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Budget impact analysis of alternative strategies for initiating antiretroviral therapy in Nigeria

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Abstract: The World Health Organization (WHO) has recently made recommendations for treating all Human Immunodeficency Virus (HIV/AIDS) patients irrespective of their immune status. This issue poses challenges to lower-middle-income countries like Nigeria due to resource limitations. This study performed a budget impact analysis (BIA) of different strategies for the initiation of antiretroviral therapy (ART) among individuals living with HIV/AIDS in Nigeria. A dynamic cohort budget impact model was used to compare two initiation arms (CD4 < 350 cells/ml and CD4 > 500 cells/ml), with CD4 > 500 cells/ml representing the 2015 WHO guidelines for initiation of ART. Outcomes were hospitalization costs, new infection transmission, and overall budget impact. Key inputs included HIV prevalence in Nigeria, ART access and costs, hospitalization rates and costs, ART uptake trends, and transmission rates. Sensitivity analysis empolyed Monte Carlo simulations to assess the impact of selected parameters. At the end of year five, applying the 2015 WHO guidelines reduced new HIV transmissions by 87.0%, preventing 77,000 infections. Hospitalization cost reductions saved $1.12 million. Overall budget impacts were $718 million for immediate initiation versus $903 million for deferred initiation, yielding $184 million in savings. Monte Carlo simulations showed reduced transmission as the main driver of savings. Prioritizing early treatment initiation espoused by the 2015 WHO guidelines maximize resource efficiency, reduces long-term healthcare costs, and accelerate progress toward epidemic control targets. The findings strongly support the adoption and sustained implementation of the 2015 WHO guidelines for immediate ART initiation. It has public health and economic benefits.

Introduction

Human immunodeficiency virus/Acquired immune deficiency syndrome (HIV/AIDS) remains a major cause of morbidity and mortality in many parts of the world, particularly in low- and middle-income countries (LMICs) [1]. AIDS, which results from untreated infection with HIV-1 or HIV-2, is characterized by a profound defect in

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cell-mediated immunity and represents the advanced stage of HIV infection [2]. Nigeria bears the second-largest HIV epidemic globally, with a prevalence rate of 1.4% as of 2020, indicating that about 1.9 million individuals were living with HIV [3]. This epidemic poses a significant global health challenge, as it overstretches healthcare services, reduces life expectancy, lowers child survival rates, and increases the number of orphans. If left untreated, HIV/AIDS can progress to advanced stages, leading to the development of opportunistic infections and malignancies [4]. Antiretroviral therapy (ART) remains the cornerstone of HIV/AIDS management. However, the initiation guidelines from the World Health Organization (WHO) have evolved over time. Initially, initiation was reserved for patients with the lowest CD4 cell counts who faced the highest risks of mortality and morbidity. This approach required minimal resource allocation due to the limited number of patients initiated [1]. Yet, clinical trials conducted in the past decade have demonstrated the clinical advantages of early initiation of ART for all patients, prompting the WHO to update its recommendations [5]. Consequently, the reference CD4 levels for initiating HIV treatment shifted over time, from a threshold of < 200 cells/ml in 2003 to a range of 200-500 cells/ml in 2013, and by 2015, treatment was recommended for all patients regardless of CD4 count, including those with counts above 500 cells/ml [5]. Despite these progressive changes in treatment guidelines, a persistent disparity remains between the available funding and the financial resources required to meet global HIV/AIDS targets [6-8]. This disparity can be shown in the fact that total HIV/AIDS expenditure in Lower Middle-Income Countries (LMICs) rose from $4.0 billion to $19 billion between 2000 and 2016. However, much of this increase in funding has been concentrated in just ten LMICs, including Nigeria, thereby reflecting a significant imbalance in resource distribution [6]. The Nigerian Government has adopted and implemented the 2015 guidelines for the initiation of ART at the facility level [4]. Therefore, it is crucial to examine the affordability of this initiation strategy for the National health systems. This is particularly pertinent due to several factors: the country's relatively low health expenditure per capita, which is characteristic of low-income countries [9]; a decrease in foreign aid previously provided by high-income countries [10]; and a relatively high HIV prevalence rate of 1.4%, driven by Nigeria's large total population of over 200 million people [11]. A Budget Impact Analysis evaluates the anticipated changes in healthcare system expenditures following the implementation of a new intervention. Used for budget or resource planning, it can be freestanding or part of a comprehensive economic assessment along with a cost effectiveness analysis (CEA) [12]. It provides data on the affordability of new health-care technologies at a given price for a specified population prior to reimbursement [13]. CEA compares costs and outcomes of competing interventions; it tends to portend which intervention gives more value for money [14-16]. Past literature has revealed that the initiation of ART using the 2015 guidelines (which recommend starting treatment regardless of CD4 count) has been found to be cost-effective, offering greater clinical and economic benefits compared to previous guidelines [1, 5, 17], thereby providing value for money. Similarly, a budget impact analysis conducted in Côte d'Ivoire reported that immediate ART initiation increased the 5-year HIV care budget from $801.9 million to $812.6 million, compared to initiation at CD4 < 350 cells/μL1. This study aims to evaluate the budgetary impact of alternative strategies for initiating ART in patients with HIV/AIDS in Nigeria, through an assessment of, the incidence of new HIV infections, the number of unscheduled hospitalizations, associated hospitalization costs, and overall budget impact.

Materials and methods

Setting and location: Nigeria, officially known as the Federal Republic of Nigeria, is located in the southeastern region of West Africa, with a coastline along the Bight of Benin and the Gulf of Guinea. It shares land borders with Benin, Cameroon, Chad, and Niger, and maritime borders with Equatorial Guinea, Ghana, and São Tomé

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and Príncipe. Covering an area of 923,768 km², it is nearly four times the size of the United Kingdom and slightly more than twice the size of the U.S. state of California [18]. The capital city is Abuja, situated in the central part of the country [19]. Nigeria has a GDP per capita of $2,222.01[20], a life expectancy at birth of 55 years, and a per capita health expenditure of $21715.

Input parameters

Target population and subgroups: The total population followed for this study was determined by considering the epidemiology of the disease and accessibility to antiretrovirals. Based on a national HIV prevalence rate of 1.4% in 2020 and an estimated population of 206 million, approximately 1.9 million people were living with HIV in Nigeria [21], as confirmed by previously published sources [22, 23] (**Table 1**). Although Nigeria adopted the 2015 ART guidelines, only 55.0% of people living with HIV had access to ART as of the latest reports [19, 22]. As a result, the total population that is already on ART as at 2019 is 1,045,000. It is worth mentioning here that at Nigeria's national health systems level, certain factors have influenced access to antiretroviral, including poor financing and logistics, poor political will and corruption, uneven spread and reach of government health facilities, low employment of health workers, and low wages [19].

Table 1: Input parameter: Target population and subgroups

Prevalence	1.4%, [19, 22]
Number living with HIV	1.9 million, [19, 22]
Access to ART adult	55.0%, [19]
Annual cost per person of ART	$ 397, [24]
Cost of Hospitalizations	$ 51, [24]

Comparators /assumptions for budget impact analysis: The two competing strategies that are being compared are: Previous methods of initiation / deferred therapy initiation. This is defined as initiation in patients with a CD4 cell count of < 350 cells/ml, and the 2015 guidelines of initiation of antiretroviral therapy/immediate therapy initiation, which is defined as initiation in patients with a CD 4 cell count > 500 cells/ml. The deferred therapy initiation methods were compared with the immediate therapy arm of initiation. The deferred therapy served as the reference method. The model had annual cycles with a 5-year time horizon. At the end of each cycle, the annual budget impact was computed. This was done in relation to the anticipated change in sexual transmission of HIV (hence the number of new cases of HIV) and the number of unscheduled hospitalizations. The number of new HIV cases was added at the beginning of each new cycle. Precisely, the base case values are assumed to be in operation in 2019, which is completely substituted by the immediate therapy initiation by 2020. In subsequent years after 2020, it is assumed that uptake of antiretroviral will increase at 10.0% per year (**Table 2**). This assumption was made since this method of initiation entails that 100% of patients should be administered antiretroviral therapy. According to studies, 100% access to antiretroviral has not been achievable in most countries that have adopted the guideline [25], for instance, 70.0% of Lower Middle-Income Countries (LMIC) had this guideline adopted, and 69.0% were involved in its implementation, and global access to ART has been reported as 79.0% as opposed to 100%.

Time horizon: The time horizon for this analysis was five years, and this time was chosen because policy makers usually occupy their offices for about four years in Nigeria. This time horizon will enable them to determine the affordability of the new guidelines while still in office. Incidence of HIV and cost may also change and affect results of the analysis if a longer time horizon is chosen.

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Discount: Discounting was not employed in this analysis since, in accordance with expert opinion and standard methodology, it should be avoided in BIA.

Study perspective: Perspective of the study was that of the Nigerian National Health Systems, since funding of the HIV programmed was by the governments of Nigeria in conjunction with international donors.

Health outcomes: The main health outcome were changes number of unscheduled hospitalizations, associated hospitalization costs, the incidence of new HIV infections, and overall budget impact. Conditions associated with the two initiation strategies had earlier been investigated in a randomized control trial known as the strategic timing of antiretroviral therapy trial (START). This trial was designed to assess the clinical risks and benefits of initiating ART immediately in asymptomatic HIV-positive patients with a CD4+ count greater than 500 cells/μL, compared to deferring treatment until the CD4+ count falls below 350 cells/μL. The results of this trial showed that initiation in patients with CD4 count of > 500 cells/ml was associated with less negative clinical events when compared with initiation in patients with CD4 count of <350 cells/ml, in addition to the above there was a significant reduction in the rates of unscheduled hospitalization in patients with CD4 count of > 500 cell/ml [5]. Other studies has also suggested that immediate therapy method of initiation of antiretroviral reduces infectivity [26-29]. It is on this premise that the model in this study was made to include changes in rates of unscheduled hospitalizations and changes in infectivity. This was later translated to changes in the cost of these two variables as indicated on **Table 2**.

Table 2: Input parameter: Assumptions for budget impact analysis Nigeria

Variable		Immediate initiation	Deferred initiation
Rates of Unscheduled Hospitalizations		3.94%, [1]	4.3%, [1]
Rates of Transmission of new infections		0.85%, [26]	5.6%, [26]
Annual increase in cost per patient of Antiretroviral	10.0% for one year (Expert opinion)		
Annual increase in access to Antiretroviral therapy	10.0% for one year (Expert opinion)		

Estimating resources and costs: The source of data on average cost per person on ART was a study conducted by the world bank. The study had the aim of understanding the costs and developing a practical, sustainable financing plan as a core requirement for each country to successfully achieve HIV and Universal Health Coverage (UHC) goals. The analysis evaluated the current costs and financial requirements for UHC and HIV, projecting future needs through to the 2030 target. This assessment focused on four countries: Côte d'Ivoire, Kenya, Tanzania, and Nigeria. The findings revealed that these programs currently cost approximately US $481 per person living with HIV (PLWH), largely sustained through significant donor support. Specifically for Nigeria, the cost per person on ART was estimated at US$329, with a range of US$301 to US$376.

Annual cost for hospitalizations were derived from publications of local health expenditures adjusted to the value of 2019 dollars (20A) as shown on **Table 2**. The model of choice is shown in **Figure 1**.

Further assumptions: The study adheres to the BIA guidelines regarding principles of good practice from the International Society for Pharmacoeconomics and Outcome Research (ISPOR) [12]. The BIA was performed using a dynamic model, a model that allowed the entrance of new patients every year. The new entrants were determined from hazard rates derived from meta-analysis on the risk of sexual transmission of HIV [26]. Dynamism of the model would also indicate an assumed increase in annual cost per patient of antiretroviral by 10.0% and an assumed 10.0% yearly increase in uptake of antiretroviral.

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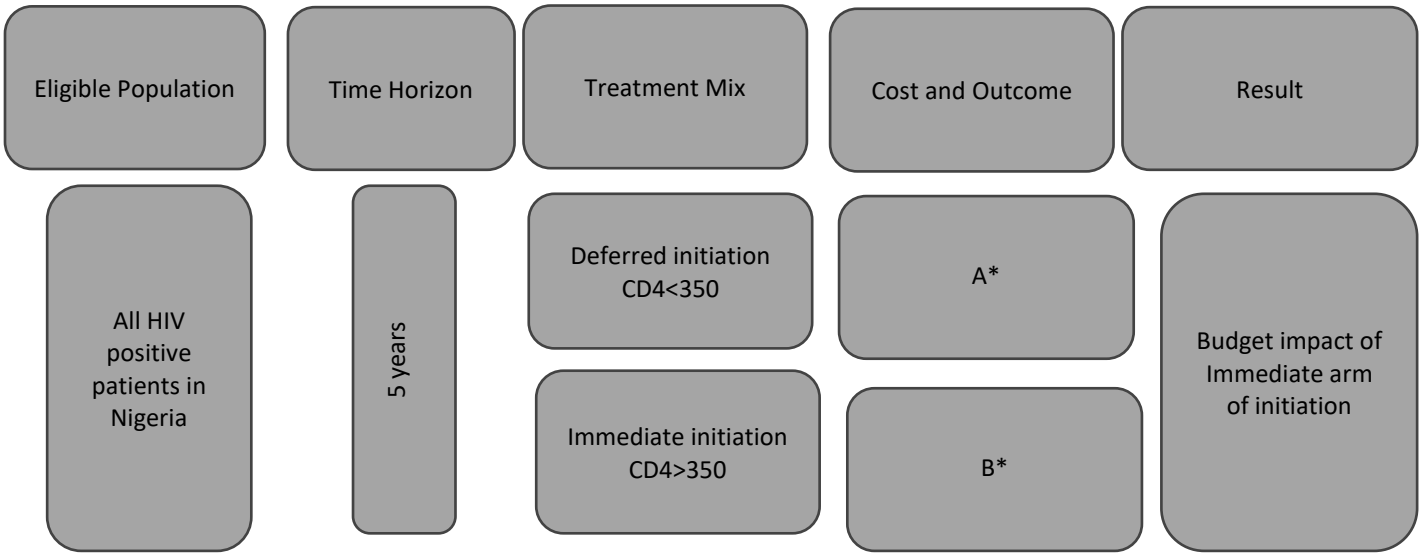
Sensitivity analysis: uncertainty was assessed using Monte Carlo simulations, and model validation was performed by comparing the results with findings from previous studies in the field.

Figure 1: Model for budget impact analysis



A* Number of unscheduled hospitalizations, total cost of hospitalizations, transmission of new infections, the overall budget impacts
B* Number of unscheduled hospitalizations, total cost of hospitalizations, transmission of new infections, the overall budget impacts

Results

Number of new transmissions: At the end of year 5, comparing the immediate therapy arm to the deferred therapy arm revealed an 87.0% reduction in new transmissions. This resulted in the prevention of about 77,000 infections, as shown on **Figure 2**.

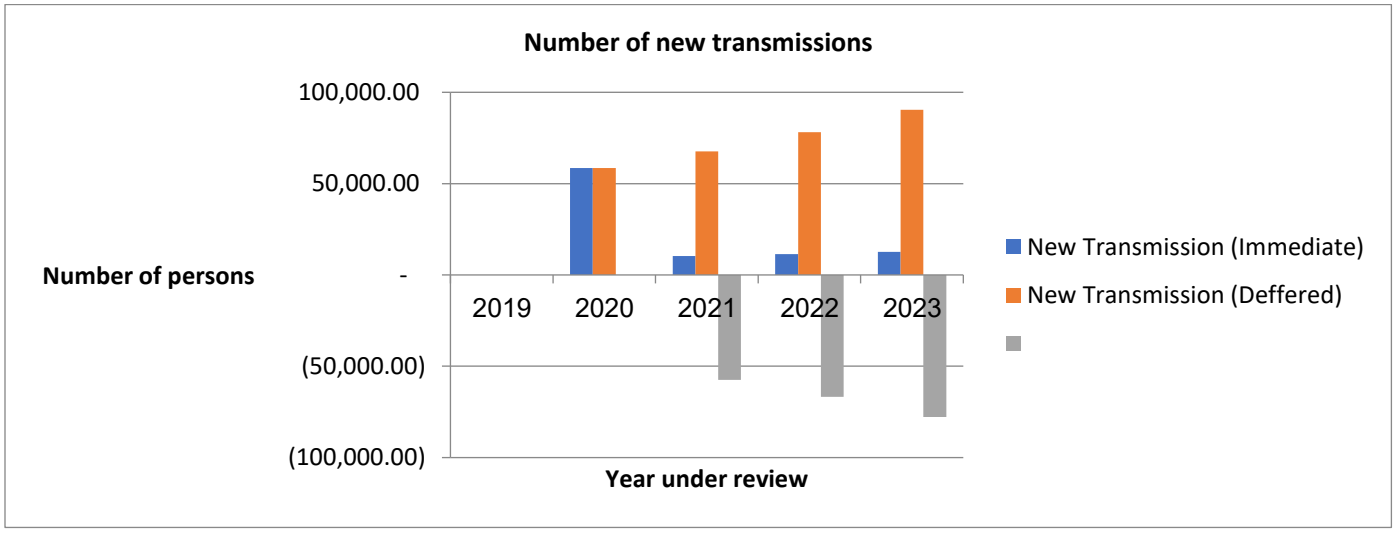


Figure 2: Number of new infections

Number and cost of hospitalizations: Over five years, comparing deferred therapy to immediate therapy showed a reduction in both the number and cost of hospitalizations. This resulted in a net savings of $1,116,796.84 in hospitalization expenses by the end of year 5, amounting to a 27.0% net savings (**Figure 3**).

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ISSN: 2958-3101 print

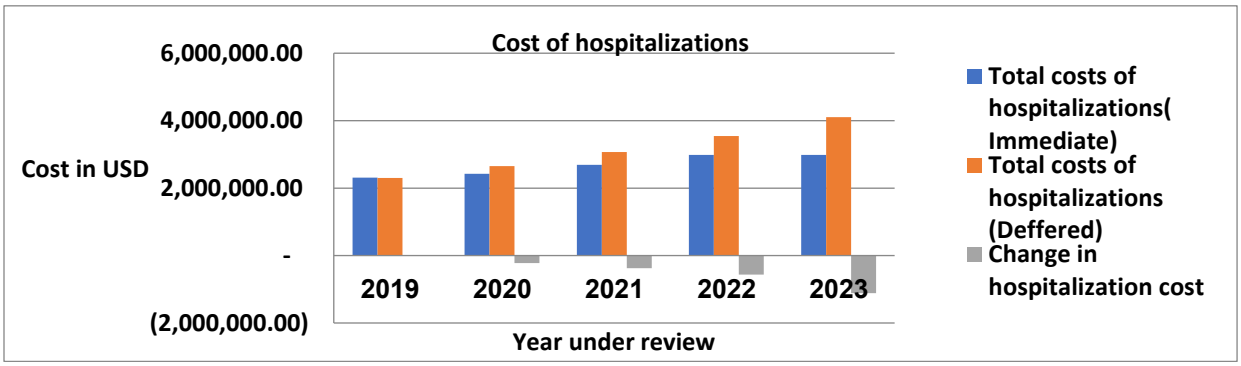

Figure 3: Cost of hospitalizations

Budget impact analysis: While both initiation arms experienced an increase in budget impacts, the deferred therapy arm showed a higher rise. Consequently, by year 5, there was a net saving of 20.0%. This equated to an absolute net saving of $ 184,452,491.44 as illustrated on **Figure 4**.

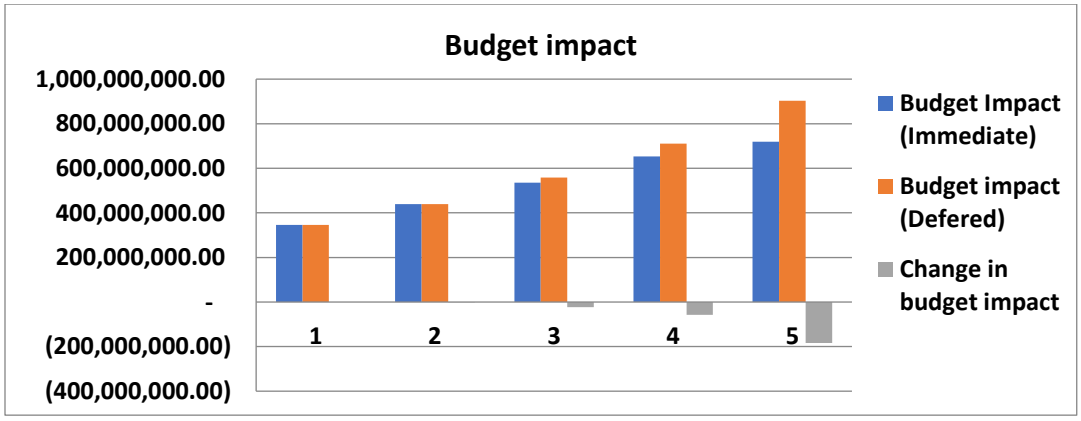

Figure 4: Budget Impact analysis of alternative arms of initiating antiretroviral therapy

Monte Carlo simulation: Transmission rate was the largest contributor to savings, because Lower transmission reduces future patient load, and this amounts to less ART, hospitalization, and downstream costs. Hospitalization rate was the second largest contributor to savings. Early treatment reduces hospitalizations, then savings grow over time 10.0% ART price increase has the same rate applied to both, but penalizes deferred more because it treats more patients at higher future prices. Acts as a multiplier (**Figure 5**).

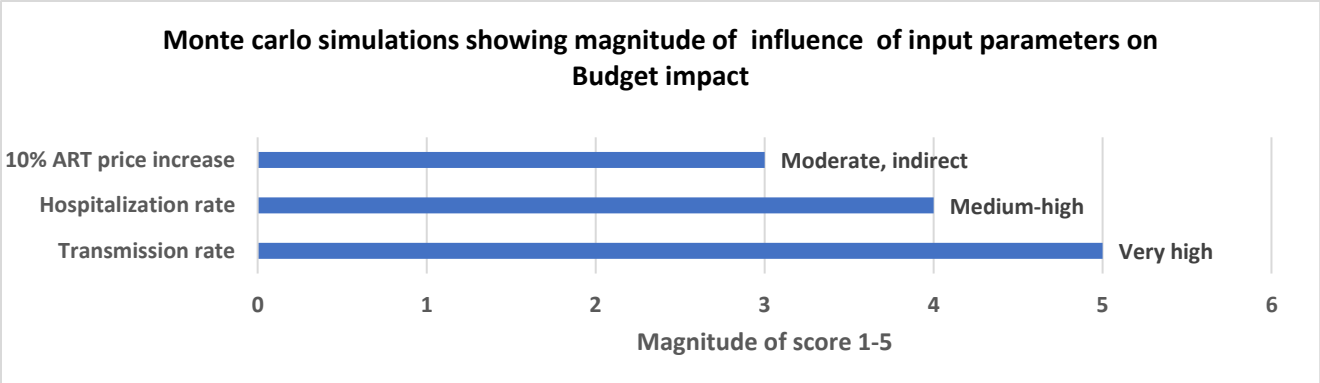

Figure 5: Monte Carlo simulations showing the magnitude of influence of input parameters on budget impact for immediate versus deferred ART

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Discussion

The 87.0% reduction in new HIV transmissions over five years led to significant healthcare cost savings. Also, decreased morbidity and mortality among patients initiated on ART under the 2015 guidelines is expected to result in increased productivity over the same period and into the future years. This aligns with the findings that expanding access to ART, along with testing and prevention efforts, has resulted in a 59.0% decline in new HIV infections since the peak in 1995 [30]. The report emphasizes that universal ART access and achieving viral suppression are critical to stopping HIV transmission. This is consistent with the findings of Eisinger et al. [31], who emphasized that ART leading to viral suppression eliminates the risk of sexual HIV transmission. They noted that achieving widespread viral suppression has the potential to significantly reduce HIV incidence and move closer to elimination. Likewise, the study by Gazzino et al. [32], which explored the Undetectable = Untransmutable concept, confirmed that effective ART eliminates the risk of HIV transmission. When implemented at scale, this has a significant impact on reducing transmission at the population level. The decreased number and cost of hospitalizations observed which resulting cost savings of $1,116,796.84, was as a result of decreases in the rates of hospitalizations and incidence of new infections observed when the new guidelines are utilized. This is in similarity to studies that linked ART initiation to a threefold reduction in hospitalization rates after four years on treatment [33]. It is estimated that starting ART earlier could save over US $300,000 per 1,000 person-years in hospitalization costs during the first four years of therapy [34]. Also, it was found that treatment-experienced people with HIV using B/F/TAF (Bictegravir/Emtricitabine/Tenofovir alafenamide) experienced 20.0% lower HIV-related medical costs compared to some other regimens, largely through reduced hospitalizations. Also, a real-world analysis from Italy showed that adherence to TAF-based ART significantly reduced healthcare resource use and hospital-related costs, compared to less persistent regimens [35].

The total cost requirements for treatment of the disease, which were 718 and 903 million for the immediate and delayed arm of therapy respectively, were similar to that gave estimates for spending for high-burden low-income countries (HBLI) like Nigeria [36]. It was mentioned that HBLI countries will tend to spend more than low burden middle income countries for the management of HIV/AIDS. Countries in the HBLI category were advised to intensify preventive strategies such as prevention of mother-to-child transmission, male circumcision, and packages of community mobilization, such as testing, counseling, and condom promotion for sex workers, their clients, and men who have sex with men. Adoption of low-cost management approaches like obtaining further reductions in the prices of antiretroviral. Policymakers will be able to use this information to measure the affordability of the 2015 guidelines for initiation of ART to decision making, and will provide information regarding the financial consequences of the 2015 guidelines. The absolute net savings of $184,452,491.44 observed when comparing the 2015 guidelines to older methods of initiation of ART gives credit to the new guidelines, showing there would be an increase in affordability to health payers. There would be the advantage of the net savings offsetting the net cost of the disease in the near future. This study agrees with those who also found that the new guidelines will result in cost savings into future years [37]. The increases in cost components observed were due to an annual 10.0% increase in excess of ART. The findings showing decreased incidence, cost of unscheduled hospitalizations, and cost savings in terms of annual budget impacts for the 2015 guidelines for initiation of ART will enhance the achievement of UNAIDS of ending AIDS as a global public health threat by 2030. It is worthy of note that these targets cannot be achieved by implementation of this guideline alone, at the population level success can only be achieved when there is widespread testing uptake, linkage with care, uptake of therapy, retention of these in therapy, adherence to medications and a favorable social context for the occurrence of all these [19, 38] and lastly reduction of the time between diagnosis and initiation of therapy [39].

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Conclusion: The net savings of $184 million, reduction in incidence, and reduction in rates and cost of unscheduled hospitalizations under the immediate therapy model not only demonstrate affordability but also offer long-term financial sustainability for health systems. These results strongly support the implementation of the 2015 WHO ART initiation guidelines as a strategic investment. However, achieving the global HIV targets will require more than policy change; it demands comprehensive population-level efforts, including widespread testing, linkage to care, adherence support, and reduced delays between diagnosis and treatment. Only through such coordinated actions can countries fully realize the benefits of ART scale-up and meet the UNAIDS 2030 goals.

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