



Trend in Adult 1st Line Antiretroviral Therapy Regimen in Nigeria Antiretroviral Treatment Program: A 20-Months Retrospective Assessment (September-October 2018 to March-April 2020 Reporting Cycle)

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Abstract

Background: Nigeria Federal Ministry of Health (FMOH) in 2018 adopted World Health Organization (WHO) recommended Dolutegravir (DTG) based Antiretroviral Therapy (ART) regimen Tenofovir/Lamivudine/Dolutegravir (TDF+3TC+DTG) as the preferred 1st line ART for adult and adolescent patients and recommended Tenofovir/Lamivudine/Efavirenz (TDF+3TC+EFV) for women who want to become pregnant. The FMOH also approved gradual transition of eligible adult and adolescent patients from TDF+3TC+EFV and Zidovudine/Lamivudine/Nevirapine (AZT+3TC+NVP) to TDF+3TC+DTG from November 2018. The objective of this analysis was to evaluate the trend in adult 1st line ART regimen following twenty months of implementation of the transition to TDF+3TC+DTG.

Method: An analysis was conducted to review retrospective patients per regimen data from September/October 2018 to March/April 2020 reporting cycle. Data was retrieved from Nigeria Health Logistics Management Information System, exported to and analyzed with Microsoft Excel.

Results: 85.5% of the patients on adult 1st line regimen were taking TDF+3TC+DTG, 13.3% were on TDF+3TC+EFV, no patient was taking AZT+3TC+NVP while 1.1% was on Abacavir based regimen as of end of April 2020.

Conclusion: The evaluation shows that majority of adult and adolescent patients on 1st line ART have been transitioned to TDF+3TC+DTG in line with government recommendation.

Keywords: HIV/AIDS; Antiretroviral therapy; kidney disease; Dolutegravir; Abacavir; Tenofovir; National HIV/AIDS Indicator and Impact Survey

Introduction

Nigeria reported her first HIV/AIDS case in 1986 [1] and National HIV/AIDS Indicator and Impact Survey [2] put Nigeria's HIV/AIDS prevalence at 1.4% in 2018, with about 53,000 AIDS related deaths and over 1,30,000 new infections occurring in 2018 [2,3]. In absolute numbers, about 1.9 million people are living with HIV in Nigeria in 2018 [2,3]. Early in the evolution of HIV/AIDS epidemic in Nigeria, Anti-Retroviral Therapy (ART) was minimal and often initiated with single or dual agents [4]. In 1999 however, the national AIDS treatment program geared towards expanding access to antiretroviral drugs was instituted and was followed by rapid scale-up in the subsequent years [4]. Currently, nearly 61% of estimated 1.9 million persons requiring treatment in Nigeria are receiving highly active antiretroviral therapy [5] in accordance with WHO 2006 criteria for initiating ART [6]. This is a long way off meeting the global target of enrolling 90% of people diagnosed with HIV on Antiretroviral Treatment (ART) [7]. 96% of patients on treatment are adults while 4% are pediatrics [6]. About 93.3% of these adult patients are on first line regimen, 6.7% are on second line regimen while 0.02% are on third line regimen [6]. Nigeria aims to improve treatment coverage, ensuring that 90% of the population living with HIV are on treatment by 2021 [8].

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Received Date: 03 Jul 2020

Accepted Date: 21 Aug 2020

Published Date: 25 Aug 2020

Citation:

Urama B, Anonyuo N, Ibeme A, Atu U, Ologun T, Odelola B, et al. Trend in Adult 1st Line Antiretroviral Therapy Regimen in Nigeria Antiretroviral Treatment Program: A 20-Months Retrospective Assessment (September-October 2018 to March-April 2020 Reporting Cycle). *Am J Med Public Health*. 2020; 1(2): 1006.

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Table 1: Trend in Adult 1st line ART Regimen in Nigeria: Sept 2018 - April 2020.

Regimen	Oct-18	Dec-18	Feb-19	Apr-19	Jun-19	Aug-19	Oct-19	Dec-19	Feb-20	April-20
ABC+3TC+EFV	1.60%	1.10%	1.20%	1.10%	0.90%	1.00%	1.20%	0.70%	0.70%	0.70%
ABC+3TC+DTG	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.30%
TDF+3TC+EFV	66.60%	62.70%	59.00%	53.90%	48.90%	42.20%	26.80%	21.10%	17.40%	13.3m0%
TDF+3TC+DTG	1.00%	4.20%	13.00%	21.90%	36.50%	44.50%	68.40%	75.60%	79.80%	85.50%
AZT+3TC+ABC	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.10%
AZT+3TC+NVP	30.80%	32.00%	26.80%	23.10%	13.70%	12.30%	3.60%	2.60%	2.10%	0.00%

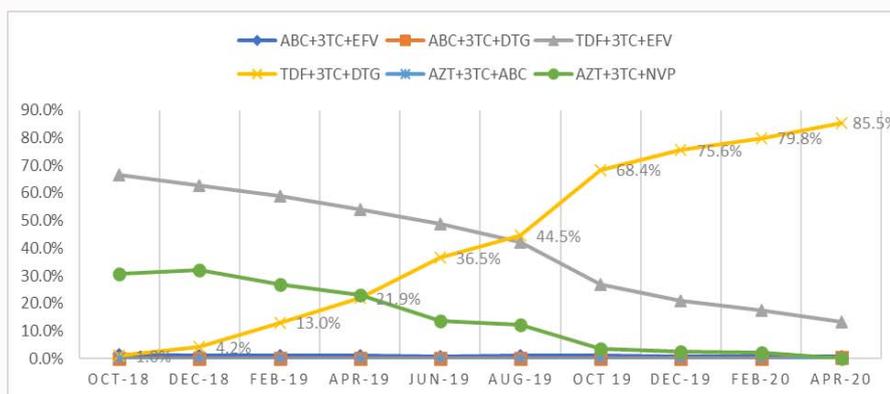


Figure 1: Trend in Adult 1st line ART Regimen in Nigeria: Sept 2018 to April 2020.

In 2018, the Federal Ministry of Health released a Rapid Advice providing updated recommendations for first line ART. The use of Tenofovir/Lamivudine/Dolutegravir (TDF+3TC+DTG) as the preferred 1st line ART for adults and adolescents and Tenofovir/Lamivudine/Efavirenz (TDF+3TC+EFV) as the recommended regimen for women who want to become pregnant were the key changes for adult ART in the Rapid Advice document (FMOH, 2018). The National HIV/AIDS Program also approved gradual transition of eligible adult and adolescent patients from Tenofovir/Lamivudine/Efavirenz (TDF+3TC+EFV) and Zidovudine/Lamivudine/ Nevirapine (AZT+3TC+NVP) to Tenofovir/Lamivudine/ Dolutegravir (TDF+3TC+DTG) from November 2018.

Prior to the issuance of Rapid Advice document by Federal Ministry of Health in 2018, Tenofovir/Lamivudine/Efavirenz (TDF+3TC+EFV) was the preferred 1st line ART regimen for adults and adolescents in Nigeria while Zidovudine/Lamivudine/ Nevirapine (AZT+3TC+NVP), abacavir/lamivudine+(efavirenz or dolutegravir) ABC+3TC+(EFV or DTG) and other regimens were used as alternative options [9]. Abacavir based regimen ABC+3TC+(EFV or DTG) were used mainly by patients with renal impairment since tenofovir based regimen is associated with higher risk of kidney disease [10].

This evaluation is aimed to assess the trend in adult 1st line ART regimen in Nigeria Antiretroviral Treatment Program following twenty months of implementation of the Rapid Advice recommendations.

Methodology

Data source

In this retrospective longitudinal study, the Nigeria Health Logistics Management Information System database (NHLMIS) was accessed to categorize patients per regimen data from September/

October 2018 to March/April 2020 reporting cycle. The National Health Logistics Management Information System (NHLMIS) is Nigeria’s first full-service web portal created to allow full end to end visibility into the country’s stock situation and enable stakeholders analyze critical data trends that help support key inventory decision-making process (UNFPA, 2018). Health facilities implementing public health programs such as HIV, Malaria and Family Planning submit bimonthly Logistics Management Information System (LMIS) reports to Federal Ministry of Health through the NHLMIS with the State Logistics Management Coordination Unit (LMCU) as the intermediary. It is mandatory for health facilities providing ART services and desirous to be resupplied HIV commodities to submit bimonthly LMIS within the timeline approved by Federal Ministry of Health.

The NHLMIS database can be accessed after obtaining approval from the USAID Global Health Supply Chain Program- Procurement and Supply Management (GHSC-PSM) project, the partner providing technical assistance to the National Product Supply Chain Management Program (NPSCMP) of the Federal Ministry of Health in managing the NHLMIS.

HIV LMIS data for the respective periods under consideration was downloaded from the NHLMIS exported to and analyzed using MS Excel.

Main descriptive variable

Antiretroviral Therapy (ART) was the main descriptive variable in this evaluation. People Living with HIV (PLHIV) who received ART were defined as those receiving a combination of three or more antiretroviral drugs.

Result

In total, dataset for 10 reporting cycles were analyzed to evaluate regimen trend within the twenty months period. As summarized in

Table 1 and Figure 1 below, the vast majority (85.5%) of the patients on adult first line regimen were taking TDF+3TC+DTG, while small number (13.3%) of the patients were on TDF+3TC+EFV as of April 2020. No patient was taking AZT+3TC+NVP.

Discussion

Once initiated on treatment, a PLHIV is expected to remain on initial ART regimen for a long duration because frequent change in regimens will lead to narrowing available treatment options [11]. Before Nigeria adopted WHO recommendations for the use of Dolutegravir as the preferred first-line regimen in 2018, majority of adult first line patients in Nigeria (66.6%) were using TDF+3TC+EFV followed by those who were on AZT+3TC+NVP (FMOH, 2020). The evaluation compared trend in adult first line ARV regime: ABC+3TC+EFV, ABC+3TC+DTG, TDF+3TC+EFV, TDF+3TC+DTG, AZT+3TC+ABC and AZT+3TC+NVP twenty months following government approval for eligible patients on AZT+3TC+NVP and TDF+3TC+EFV to be transitioned to TDF+3TC+DTG. The assessment predicted that TDF+3TC+DTG will be the dominant regimen after one year of transition implementation and will increase higher compared to most widely used adult first line regimen before transition commencement.

The finding is consistent with the prediction as the data showed that proportion of adult first line patients on TDF+3TC+DTG started off with 1% in October 2018 and increased to about 86% in April 2020. The proportion of adult first line patients on TDF+3TC+EFV decreased from about 67% in October 2018 to 13.3% in April 2020. This represents 80.03% transition of patients from TDF+3TC+EFV to TDF+3TC+DTG. Proportion of adult first line patients on AZT+3TC+NVP decreased from almost 31% in October 2018 to 0% in April 2020, representing 100% transition of patients from AZT+3TC+NVP to TDF+3TC+DTG. The proportion of patients on Abacavir based regimen ABC+3TC+ (EFV or DTG) hovered around 1% through the periods but never exceeded 1.6% at any point. This is expected as the regimen is mainly for patients with renal impairment.

The rate of transition from TDF+3TC+EFV and AZT+3TC+NVP to TDF+3TC+DTG was slower in the early stage of the transition process (October 2018 to February 2019) and gradually increased around the mid-period (April to August 2019) and spiked from October 2019.

The finding also aligned with several studies which have concluded that DTG-based regimens are dominant compared to Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) based ART regimen such as TDF+3TC+EFV or AZT+3TC+NVP in multiple countries and settings [12].

Conclusion

In conclusion, all patients on AZT+3TC+NVP and majority of patients on TDF+3TC+EFV (80.03%) have been transitioned to TDF+3TC+DTG in line with government decision. TDF+3TC+DTG

is now the predominant regimen among PLHIV on adult first line regimen in Nigeria which consist majority of PLHIV on treatment (93.3%). This is in line with government position on the use of first line ARVs as a public-health approach to improve access to Antiretroviral Therapy (ART). With the net public health benefits associated with WHO recommendation in 2019 on the use of TDF+3TC+DTG in all population, it is expected that at least 98% of people receiving ART in Nigeria before end of 2020 would be on TDF+3TC+DTG. This is considering that PLHIV using ABC+3TC+ (EFV or DTG) constitute less than 2% of entire adult first line ART population. Andrew et al in 2019 reported that the benefit of transition to TDF+3TC+DTG is high from a public health perspective because of its high potency and barriers to resistance, good tolerability, and low cost. Regardless of the projected benefits, caution against prolonged exposure to tenofovir is required to forestall health risks association with tenofovir.

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