

Research Article



Assessment of Nigerian Tertiary Healthcare Institutions' Compliance to Prevention of Mother-to-Child Transmission Treatment Guidelines: A Ten-Year Retrospective Study of US Presidents' Emergency Plan for AIDS Relief (PEPFAR)-AIDS Prevention Initiative in Nigeria (APIN) Clinics

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ABSTRACT

This study was conducted to compare the PMTCT practices in some Nigerian tertiary health institutions to PMTCT guidelines. A multi-site retrospective design was used in this study to collate data from Ahmadu Bello University Teaching Hospital (ABUTH), Jos University Teaching Hospital (JUTH), University of Maiduguri Teaching Hospital (UMTH), and University College Hospital (UCH). Appropriate descriptive and inferential statistics were conducted. Data from the same number of mothers and infants (5378) were retrieved for the compliance audit. The ARVs used for PMTCT were not documented in 3590(66.75%) mothers. ARV prophylaxis was administered to 4829(89.79%) infants. Polymerase Chain Reaction test was conducted for 4516(83.97%) infants, while Rapid test was conducted for 1677(31.18%). UCH had a total compliance of 69.55%, while UMTH had 0.00%. The group mean was 41.14(16.48); $F(3,0)=0.00$, $p \leq 0.0001$. The compliance of Nigerian tertiary hospitals to PMTCT treatment guidelines was determined to be fair.

Keywords: Compliance, Nigeria, Prevention of Mother-to-Child Transmission, Treatment Guidelines, PEPFAR-APIN.

INTRODUCTION

Prevention of mother-to-child transmission (PMTCT) is a HIV prevention strategy that is provided to a HIV-positive woman with the ultimate purpose of giving birth to HIV-free children. In the strategy, the risk of mother-to-child transmission (MTCT) of HIV is reduced through well-designed programmes¹ that involve the use of drugs and non-drugs related services. The non-pharmacological aspects of the programmes are primary prevention of HIV infection, prevention of unintended pregnancies among women infected with HIV, and prevention of HIV transmission from women infected with HIV to their infants. The pharmacological component involves the provision of treatment, care, and support to pregnant women who are infected with HIV, their children, as well as their families^{1, 2}. Parts of these programmes also include support for safe childbirth practices, appropriate infant feeding, provision of exposed infants with virological testing after birth and during breastfeeding, and use of ART for prevention and treatment. This drug component primarily has to do with the provision of ARVs for the mothers at any point of the pregnancy, delivery and breastfeeding, and a short course of ARVs for their babies. In 2010, the WHO revised its PMTCT guideline by introducing two critical approaches geared towards enhancing the uptake and outcomes of PMTCT. The approaches include the lifelong provision of ART for all HIV-infected women in need of treatment for their benefit. In such a therapy, the drugs should be safe and effective in reducing MTCT. The approaches also include the provision of a short-term ARV prophylaxis to prevent MTCT of HIV from the women during pregnancy,

delivery and breastfeeding for all HIV-infected women, not in need of treatment³. This provision has, however, been overtaken by the recent recommendations of the WHO that all HIV-positive patients should be on highly active antiretroviral therapy (HAART). With the optimization of PMTCT, the risk of transmission of HIV from an infected mother to her child is reduced from 15 – 45 % to below 5 %.

Sub-Saharan Africa harbours more than 90 % of the children living with HIV in the world⁴. The HIV epidemic has been sustained mostly by mother-to-child transmission (MTCT) of HIV⁵ as it remains the primary route of acquiring HIV among children⁶. Despite the successes achieved over the years, there were 180000 new infections in 2018 alone, majority of which mainly occurred through MTCT. The risk of MTCT is abated to a little over 1 % with effective antiretroviral therapy and other preventive measures to both the mother and her infant.

In Nigeria, the PMTCT services began in eleven tertiary health facilities in 2002, intending to involve the four approaches. Nevertheless, most of the centres run by government and other partner organizations concentrate more on the therapeutic intervention around delivery, leaving significant gaps regarding the other three areas⁷. Achieving an optimal outcome in the deployment of PMTCT services is largely dependent on the application of recommended guidelines which are products of well-researched findings. Despite the long history of the use of the services in Nigeria and the persistent burden of the mode of transmission in the country, there is no published study in both the print and electronic



literatures that has evaluated the level of compliance of the hospitals in the country to treatment guidelines. Thus, this present study was conducted to compare the PMTCT practices in some Nigerian tertiary health institutions to standard treatment guidelines.

METHODS

Study Design

This part was a multi-site retrospective study. It involved the use of the PMTCT databases of four purposively selected tertiary healthcare facilities in Nigeria.

Study Settings

This study was conducted in the tertiary healthcare facilities that had the longest history of provision of HIV/AIDS treatment and care with the highest number of clients. They also had comprehensive electronic medical databases managed by the United States President's Emergency Plan for AIDS Relief – AIDS Prevention Initiative in Nigeria (PEPFAR - APIN). The centres that met the criteria representing different zones of the country were: Ahmadu Bello University Teaching Hospital (ABUTH) Zaria, Jos University Teaching Hospital (JUTH) Jos, University of Maiduguri Teaching Hospital (UMTH) Maiduguri, and University College Hospital (UCH) Ibadan

Study Sample

Relevant data of all the patients that met the eligibility criteria of the study from 2006 to 2015 were used for the study. The requirements for inclusion were the data of HIV-infected pregnant women and their resulting infants who received HIV/AIDS treatment and care from the same facility, and the data of the HIV-infected pregnant women and their infants with complete demographic information in the database.

Source of Data Collection

The source of data for this study was the File-Maker Professional (FMPro) database of the HIV Clinics of the healthcare facilities. The FMPro database contained demographic and clinical information about all patients who received treatment and care for HIV from the sites. The data was abstracted from the FMPro into Microsoft Excel (2016).

The variables abstracted from the database for the PMTCT study were: gestational age at delivery, gender of infant, birth weight, infant ARV prophylaxis, and 18 month follow-up (for the children), mother's demographic characteristics (age at delivery, educational level, marital status), and mother's clinical characteristics (HAART administered, CD4 count, viral load, delivery site, mode of delivery).

Data Management and Analysis

The abstracted data in Microsoft Excel (2016) was checked for correctness before been exported to IBM SPSS (Version 25) for appropriate descriptive and inferential statistical analysis. Results of the descriptive

analysis were presented in frequencies (percentages) and/or mean \pm standard error of mean. Chi-square test was conducted on categorical data. Odd ratio (OR) and confidence interval (CI) were used in the presentation of the results of the inferential analysis. The level of compliance to guideline was computed as a mean score for each hospital, before using one-way analysis of variance (ANOVA) to compare their performances. For all the statistical analysis, 2-tailed association was considered with the significance level set at $p < 0.05$.

Ethical Consideration

Ethical approval was obtained from the Health Research Ethics Committees (HRECs) of the health institutions, and Institutional Review Boards (IRBs) of PEPFAR (Appendix VI) and APIN (Appendix VII) who managed the databases that were used for this part of the study. Strict confidentiality was ensured in the conduct of this study. All data gotten throughout the course of this study that related directly or indirectly to the identification of the subjects were concealed from any third party, and never included in any results that were reported.

RESULTS AND DISCUSSION

Results

Enrolment

Data from the same number of mothers and infants (5378) were retrieved for the guideline compliance audit. The highest proportion of data was for patients from UCH (2269), then JUTH (2605) and ABUTH (504). UMTH had no PMTCT data covering the period of the study. Figure 1 contains the trend of patient enrolment into PMTCT programme in the three hospitals from 2006 to 2015.

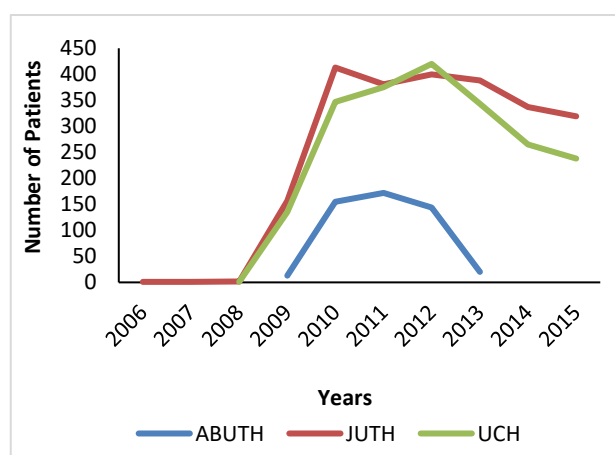


Figure 1: Trend of Enrolment into PMTCT in the Three Hospitals

ARVs Prescription

The ARVs used for PMTCT was not documented in 3590 (66.75 %) mothers. Only UCH documented guideline-approved Nevirapine and Efavirenz-based regimens in 1016 (18.89 %) and 456 (8.48 %) mothers respectively. The proportion of each regimen prescribed for the patients are listed in Table 1.

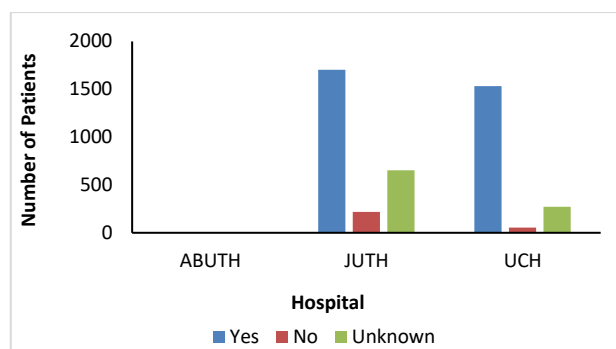


Table 1: Prescribed Regimen for the Mothers in the three Hospital

| Regimen | Frequency | Percentage |
|----------------------------------|-----------|------------|
| 3TC+d4T+NVP | 6 | 0.112 |
| ABC+3TC+EFV | 3 | 0.002 |
| ABC+3TC+LPV/r | 13 | 0.242 |
| ABC+3TC+NVP | 10 | 0.186 |
| AZT+3TC | 5 | 0.093 |
| AZT+3TC+ATV/r | 16 | 0.298 |
| AZT+3TC+EFV | 138 | 2.566 |
| AZT+3TC+NVP | 819 | 15.229 |
| AZT+3TC+TDF+ATV/r | 38 | 0.707 |
| AZT+3TC+TDF+LPV/r | 51 | 0.948 |
| d4T+3TC+AZT | 1 | 0.019 |
| Eligible but <13 weeks gestation | 21 | 0.390 |
| SQV+AZT+3TC+RTV | 2 | 0.037 |
| TDF+3TC | 2 | 0.037 |
| TDF+3TC+ATV/r | 60 | 1.116 |
| TDF+3TC+EFV | 315 | 5.857 |
| TDF+3TC+LPV/r | 78 | 1.450 |
| TDF+3TC+LPV/r+ AZT | 29 | 0.539 |
| TDF+3TC+NVP | 181 | 3.366 |
| Undocumented | 3590 | 66.753 |
| Total | 5378 | 99.947 |

Eligibility Criteria Classification

ABUTH did not document the eligibility criteria used in classifying all their PMTCT patients. JUTH did not document for 217 mothers that assessed PMTCT services in the hospital, while UCH did not document for 54 mothers. The distributions of eligibility classifications used in enrolling patients into PMTCT in the three hospitals are shown in Figure 2.

**Figure 2:** Documentation of Eligibility Classification of the Mothers in the Three Hospitals**Enrolment, ARVs Administration and HIV Tests in Infants**

Infant ARV(s) prophylaxis was administered to 4829 (89.79 %) infants after birth. Polymerase Chain Reaction (PCR) test was conducted for 4516 (83.97 %) after birth, while Rapid HIV Test was conducted for 1677 (31.18 %) infants after therapy. The distribution of ARV administration and HIV tests for patients in the three hospitals are documented in Table 2.

Table 2: Compliance of Treatment Guidelines Related to Infants

| | JUTH | | ABUTH | | UCH | | Total | |
|--------------------|-----------------------|-------|----------------------|-------|-----------------------|-------|-----------------------|-------|
| | Compliance (N = 2605) | | Compliance (N = 504) | | Compliance (N = 2269) | | Compliance (N = 5378) | |
| | n | % | n | % | n | % | n | % |
| NVP Administration | 2477 | 95.09 | 489 | 97.02 | 1863 | 82.11 | 4829 | 89.79 |
| Rapid HIV Test | 1130 | 43.38 | 0 | 0.00 | 547 | 24.11 | 1677 | 31.18 |
| PCR Test | 2266 | 86.99 | 0 | 0.00 | 2250 | 99.16 | 4516 | 83.97 |

Overall Compliance to PMTCT Guideline

UCH has a total compliance to PMTCT guideline of 69.55 %, while UMTH has a total compliance of 0.00 %. The

total compliance scores of the hospital to the component of the PMTCT guideline and overall are as presented in Table 3.

Table 3: Overall Compliance to PMTCT Guideline in the Hospitals

| Facility | Maternal ARV (10.00%) | Status of Mothers (15.00%) | Infant Prophylaxis (30.00%) | Rapid Test (30.00%) | PCR Test (15.00%) | Total (100.00%) |
|---|-----------------------|----------------------------|-----------------------------|---------------------|-------------------|-----------------|
| ABUTH | 0.00 | 0.00 | 29.11 | 0.00 | 0.00 | 29.11 |
| JUTH | 0.00 | 11.32 | 28.53 | 13.01 | 13.05 | 65.91 |
| UCH | 10.00 | 12.81 | 24.63 | 7.23 | 14.88 | 69.55 |
| UMTH | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean = 41.14(16.48); F (3,0) = 0.00, p ≤ 0.0001 | | | | | | |

DISCUSSION

Extensive data was extracted from the HIV clinics of three of the four hospitals whose databases were used. In each hospital, data was extracted from an equal number of mothers and children. The highest enrollment was in UCH, then JUTH before ABUTH. UMTH had no record of the PMTCT services that they rendered to mothers and their children for the period covered by the study. A common trend noted in the enrollment in all the hospitals was the inconsistency throughout the period. There was a steady rise in the number of patients enrolled in the services from inception until the fifth year. After that, the enrollment became unsteady, rising and falling over the years until a gradual decline in the last four years.

The most current standard treatment guideline for the management of HIV/AIDS in Nigeria is the 2016 Nigeria Integrated Guidelines for HIV Prevention, Treatment and Care ^{8,9}, with a slight modification in 2018. However, the first draft of a treatment guideline for HIV/AIDS in Nigeria was developed in 2003. This was more than a decade after the first incidence of the disease was discovered in the country. That first guideline has undergone revisions, first in 2005, with a separate document that focused on children alone in 2007, then in 2010. In all cases, the Nigerian treatment guidelines are often the domestication of the WHO versions. As it is with all treatment guidelines which are products of extensive and evidence-based research ^{10,11}, the Nigeria Integrated Guidelines for HIV Prevention, Treatment and Care aimed to ensure the universal access to all services related to HIV treatment and care.

PMTCT services were introduced into the HIV management in Nigerian hospitals in 2006, starting from UCH and JUTH. This explains the findings of this study that higher proportions of patients on PMTCT were from the two hospitals. It should also be noted that ABUTH HIV Treatment Centre withdrew from PEPFAR-APIN as its partner agency for the provision of ARVs and other HIV-related equipment. The unsteady enrollment of patients is consistent with most government-run programmes in Nigeria in which the actors start with high zeal which depreciates over time, only to rise (and later fall again) when an alarm is raised ¹²⁻¹⁴.

All drugs provided for HIV patients are supposed to be documented for several reasons. The knowledge of the earlier drugs that a patient is prescribed determines the choice of other drugs that the patient would be provided if there is a reason for a switch or substitution. It is also needed to detect offending drugs in the instance of a side effect or a suspected anaphylactic reaction. JUTH and ABUTH thus did not comply with the dictate of the guidelines in documenting ARVs used in the patients. For UCH that documented the ARVs that they prescribed to their PMTCT patients, almost all the patients were provided ARVs that were in adherence to the treatment guideline at the time of such prescriptions. Although most patients were prescribed NVP and EFV-based regimens,

NVP-based regimens were the most commonly prescribed drugs for the patients before 2010. This was in compliance to the earlier guideline which approved only NVP as the NNRTI in pregnancy, with the warning that EFV should not be used because of the risk of neural tube defect ¹⁵⁻¹⁷. For the patients that were on second-line drugs, there was the prominence of prescribing three NRTIs in addition to a ritonavir-boosted PI. That practice was not in compliance with any guideline ever approved for use in Nigeria, or by the WHO. For the infants, the guideline stipulates that ARV prophylaxis should be provided to all infants after birth, except for a child who is identified as HIV exposed after birth (through infant or maternal HIV antibody testing) but is not breastfeeding. The findings of this study showed that almost all the infants were prescribed the prophylactic ARV, with no record of the possible reasons for not providing ARV for the remaining few. NVP that was the guideline-approved ARV for infant prophylaxis after birth, was the only one documented for all infants with records of an ARV. Although AZT can be combined with NVP to infants who are regarded as highly exposed⁸, none of such a case existed in the reviewed document. The HIV status of the infants is supposed to be determined after 6-8 weeks of age and/or six weeks after stopping breastfeeding using a PCR test. Another HIV status determination is required after one year of age using Rapid Test. The first test (PCR) was done for most of the infants, while the second test (Rapid) was not done for many infants. This is most probably due to the incidence of loss to follow-up, which has been established in many hospitals in Nigeria, including some that were used for this study.

No nationwide study has evaluated the adherence of health facilities to treatment guidelines in Nigeria. The study by Isah *et al.* (2016) that assessed PMTCT services in UNTH for two years is grossly limited by the use of a single centre and covering just a few years. Thus, its findings could not be extrapolated for the country as a whole, or for a programme that has been implemented for over a decade in the country. However, studies that evaluated the compliance to treatment guidelines for HIV generally and PMTCT, in particular, have been conducted in other African countries as well as other parts of the world. In their study, which was a retrospective analysis of PMTCT data in government facilities like this present study, Miller *et al.* (2017) evaluated the level of implementation of PMTCT recommendations in a PEPFAR-supported clinic in Mbarara, Uganda. Their study identified that the clinic changed to the PMTCT Option B+, which was the regimen according to their government-approved guideline. ARVs and tests were provided as at when needed. They were of the opinion that the compliance to the new guideline even improved retention in care for the mothers. Their study, however, did not document anything about the infants whose mothers were enrolled in the PMTCT service. This limitation in their study was the main focus of a study by Goggin *et al.* in Kenya. The latter only sought to identify



the predictors of enrolment to infant HIV status diagnosis after PMTCT. Their study, conducted at six health facilities in Kenya, identified that about a quarter of infants failed to be tested on time for their HIV status¹⁸. The level of compliance is far below the one reported in the present study. It is worthy of mentioning that their study was able to determine the predictors of noncompliance to test to include ignorance of availability of the tests by the mothers and distance from the hospitals. Chi *et al.* conducted a review of PMTCT programme implementation and advances in sub-Saharan Africa in 2013 when the 2010 guideline was the current treatment guideline in use. They concluded that healthcare practitioners in the region knew how to prevent MTCT using the available guidelines, but the challenges that they predicted were those of sustaining the implementation and effectiveness of the programme¹⁹. In a study in Congo to measure the level of compliance of nurses to PMTCT treatment guidelines, Amboko and Brysiewicz used 18 selected sites in Kinshasa to determine a score for level of compliance. At the end of their study, they scored the nurses in the facilities 74 % (95% CI: 69 % – 78 %), which they still termed as noncompliance. The study concluded that an intervention programme was required to improve the level of compliance of all the nurses since none of their sociodemographic characteristics influenced the compliance score²⁰. Outside the shores of Africa, Voramongkol *et al.* evaluated the compliance with PMTCT guidelines in Thailand. Although the study only covered a year and restricted the aspect of PMTCT assessed to the use of CD4 as a yardstick for eligibility (which was the case in that period), it was a good measure of compliance to guidelines based on the presented findings. The study was a national one, covering 27 facilities spread across 11 provinces in Thailand. The authors concluded that compliance with the guideline in use at that time was low, leading to a high level of MTCT²¹. They, however, expected that the 2010 guideline might improve compliance due to its simplified format.

A US study evaluated compliance with HIV treatment guidelines as a whole and not just PMTCT. In that study, which covered a four-year duration, Tandon *et al.* used the records of over 25000 patients and concluded that there was a high level of noncompliance to treatment guidelines in the hospitals whose data was assessed²². Mwangome *et al.* also conducted a review of compliance to treatment guidelines for HIV generally, but only in Tanzania and involving qualitative design. Their study focused on such aspects of HIV service as PMTCT, HTC, among others. They concluded that the level of compliance with the guidelines was suboptimal, despite the availability of factors that could have facilitated compliance²³. The issue of compliance to treatment guidelines may thus not be a Nigerian problem alone, as identified in the present study, but a menace that crosses an international border. It has also been shown that apart from HIV, the issue of noncompliance to treatment

guidelines, especially for chronic diseases, exists even in developed nations like the US. That was the summary of the findings of Cantrell *et al.*, who conducted a cross-sectional retrospective study utilizing a commercial database in the US. The study posits that noncompliance to treatment guidelines in terms of under-treatment can lead to increased medical and nonmedical costs in the management of chronic diseases²⁴.

The retrospective design of this study presents the limitation of not being able to identify the causes of non-compliance; neither did it give the opportunity to correct the non-compliance. The compliance study also determined the level of compliance for a very long period during which different guidelines were used. However, the findings of the level of compliance were not separated into different sub-period based on the existing guidelines.

CONCLUSION

Compliance to PMTCT treatment guidelines in the Nigerian tertiary hospitals that were assessed was fair. This study, which is the first of its kind, reports the existence of a less-than appropriate practice of PMTCT in major Nigerian tertiary hospitals. This knowledge will find use among clinicians, policy, makers, and all stakeholders involved in the treatment and care of PMTCT patients in Nigeria.

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