

CURRENT NATIONAL HIV/AIDS TREATMENT GUIDELINES 2016

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OUTLINE

- Background
- What the 2016 guideline is about
 - Key principles guiding the guideline
 - Rationale for review of the guideline
 - The guideline review process
 - What will the guideline do
 - Central theme of the guideline
 - Structure of the guideline
- What's new in the guideline
 - HIV Re-testing
 - ART Initiation
 - Recommended ART regimen
 - ARV prophylaxis for high risk exposed infants
 - Pre-exposure Prophylaxis (PrEP)

BACKGROUND

- The 2016 Integrated National Guidelines on HIV Prevention, Treatment, and Care was an adaptation of WHO 2016 Consolidated Guidelines on the use of ARVs for preventing and treating HIV infection and the 2014 integrated National Guidelines for HIV Prevention, Treatment and Care.
- The Guidelines recommendations were a product of stakeholder consensus and the principal consideration guiding choice of recommendation is well being of the patients.
- The new guideline was officially disseminated on March 2nd 2017.

WHAT IS THE HIV GUIDELINE ABOUT

To provide updated and evidence-based clinical recommendations for provision of HIV prevention, treatment, care and support services.

To provide guidance on key service delivery and operational issues needed to increase effectiveness and efficiency of HIV service delivery and to strengthen the continuum of HIV care

To provide programmatic guidance for the effective delivery of HIV/AIDS prevention, treatment, care and support services at all levels of the health care system.

KEY PRINCIPLES GUIDING THE 2016 GUIDELINE

- Public Health Approach
 - Services universally available to all Nigeria irrespective of socioeconomic class or creed
- Equality, equity and social justice
- Contribution to national and Global Health Goals
- Human rights
 - Health is everybody's entitlement, services provided in environment with no discrimination and stigmatization, Informed consent and confidentiality

RATIONALE FOR REVIEW OF THE GUIDELINES

Release of new Guidelines by WHO in 2016 and need to keep pace with global trends

Existing guidelines and protocol insufficient to meet the demands of the UNAIDS 90-90-90 initiative

Poor retention in care and high rates of loss to follow demands adoption of improved systems for service delivery

GUIDELINE REVIEW PROCESS

The review and development of the 2016 National Guidelines on HIV prevention, treatment, and care, commenced after the official release of WHO 2016 Consolidated Guidelines on the use of ARV drugs for preventing and treating HIV infection.

The process involved several stakeholders meetings convened by NASCP-FMOH that reviewed and adopted recommendations of WHO 2016 Consolidated Guidelines on the use of ARVs for preventing and treating HIV infection and the 2014 Integrated National Guidelines for HIV Prevention Treatment and Care.

The recommendations are essentially guidance on HIV diagnosis, general HIV care and support and the rational use of ARV drugs for treating and preventing HIV infection.

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The process was coordinated by the NASCP.

WHAT WILL THE GUIDELINE DO?

Supports:

- Early diagnosis of HIV infection, earlier initiation of lifelong ART regardless of clinical stage or CD4+ cell count
- Use of viral load testing for monitoring ART treatment and diagnosis of treatment failure
- Offer of ARV prophylaxis to HIV exposed infants, timely DNA PCR testing and early linkage of HIV positive infants to treatment and care
- Prevention of HIV infection using ARVs as pre and post exposure prophylaxis
- Differentiated/individualized care, task shifting and improved linkage of patients to other care.

THE CURRENT GUIDELINE

This is the 'Test and Treat' Guidelines

ART should be initiated for **EVERY** HIV positive person regardless of age, gender, clinical stage of disease or CD4+cell count

STRUCTURE OF GUIDELINES

The National Guidelines for HIV Prevention Treatment and Care is a ten-chapter, 148 page document

Chapter One –Introduction; focus is on the guiding principles, guidelines review process and the epidemiology of HIV/AIDS in Nigeria.

Chapter Two –Diagnosis of HIV Infection; focus on HIV Testing Services, Laboratory and Clinical diagnosis of HIV infection

Chapter Three-Antiretroviral Therapy; focus on classification and mechanism of action of ARV drugs, initiation of ART for all age groups and pregnant women, initiation of ART, recommended ART regimen and management of treatment failure.

STRUCTURE OF GUIDELINES

Chapter four –Pharmacovigilance in ART; focus on adverse drug reactions, management of adverse drug reactions, ARV drug interactions

Chapter Five: Adherence to Antiretroviral Therapy; focus on adherence preparation, monitoring of adherence, factors that influence adherence, recommendations for clinic visits and drug refill and specific populations

Chapter Six: Prevention of Mother to Child Transmission of HIV; focus on benefits of PMTCT, pre-ART care in HIV positive pregnant women, Use of ART for PMTCT, Comprehensive Care of the HIV positive pregnant woman, Care and Support of the HIV exposed Infant

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What is new in Guidelines??

<p>What is new for HIV positive adults and adolescents</p>	<ol style="list-style-type: none"> 1. Initiate ART in all adults and adolescents with a diagnosis of HIV. This is regardless of the clinical stage of the disease and also regardless of CD4+ cell count. 2. Dolutegravir (DTG) and Efavirenz (EFV) 400mg are new alternative options in first line ART regimens.
<p>What is new for HIV positive pregnant and breast feeding women.</p>	<ol style="list-style-type: none"> 3. Initiation of ART for all HIV-positive and pregnant, post-partum and breast-feeding women, regardless of CD4+ cell count 4. ART is lifelong in all HIV positive women including pregnant and breastfeeding women. 5. Repeat HIV testing for HIV-negative pregnant women in the last trimester 6. Viral load testing for pregnant women in the last trimester of pregnancy
<p>What is new for HIV exposed infants</p>	<ol style="list-style-type: none"> 1. Infants born to mothers with HIV who are at high risk of acquiring HIV should receive dual prophylaxis with AZT (twice daily) and NVP (once daily) for the first 6 weeks of life, whether they are breastfed or formula fed 2. Breastfed infants who are at high risk of acquiring HIV, should continue infant prophylaxis for an additional 6 weeks (total of 12 weeks of infant prophylaxis)
<p>What is new in prevention</p>	<ul style="list-style-type: none"> - Pre-exposure prophylaxis is recommended for most at risk persons with special emphasis on serodiscordant couples and key populations



WHAT IS NEW?

HIV RE-TESTING

RETESTING IN DIAGNOSIS OF HIV

- All HIV positive tests should be **retested**
- Retesting is recommended to verify the diagnosis of HIV infection and rule out possible technical and clerical errors and random errors by the provider or faulty test device
- **Caution:** Not advisable to **retest persons already on ART**
- Retest should be done by:
 - A different provider using same algorithm
 - At a different sites where decision on starting ART is made



WHAT IS NEW?

ART INITIATION: TEST&START

ART INITIATION

- General principles
 - ART should be initiated in all patients living with HIV, regardless of WHO clinical stage and at any CD4 cell count preferably within two weeks of diagnosis.
 - In conditions such as pregnancy, labor and serious ill health, treatment should be initiated with an increased sense of urgency.
 - Patients who are not willing and ready to start ART should receive on going counselling and education to promote retention in care.

ART INITIATION: ADULTS

- Initiating ART in Adults
 - ART should be initiated in all adults living with HIV, regardless of WHO clinical stage and at any CD4 cell count
- **Caution:**
 - Those with high CD4 > 500 cells/mm³ and are on NNRTI (NVP) should be monitored closely in first couple of months
- **Priority:**
 - Severe and advanced HIV clinical disease (WHO stage 3 and 4)
 - Adults with CD4 count ≤ 350 cells/mm³

ART INITIATION: ADOLESCENTS

- Initiating ART in Adolescents (10-19 years)
 - ART should be initiated in all adolescents living with HIV, regardless of WHO clinical stage and at any CD4 cell count
- Priority:
 - All adolescents living with HIV should be given priority
 - Severe and advanced HIV clinical disease (WHO stage 3 and 4)
 - Adults with CD4 count ≤ 350 cells/mm³

ART INITIATION: CHILDREN

- Initiating ART in infant and young children less than 10 years
 - ART should be initiated in all children living with HIV, regardless of WHO clinical stage and at any CD4 cell count
- Priority:
 - All children less than 2 years
 - All children younger than 5 years of age with WHO clinical stage 3 or 4 or CD4 cell count ≤ 750 cell/mm³ or CD4 percentage $<25\%$
 - All children 5 years and older with WHO clinical stage 3 or 4 or CD4 count ≤ 350 cells/mm³

ART INITIATION: TB/HIV CO-INFECTION

- Initiating ART in TB/HIV co infection
 - Basically no change:
 - Start ART in all after two weeks of anti-kocks therapy or as soon as possible

HIV/HCV co-infected people, including those with cirrhosis, the benefits of ART outweigh concerns regarding drug induced liver injury



WHAT IS NEW?

RECOMMENDED ART REGIMEN

WHEN TO INITIATE ART

TARGET POPULATION

RECOMMENDATION

All HIV positive adult and adolescents (including pregnant women)

Initiate ART in all regardless of WHO clinical stage and at any CD4+ cell count.

As a priority, ART should be initiated in all adults with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and adults with a CD4+ cell count of ≤ 350 cells/mm³

All HIV positive Children

Initiate ART in all children regardless of WHO clinical stage and at any CD4 cell count.

As a priority, ART should be initiated in the following situations

- All children < 2 years of age**
- All children younger than 5 years of age with WHO clinical stage 3 or 4 or CD4+ cell count <750 cells/mm³ or CD4+ percentage <25%**
- All children 5 years and older with WHO HIV clinical stage 3 or 4 disease or CD4+ cell count <350 cells/mm³**

WHEN TO INITIATE ART

TARGET POPULATION	RECOMMENDATION
Patients with TB/HIV Co-infection	TB treatment should be initiated first, followed by ART as soon as possible thereafter (and within the first two weeks of initiating TB treatment).
Patients with HIV/HCV Co-infection	For most HIV/HCV co-infected people, including those with cirrhosis, the benefits of ART outweigh concerns regarding drug-induced liver injury.

RECOMMENDED FIRST LINE ART REGIMENS FOR ADULTS, ADOLESCENTS, PREGNANT AND BREAST FEEDING WOMEN

First-line ART	Preferred first-line regimen	Alternative first-line regimens
Adults	TDF + 3TC (or FTC) + EFV	TDF + 3TC (or FTC) + DTG AZT + 3TC + NVP (or EFV) TDF + 3TC (or FTC) + EFV400 ABC +3TC +EFV TDF + 3TC (or FTC) + NVP
Pregnant/breastfeeding women	TDF + 3TC (or FTC) + EFV	AZT + 3TC + EFV (or NVP) TDF + 3TC (or FTC) + NVP
Adolescents (10-19 years)	TDF + 3TC (or FTC) + EFV	TDF + 3TC (or FTC) + *DTG TDF + 3TC (or FTC) + *EFV400 AZT + 3TC + NVP or EFV ABC + 3TC (or FTC) + *DTG ABC + 3TC + (or FTC) +*EFV400 TDF + 3TC (or FTC) + NVP ABC + 3TC (or FTC) + NVP

RECOMMENDED FIRST LINE ART REGIMENS FOR CHILDREN AND SPECIAL CONSIDERATIONS

First-line ART	Preferred first-line regimen	Alternative first-line regimens
Children 3 years to less than 10 years	TDF + 3TC (or FTC) + EFV	ABC + 3TC + NVP AZT + 3TC + EFV (or NVP) TDF + 3TC (or FTC) + EFV (or NVP)
Children less than 3 years	ABC + 3TC + LPV/r AZT + 3TC + LPV/r	ABC + 3TC + NVP AZT + 3TC + NVP AZT + 3TC + RAL
Patients with impaired renal function	ABC + 3TC + EFV	
Patients with osteoporosis (TDF induced or post-menopausal)	ABC + 3TC + EFV	

RECOMMENDED SECOND LINE ART REGIMENS FOR ADULT, ADOLESCENT & PREGNANT WOMEN

3.6.3 Second line ART regimen

Table 3.10: Preferred Second line ART regimen for Adult and Adolescents including Pregnant women

Target Population		Preferred Options
Adults and adolescents (including pregnant women)	If TDF used in first-line therapy	AZT + 3TC + LPV/r or AZT + 3TC + ATV/r
	If AZT is used in first-line therapy	TDF + 3TC + ATV/r or TDF + 3TC + LPV/r
TB/HIV coinfection	*Rifabutin should replace Rifampicin.	Same regimens as recommended above for adults and adolescents, where

RECOMMENDED SECOND LINE ART REGIMENS FOR PAEDIATRICS

Table 3:11 Second Line ART regimens for children

Children	First-Line ART regimens	Second-line ART regimens
Children less than 3 years	ABC + 3TC + LPV/r	AZT or ABC + 3TC + RAL ^a
	AZT + 3TC + LPV/r	
Children 3 years and older	ABC + 3TC + EFV	AZT + 3TC + LPV/r
	AZT + 3TC + EFV	ABC or TDF ^b + 3TC + LPV/r ^c

RECOMMENDED THIRD LINE ART REGIMENS

Table 3.12 Sequence of Switching ART from first Line to third Line regimens

Population	First-line regimens	Second-line regimens	Third-line regimens
Adults and adolescents (>10 years)	2 NRTIs + EFV	2 NRTIs + ATV/r or LPV/r ^a	DRV/r ^b + DTG ^c (or RAL) ± 1–2 NRTIs
		2 NRTI + DRV/r ^b	
	2 NRTIs + DTG	2 NRTIs + ATV/r or LPV/r	DRV/r ^b + 2 NRTIs ± NNRTI
		2 NRTI + DRV/r	Optimize regimen using genotype profile
Pregnant or breastfeeding women	2 NRTIs + EFV	2 NRTIs + ATV/r or LPV/r ^a	DRV/r ^b + DTG ^c (or RAL) ± 1–2 NRTIs
		2 NRTIs + DRV/r ^b	
Children (0–10 years)	2 NRTI + LPV/r	If less than 3 years: 2 NRTIs + RAL ^d	RAL (or DTG) ^f + 2 NRTIs
		If older than 3 years: 2 NRTIs + EFV or RAL	DRV/r ^a + 2 NRTIs
	2 NRTI + EFV	2 NRTIs + ATV/r ^a or LPV/r	DRV/r ^a + RAL (or DTG) ^f ± 1–2 NRTIs



WHAT IS NEW?

**ARV PROPHYLAXIS FOR
EXPOSED INFANTS**

ARV PROPHYLAXIS FOR EXPOSED INFANTS

- High Risk Exposed Infants:
 - ✓ Exposed infants with High risk of acquiring HIV should receive dual prophylaxis
 - AZT (twice daily)+ NVP (once daily) for 6 weeks whether breastfed or Not and should be extended to 12 weeks for breastfed infants only.
- Low Risk Exposed Infants:
 - ✓ Infants delivered by mothers who are stable on ART should receive prophylaxis as we know it before
 - NVP (once daily) for 6 weeks

WHO IS A HIGH RISK EXPOSED INFANTS

High Risk Exposed Infants are defined as:

- Born to women with established HIV infection who have received less than four weeks of ART at the time of delivery

OR

- Born to women with established HIV infection with viral load > 1000 copies/mL in the four weeks before delivery, if viral load measurement available;

OR

- Born to women with incident HIV infection during pregnancy or breastfeeding;

OR

- Identified for the first time during the postpartum period, with or without a negative HIV test prenatally.

ARVS PROPHYLAXIS FOR HIGH RISK INFANTS

Infant age	Nevirapine daily dosing	Zidovudine daily dosing
Birth to 6 weeks Birth weight <2.5kg Birth weight >2.5kg	10mg once daily 15 mg once daily	10mg twice daily 15mg twice daily
6 weeks to 12 weeks	20mg once daily	20mg twice daily

Infants whose mother received NVP containing regimen, should be managed with twice daily ZDV

WHAT IS NEW-BOLDER STATEMENT?

**Pre-exposure
prophylaxis (PrEP)**

PRE-EXPOSURE PROPHYLAXIS (PREP)

- Offered as an additional prevention choice for HIV negative persons who are exposed to prolonged and substantial risk of acquiring HIV
 - Categories of individuals
 - Sero-discordant couples
 - Commercial sex workers
 - IDU
 - Anal sex on a prolonged and regular basis
- Prep should be discontinued once the individual is no longer considered MARPS

INITIATING PREP

- Confirm HIV negative status
- Screen for HBV and ALT. If value ALT is twice the upper limit, consider treatment for HBV in people with detectable HBsAg.
- Do baseline urinalysis and creatinine level-Renal function
- Preferred drug
 - Truvada (TDF+FTC)
 - Alternate TDF only

MONITORING OF PATIENTS ON PREP

- Every 3 months
 - Screen for HIV
 - Women of reproductive age group, screen for pregnancy
 - Support adherence and assess for side effects of medication
- Every 6 months
 - Creatinine clearance
 - Urinalysis for proteinuria if renal threat exist
- Every 12 months
 - Evaluate for the need to continue PrEP



WHAT IS NEW

DIFFERENTIATED CARE

DIFFERENTIATED CARE

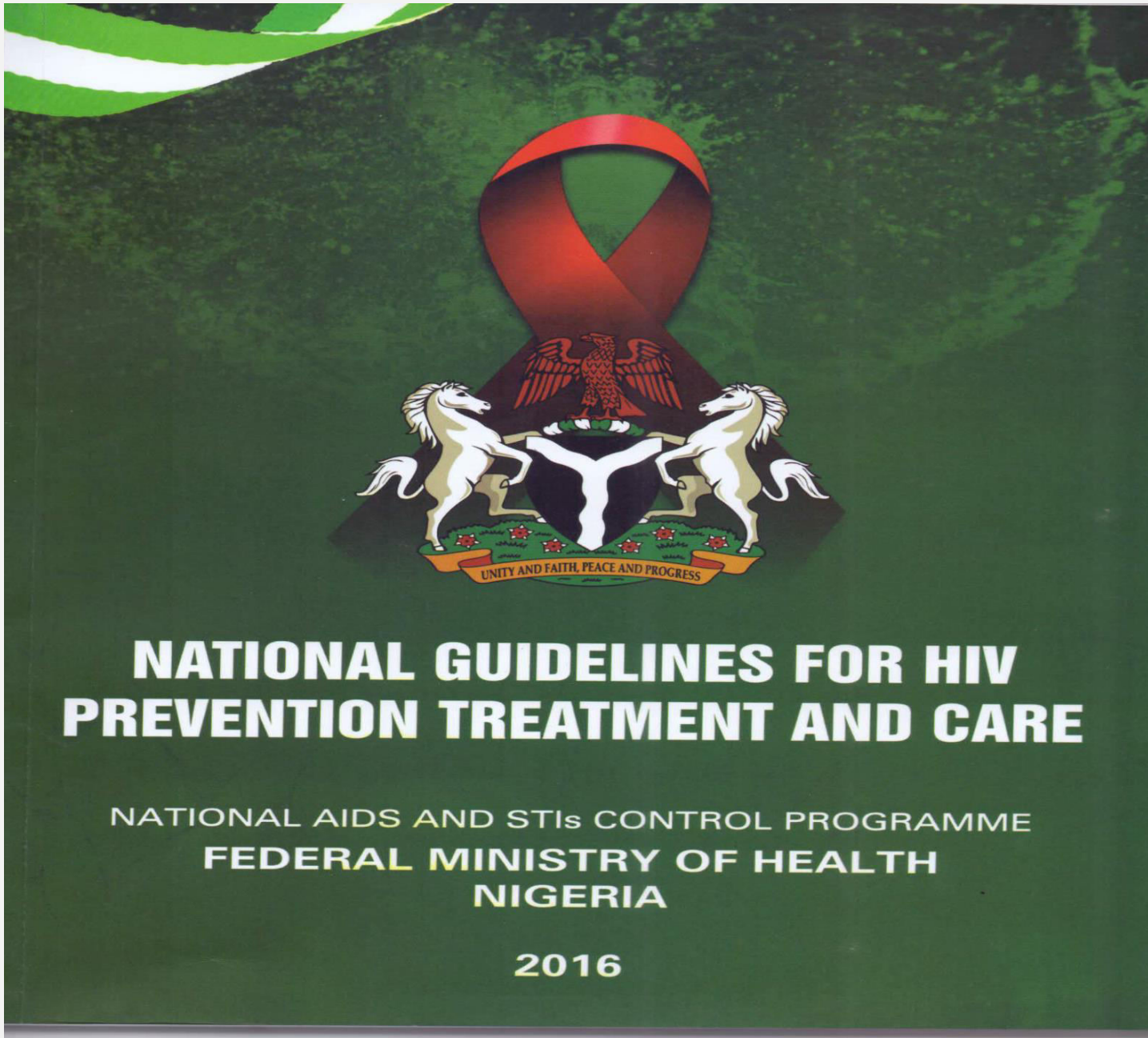
- **Differentiated care is the diversity of a minimum package of HIV/AIDS treatment care and support services according to the diversity of the care need of PLHIV**
- **Four categories of PLHIV with specific services need**
 - **Newly diagnosed presenting well**
 - **Newly diagnosed presenting with advanced disease**
 - **Unstable individuals**
 - **Stable individuals**

SUMMARY

- The guideline is a 'Test and Start' guideline
- All HIV positive patients should be retested before initiating HAART
- All HIV positive patients should be placed on HAART irrespective of the CD4 count and clinical staging
- Dual ARV prophylaxis for high risk exposed infants
- DTG can be used as new alternative first line and third line ARV regimen
- Differentiated care helps to improve quality of care and retention of patients on treatment

ACKNOWLEDGEMENT

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THANK YOU FOR YOUR TIME

