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Assessment of Viral Suppression among HIV Seropositive Adults on Dolutegravir-Based Regimen in Federal Medical Centre Owerri, Nigeria

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Abstract— *Introduction:* In Nigeria, the majority of patients on antiretroviral therapy are on dolutegravir-based regimens which are the result of the massive transition of patients from non-dolutegravir-based regimens to dolutegravir-based regimens. This study assessed the effectiveness of dolutegravir-based regimens in suppressing viral load in HIV seropositive adults in comparison to non-dolutegravir-based regimens.
Methods: A retrospective cohort study design was used to assess the viral loads of 385 patients accessing HIV care and treatment at Federal Medical Centre Owerri. Subjects were selected using a simple random sampling method. Data was analysed using IBM-SPSS statistics version 25, statistical charts were drawn on Microsoft Excel 16. Descriptive statistician technique (Frequency distribution) was also used. T distribution test technique for paired samples and descriptive technique were used accordingly.
Results: The result of the study shows that 96.4% of patients on dolutegravir-based regimens have a viral load of less than1000 copies/ml as against 70.4% when these patients were on dolutegravir-based regimens. Participants with poor adherence, which is less than 95%, recorded a lower suppression rate (83.6%) than those with good adherence which recorded 99.1% suppression. Similarly, the viral load suppression rate was higher among the patients without disease co-morbidity (98.9%) compared to the co-morbidity group (89.2%).
Conclusion: The study shows that 96.4% of adults accessing HIV treatment at FMC Owerri and on first-line regimens are virally suppressed.

Keywords *— HIV/AIDS; Viral Load Suppression; Dolutegravir-based Regimen; Federal Medical Centre Owerri; Nigeria..*

1. Introduction

The pandemic of the human immunodeficiency virus and acquired immune deficiency syndrome (HIV/AIDS) continues to endanger the lives of many people worldwide, especially in Nigeria. Nigeria has made considerable strides toward improving access to HIV treatment since adopting a test and treat policy in 2016. This action has hastened the process of sending those who test positive for the virus to treatment centers. Nigeria had an almost threefold increase in the number of HIV-positive individuals receiving antiretroviral medication between 2010 and 2017, going from 360 000 in 2010 to more than 1 million in 2018(NAIIS, 2018). According to the 2018 Nigeria HIV/AIDS Indicator and Impact Survey (NAIIS) report, more than half of HIV-positive individuals on ART still do not have suppressed viral levels. (NAIIS, 2018).

People who receive an early diagnosis of human immunodeficiency virus (HIV) infection and start antiretroviral medication (ART) promptly with high adherence to therapy might enjoy decades of good health and a life expectancy comparable to that of HIV-negative individuals (WHO, 2018). The risk of an individual transmitting HIV to their sexual or injecting partners is zero if they have attained an undetectable viral load (viral load less than 50 copies/ml). (UNAIDS, 2018). Suppression of viral load is advantageous for both personal and societal health. In addition to preventing ill health and AIDS-related death for the person, HIV therapy and viral suppression also help to improve public health by lowering new infections and HIV incidence (NASCP, 2020). Antiretroviral medications have been used to lower morbidity and death among HIV/AIDS patients for almost 20 years. In Nigeria as well as the rest of the world, HIV/AIDS management has steadily improved. Antiretroviral therapy, which was first launched in 1996 but has since been improved upon with the availability of five different classes of antiretroviral drugs, is responsible for this improvement (WHO, 2015). The need to ensure that all patients taking HIV medications are virally suppressed is so important that collective effort is required to achieve this goal.

The most recent antiretroviral to receive FDA approval is dolutegravir, a second-generation HIV Integrase strand transfer inhibitor (NSTI), which has impressive antiviral efficacy when compared to other first-line regimens suggested by the United States Department of Health and

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Human Services HIV treatment guidelines for adults and adolescents. The potential for viral suppression was increased with the development of dolutegravir (WHO, 2016). In 2019, the WHO recommended the use of dolutegravir as the preferred first line and second line for all populations (WHO, 2019). Achieving viral suppression is important not only to ensure that people living with HIV leave a healthy life but also to halt the further spread of the virus among the general population. This is even more important as the 2018 Nigeria HIV/AIDS Indicator and Impact Survey (NAIIS) puts the national prevalence rate of HIV in Nigeria at 1.4% for individuals aged between 15-64years which is a decline from the previous 3.1%, but the prevalence rate in Imo state stands at 1.8% which is higher than the national prevalence rate (NAIIS, 2018). The 2018 NAIIS report put the prevalence rate of HIV in Imo State at 1.8% which is quite a significant percentage of the population. Based on the report, 58,000 people in Imo state are living with HIV but not all of these are currently on treatment. The high prevalence of HIV in the state comes with an economic loss which is in part due to the morbidity and mortality associated with HIV/AIDS.

HIV-affected households in Nigeria face serious economic challenges compared with their HIV-negative counterparts. While progress has been made in this aspect, there is however the need to assess the level of viral suppression, especially in the face of the Multi-Month-Dispensing (MMD) and with most patients on a dolutegravir-based regimen, to see how far the regimen helped in achieving viral suppression and more importantly how it can affect the UNAIDS 2030 3rd target of ensuring that 95% of patients on ART achieve viral suppression by the year 2030.

2. Objectives of the Study

a. General Objective: To assess viral suppression among HIV seropositive adults on dolutegravir-based regimen in Federal Medical Centre Owerri Nigeria.
b. Specific Objectives:
   - To assess the level of viral suppression among HIV seropositive adults on dolutegravir- based regimen in FMC Owerri after at least 6 months on therapy.
   - To compare the level of HIV suppression for adults on a dolutegravir-based regimen with when on a non-dolutegravir-based regimen
   - To assess factors associated with viral suppression

3. Hypothesis

a. There is an association between dolutegravir-based regimen and HIV viral suppression.
b. There is no association between dolutegravir-based regimen and HIV viral suppression.

4. Materials and Methods

4.1 Study Design

A retrospective study design was used for this study.

3.2 Study Population

The study population comprised all HIV seropositive patients on Antiretroviral Therapy at Federal Medical Centre Owerri who are still active in care. The inclusion criteria included.

- Confirmed HIV-positive patients enrolled for care at Federal Medical Centre (FMC) Owerri.
- Patients who were 18 years and above.
- Patients who were previously on a non-dolutegravir-based regimen before the transition to a dolutegravir-based regimen.
- Patients who have been on a dolutegravir-based regimen for at least 6 months.

3.3 Study Area

Imo State is one of the 36 States in Nigeria, located in the South-East region of the Country. Formed in 1976 when it split from the former East-Central State. Imo State is bordered by Abia State on the East, Delta State to the West, Anambra State on the North, and Rivers State to the South. Owerri is the capital of the State. The State lies within latitudes 4°45'N and 7°15'N, and longitude 6°50'E and 7°25'E with an area of around 5,100 sq km. The State has over 4.8 million people, and the population density varies from 230 to 1,400 people per square kilometer. Federal Medical Centre Owerri is a tertiary health facility located in the city of Owerri, the capital of Imo State. The facility is one of the many health facilities in the state that offers quality HIV/AIDS services in the state and has over 2,600 HIV patients receiving HIV care and treatment. The health facility is in Owerri municipal local government which is one of the 27 local government areas in the state. The federal medical center is a PEPFAR-supported site where patients' viral load tests are done without patients' financial contribution and results are returned to the health facility.

3.4 Sample Size Calculation

The sample size was determined using Andrew Fisher`s formula:

$$n = \frac{(Z-score)^2 x\ Standard\ Deviation\ x(1-Standard\ Deviation)}{(Confidence\ Interval)^2}$$

Where, n = sample size
Z = Z-score @ 95%) =1.96
SD = Standard Deviation =0.5
Confidence Interval (Margin of safety) 95%

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$$\frac{1.96^2 X\ 0.5\ X(1-0.5)}{0.05^2} \quad \frac{3.8416\ X\ 0.5\ X\ 0.5}{0.0025} \quad \frac{0.9604}{0.0025}$$

n =385

3.5 Sampling Procedure

A simple random sampling method was used to select participants for the study. Data were collected at the Heart-to-Heart Centre at the Federal Medical Centre Owerri where patient folders were sorted based on predetermined inclusion criteria. Patient folders who meet the study criteria were put in a sample frame and 385 participants were selected from about 3000 patients on care and treatment at the tertiary facility.

3.5 Ethical Approval

Ethical approval was secured from the Health Research Ethics Committee of Federal Medical Centre Owerri granting permission for the research to be conducted at the hospital. A copy of the clearance was submitted to the office of the HIV Project Coordinator, FMC Owerri.

4. Data Collection

A structured Microsoft Excel checklist was used for data collection. The checklist was divided into sections to extract the required data. The checklist was validated by the Project Coordinator, heart-to-heart center, FMC Owerri. Five trained research assistants used the validated checklist to collect the required data from the medical records of the selected study participants. The required data were collected between Jan 2022 to July 2022.

4.1 Data Analysis

Data were analysed using the statistical package for service solution (SPSS) version 25, statistical charts were drawn on Microsoft Excel 16. Part of the analysis was performed using, descriptive statistician techniques such as the construction of frequency distributions, which was expressed as the percentage of the distribution. The analysis for the differences in viral load between the two regimens was performed through the T-distribution test technique for paired samples, while the adherence for the regimen was assessed via descriptive technique, The Chi-square test was used to test for association between the viral load and some other selected variables of interest. All statistical tests were performed at a 5% level of significance. The probability value (P) was used to interpret significant associations between variables. Hence $P< 0.05$ was considered significant.

5. Results

Table 1 shows the Characteristics of the Study Subjects A total of 385 HIV seropositive adults were studied and the characteristics of the study subjects are contained in Table 1. The average age of the patients is 44.3 years, with a corresponding standard deviation of 11.8 years. Close to one-third of the patients (126: 32.7%) were between 31 – 40 years of age, 41 (10.6%) were below 31 years of age and 93 (24.2%) were of age 41-50 years. Those above 60 years of age were in all 44 (11.4%). The males among the patients were 159 (41.3%) while the females were 226 (58.7%). Close to sixty percent (228: 59.2%) were married, 110 (28.6%) were singles and the remaining 47 (12.2%) were widows or widowers. The majority of them 297 (77.4%) had Tenofovir/Lamivudine/Efavirenz (TLE) as their last regimen, while the current regimen indicates that the overwhelming majority were on TLD (361: 93.8%). In terms of multi months dispensing for the regimen, 264 (68.6%) were on 6 months MMD.

Table 1: Socio-demographic profile of the study subjects

Characteristics	Frequency (n = 385)	Percent (%)
Age in years (mean: 42.3, std dev: 11.8)		
less than 31	41	10.6
31 – 40	126	32.7
41 – 50	93	24.2
51 – 60	81	21.0
61+	44	11.4
Sex		
Male	159	41.3
Female	226	58.7
Marital Status		
Married	228	59.2
Single	110	28.6
widow / widower	47	12.2
Last regimen b4 DTG-based		
ABC/3TC/EFV	26	6.8
AZT/3TC/EFV	2	.5
AZT/3TC/NVP	63	16.4
TLE	294	76.4
Current regimen		
ABC/3TC/DTG	22	5.7
AZT/3TC/DTG	2	0.5
TLD	361	93.8
Multi Months Dispensing (MMD)		
MMD 3	46	11.9
MMD 4	30	7.8
MMD 5	45	11.7
MMD 6	264	68.6

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The level of viral load suppression among HIV seropositive adults in the study area is presented in Table 2. The table clearly shows that clear majority of the subjects on a dolutegravir-based regimen (DTG), recorded a viral load (VL) of less than 1000 copies/ml (309: 80.3%). A total of 62 (16.1%) were undetected (VL < 50), while 14 (3.6%) showed a viral load of up to 1000 and above. However, for the non- dolutegravir-based regimen (last viral load before the switch to DTG), 271 (70.4%) have suppressed viral load of less than 1000 copies/ml, while a total of 114 (29.6%) recorded a viral load of more than 1000 copies/ml. None of the viral loads were less than 50 copies/ml (undetected).

Table 2: Level of Suppression among HIV seropositive adults Studied

VL classifications	VL before switch (Regimen: Non DTG b2)		Current Viral Load (Regimen: DTG b3)	
	Frequency	Percent (%)	Frequency	Percent (%)
< 50	-	-	62	16.1
Less than 1000	271	70.4	309	80.3
1000+	114	29.6	14	3.6
Total	385	100.0	385	100.0

Figure 1 shows the line relationship plot in viral load suppression between the two regimens (dolutegravir-based and non-dolutegravir-based). The plot indicates that the viral load was very much lowered at the use of DTG, compared to the level before the switch to DTG. It also shows that the chat was relatively stable among the DTG regimen on the subjects against the fluctuating patterns of viral load observed among the patients before the switch. The very high viral load of 56,000, got suppressed to 2091 at the switch to DTG.

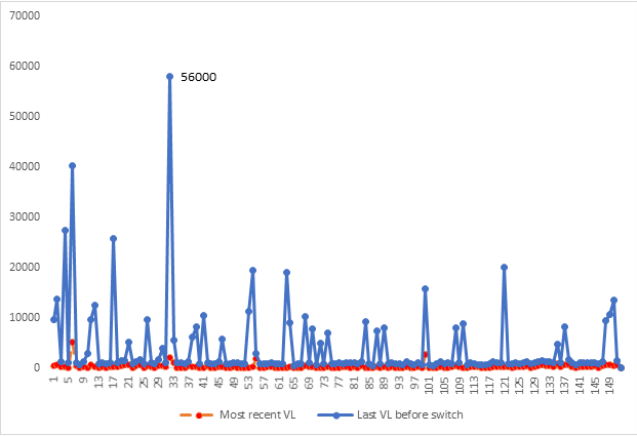

Fig.1: Viral Load Suppression Based on the dolutegravir (DTG)-based regimen, and non-dolutegravir-based regimen (Non-DTG) among HIV seropositive adults Studied

The level of viral load suppression before and after the switch to DTG-based regimen is presented in Table 3. At non-dolutegravir-based regimen, the largest viral load recorded among the subjects was 56000 copies/ml (lowest: 389 copies/ml), which reduced to 5230 copies/ml (lowest: 16 copies/ml) at the current regimen (DTG-based). Also, the mean viral load was much lower at the DTG-based regimen (341± 555) compared to the value at the non-DTG-based regimen- before the switch (3777±7319). The statistical test shows that at a 5% significant level, significant differences were evidently found in the mean viral load suppression between the two regimens, with greater suppression found in the subjects at the DTG-based current regimen. The probability value *P* is by far less than 5% while the 95% confidence interval (95% CI) did not contain zero ($P< 0.0001$, t=0.597, 95% CI = 2732 – 4139). Both clearly justified the evidence of a significant difference in the data.

Table 3: Summary Statistics and Test Comparison between DTG based regimen and Non-DTG based regimen on HIV patients studied

Regimen	Mean	Std. Dev	Std. Err	Min	Max	t	*P*	95% CI	
								Lower	Upper
Non-DTG based	3777	7319	373	389	56000				
DTG based	341	555	28	16	5230				
Difference	3436	7024	358			9.597	< 0.0001	2732	4139

Std. dev: Standard deviations, Std. err: Standard error, Min: Minimum value, Max: maximum value, t: T-test value, P: Probability value, 95% CI: 95% confidence interval.

Figure 2 is a pie graph representation of the adherence status for the DTG regimen among the subjects studied. The figure clearly shows that the level of adherence was quite reasonable. Of the 385 HIV adults studied, 318 (82.6%) adhered to the treatment regimen while 67 (17.4%) did not adhere.

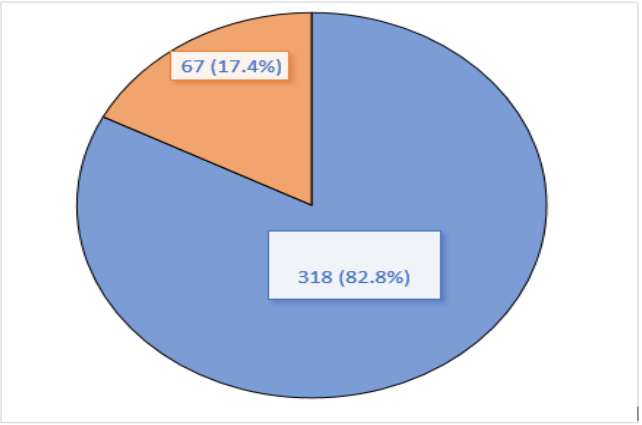

Fig. 2: Adherence Status

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The association between viral load suppression and other selected variables of interest among the adult HIV patients studied is presented in Table 4. Significant associating variables found in this study include marital status (P=0.007, X^2 = 9.816, df =2), adherence status (P < 0.0001), co-morbidity (P < 0.0001), opportunistic infections and (P < 0.0001) and Tuberculosis Preventive Therapy (P < 0.0001). All the single subjects recorded suppressed viral load. Viral load suppression was higher among the subjects that adhered to the regimen (99.1%) compared to the level among patients that did not adhere. Similarly, the viral load suppression rate was higher among the patients without the disease co-morbidity (98.9%) compared to the co-morbidity group (89.2%). All the patients with no opportunistic infections recorded viral load suppression as well as all the patients on tuberculosis preventive therapy. Both age and sex were not found significant (P>5%), but viral load suppression recorded complete success (100%) among the under 31 years of age, while the rate between the males and the females did not vary significantly (male: 96.2%, female: 965%).

Table 4: Association between viral load suppression and Selected Variables among the adult HIV Patients Studied

Variable		**Suppressed (VL< 1000)**		**Unsuppressed (VL≥ 1000)**			
	Total	**Freq**	**%**	**Freq**	**%**	**X^2 (df)**	***P***
Age in years							
Less than 31	41	41	100	0	0.0		
31 – 40	126	121	96.0	5	4.0		
41 – 50	93	90	96.8	3	3.2		
51 – 60	81	78	96.3	3	3.7		
61+	44	41	93.2	3	6.8		
Total	385	371	96.4	14	3.6	4.142 (4)	0.387[L]
Sex							
Male	159	153	96.2	6	3.8		
Female	226	218	96.5	8	3.5		
Total	385	371	96.4	14	3.6	0.015 (1)	0.904
Marital Status							
Married	228	217	95.2	11	4.8		
Single	110	110	100	0	0.0		
Widow/ widower	47	44	93.6	3	6.4		
Total	385	371	96.4	14	3.6	9.816 (2)	0.007[L]
Adherence Status							
Adhered (95+)	318	315	99.1	3	0.9		
Non-adhered (<95)	67	56	83.6	11	16.4		
Total	385	371	96.4	14	3.6		<0.001[F]
Co-morbidity							
Yes	102	91	89.2	11	10.8		
No	283	280	98.9	3	1.1		
Total	385	371	96.4	14	3.6		<0.001[F]
OIs (candidiasis, Pneumonia, TB)							
Yes	103	89	86.4	14	13.6		
No	282	282	100	0	0.0		
Total	385	371	96.4	14	3.6		<0.001[F]
TPT							
Yes	93	79	84.9	14	15.1		
No	292	292	100	0	0.0		
Total	385	371	96.4	14	3.6		<0.001[F]

P: probability value, X^2: Chi-square value, df: degree of freedom, F: Fishers Exact Test, L: likelihood ratio Test

6. Discussion

The study showed the very strong ability of dolutegravir-based regimens in suppressing HIV viral load as 80.3% of those on the regimen were suppressed after at least 6 months on the regimen with another 16.1% having an undetectable viral load which is less than 50copies/ml based on WHO definition. Only 3.1% of patients had a viral load greater than 1000 copies/ml (unsuppressed) after at least 6 months of therapy. However, only 70.4% of these patients were virally suppressed while on non-dolutegravir-based regimens while 29.6% were unsuppressed with a viral load of more than 1000 copies/ml. interestingly, none of the patients on non-dolutegravir-based patients had a viral load of less than 50 copies/ml. This result is consistent with a WHO report which indicates that DTG suppresses viral load faster than Efavirenz (WHO, 2018). Also, the result aligns with a similar study conducted in General Hospital Minna, Nigeria which shows the level of viral suppression at 95.2% for patients on dolutegravir-based regimens after at least 6 months of therapy as compared to 72.3% suppression rate for those on Efavirenz or Zidovudine combination (Bisallah *et al.*, 2020).

Another study was conducted in a hospital in Ireland that assessed the effect of Dolutegravir on HIV treatment-

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naive clients and found that 88.57% of the patients were virally suppressed after 48 weeks of treatment. While different studies have shown the efficacy of dolutegravir-based regimens in suppressing viral load, however, the rate of viral suppression in this study is 96.4% which is within the UNAIDS 2030 target which requires 95% of those on ART to be suppressed by 2030. With the 2018 Nigeria HIV/AIDS Indicator and Impact Survey (NAIIS) reported that more than half of people living with HIV and on ART do not have suppressed viral load (NAIIS, 2018), the result of this study is clearly an improvement as there is a very significant improvement which speaks to all the efforts of stakeholders in ensuring better treatment outcomes for people on ART. Also from the study, most of the clients (77.4%) were on the regimen Tenofovir/ Lamivudine/ Efavirenz before being switched to dolutegravir-based regimens following a WHO policy to transition first-line patients to dolutegravir-based regimens (WHO, 2018). For variables associated with viral suppression, the study also found that 82.6% of the subjects adhered to their regimen which is adherence greater than 95% while 17.4% did not adhere. The highest level of viral suppression in both groups was recorded for subjects that adhered to their regimen (99.1%).

This simply shows the place of adherence to treatment regimen as an important part of HIV care and treatment, thus the reason adherence counseling and subsequently optimization is an essential part of the treatment schedule. A study that was conducted in a hospital in Ethiopia on viral load suppression in HIV seropositive patients after Enhanced Adherence Counseling showed a 66.4% suppression rate after a median adherence time of 13 weeks(IQR 8-25 weeks) (Dires *et al*., 2020). Good adherence is a precursor for viral suppression and better treatment outcome in general. It was also found that viral suppression was much higher in participants without disease co-morbidity. While 98.9% of non-co-morbid subjects were suppressed, only 89.2% of those with co-morbidity were suppressed. Hypertension, diabetes mellitus and Hyperlipidemia were the key co-morbid conditions found in this study. While this study did not investigate the effect of any possible drug-drug interaction for co-morbid participants, some adverse drug interactions are known to exist with some causing decreased absorption while others increasing metabolism with both situations affecting treatment outcomes if not properly addressed. The higher suppression rate found in the group without co-morbidity also gives further credence to this position. Participants who were not on opportunistic infections (OIs) medications like Cotrimoxazole, Fluconazole & Metronidazole recorded 100% suppression as compared to 86.4% of those on OIs medications who were suppressed.

A similar trend was also recorded for Tuberculosis Preventive Therapy as 100% of those who were not currently on TPT medication were suppressed while 84.9% of those on TPT medication were suppressed. Both age and sex were not found significant (P>5%), but viral load suppression recorded complete success (100%) among the under 31 years of age, while the rate between the males and the females did not vary significantly (male: 96.2%, female: 96.5%). All the subjects were on a multi-month schedule which is refilled between 3-6 months of therapy. While 68.6% of the subjects were on multi-month dispensing (MMD) 6, 11.7%, 7.8% & 11.9% were on MMD5, MMD4, and MMD3 respectively. The result of this study shows a very high rate of viral suppression for patients in Federal Medical Centre Owerri with 96.4% having viral load lower than 1000 copies/ml, therefore suppressed. Following the passing of the year 2020 which was the deadline given by the Joint United Nations to achieve the 3rd 90 of the 90-90-90 target which is to have 90% of those on therapy to be suppressed by 2020 and 95% to be suppressed by 2030.

It is clear from this study that patients on therapy at the Federal Medical Centre Owerri on dolutegravir-based regimen are already on track because while the target is to have 95% of all patients on medication suppressed by 2030, as of January 2023, 96.4% of dolutegravir-based regimen are already cumulatively suppressed, cumulative because this includes the 16.1% with an undetectable level of viral load. The result of this study has strengthened the position of maintaining all HIV-positive patients on Antiretrovirals ensuring that adherence is maintained at 95% or higher. The fear of an MMD schedule that could lead to treatment failure occasioned by poor adherence has been shown in this study and it has no impact on the rate of viral suppression. The study showed a very strong association between dolutegravir-based regimen and viral suppression in HIV seropositive adults.

7. Conclusion

The result of this research shows the efficacy of dolutegravir-based regimens in suppressing viral load in HIV seropositive adults. 96.4% of participants on dolutegravir-based regimens were virally suppressed after at least 6 months of therapy as against 70.2% of viral suppression recorded while they were on Efavirenz or Nevirapine-based regimen. This study also highlighted the importance of good adherence to achieving viral suppression and preventing treatment failure as the rate of suppression in this study was far higher in patients with good adherence than those with less than 95% adherence.

The study also concludes that the 2020 UNAIDS target of ensuring that 90% of patients on ART were suppressed was achieved. Furthermore, the study also shows the progress that has been made towards achieving the 3rd target of UNAIDS 2030 which stipulates that 95% of all patients on Antiretroviral Therapy should be suppressed by

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2030. From the result of this study which shows that 96.4% of adult patients on dolutegravir-based are suppressed, the choice of dolutegravir as the preferred first- and second-line regimen is a right one and would accelerate the achievement of the UNAIDS 2030 target as well the achievement of epidemic control of AIDS. It will also help to improve the general wellbeing of people living with HIV/AIDS and the mobility and mortality associated with the disease. The economic fortunes of families will also be improved as suppressed patients will be able to undertake their usual tasks and minimize hospital visits. The improved suppression rate will also help reduce the transmission rate in the State due to the high level of suppression among patients on ART which some having viral loads as low as 50copies/ml which is tagged undetectable level by UNAIDS(UNAIDS, 2018). This study will contribute to the body of knowledge that already exists in HIV care and treatment and provide a platform upon which future studies can be conducted to improve HIV care and treatment in Imo State and Nigeria in general.

This study is limited to adult HIV seropositive patients on first-line therapy only at Federal Medical Centre Owerri. Patients on the second line and third lines were not assessed including the paediatric population, hence the need for further assessment to obtain a broader view of the level of viral suppression.

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