity at baseline: CD4 ≤ 100 cells/µL and VL ≥ 100,000 copies/mL. (Table 3)

• The limitations associated with any retrospective analysis apply to our findings. Additionally, HIV-1 genotype results are not available to assess baseline and time of failure mutations. However, this is the largest population receiving TDF/3TC/NVP with virologic outcomes data described to date.

DISCUSSION

• Similar to other studies, medication adherence remains an important predictor of ART success, and HIV disease progression (indicated by lower CD4 and higher viral load) at ART initiation were negatively associated with antiretroviral success in our population.

• Given the large number of patients receiving this regimen in resource-limited settings, prospective evaluation of the effectiveness of TDF/3TC/NVP in clinical trials is urgently needed.