

OVERVIEW OF THE NATIONAL HIV TREATMENT GUIDELINES

DR OGENNA OKEKE
CONSULTANT FAMILY PHYSICIAN
FCT HEALTH AND HUMAN SERVICES
SECRETARIAT.

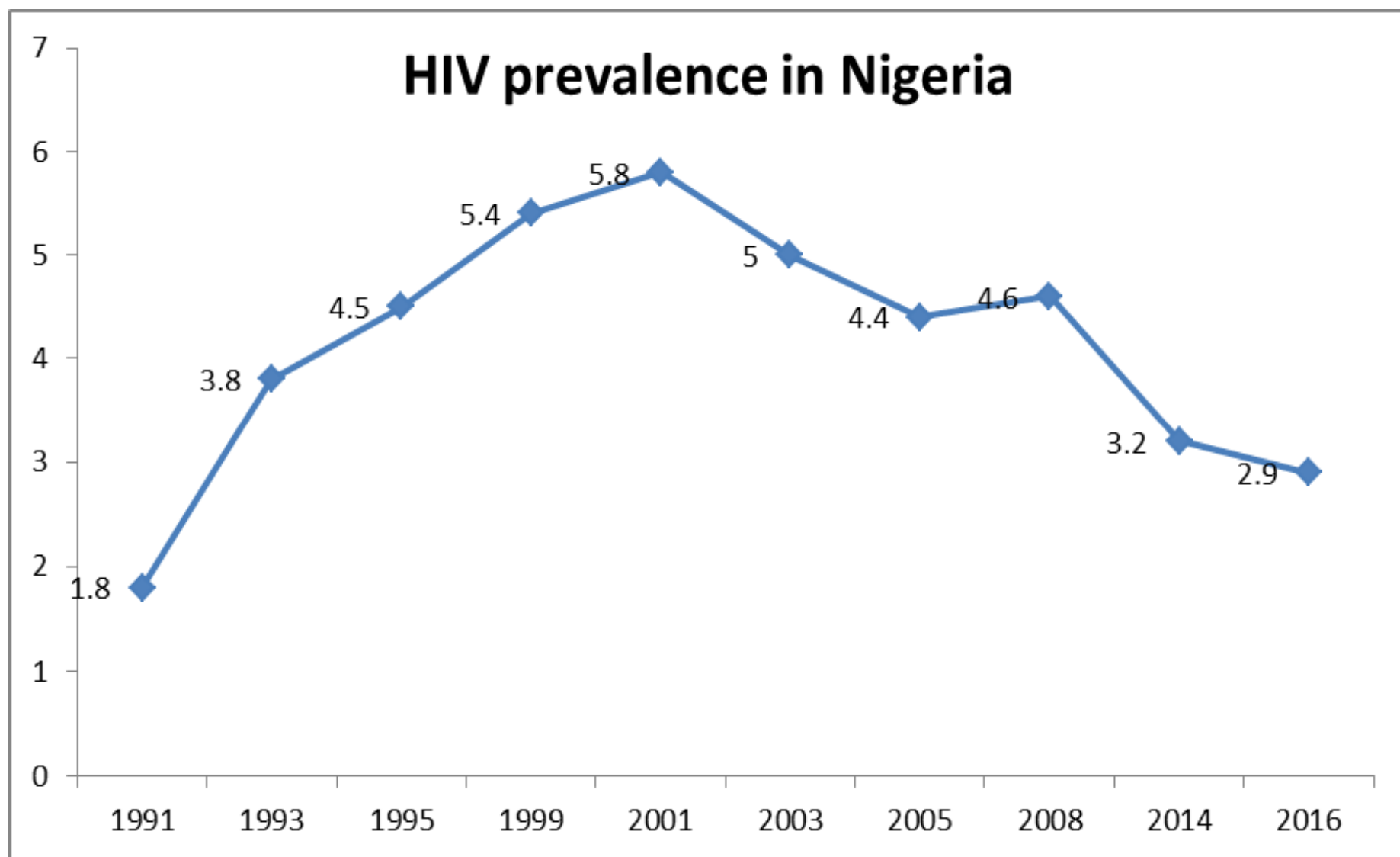
Learning Objectives

At the end of this session, participants should be able to:

- List the goals of antiretroviral therapy
- List the different classes of ARVs currently in use
- Understand the appropriate ARV combinations and the rationale for adherence counselling in HIV treatment
- Understand the rationale behind integrating HIV and SRH services

Introduction

- HIV continues to be a major global public health issue, having claimed more than 34 million lives so far.
- Nigeria has the second highest burden of HIV infection in the world, with about 3.6 million people infected.
- Nigeria contributed 9% of the people living with HIV, 10% of new HIV infections, and 14% of HIV-related deaths in the world in 2013.



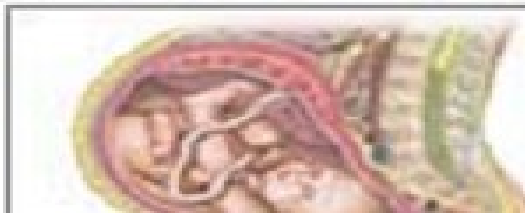
Introduction

- In 2014, UNAIDS committed to ambitious testing and treatment targets to end the AIDS epidemic.
 - By 2020, 90% of all people living with HIV will know their HIV status.
 - By 2020, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy.
 - By 2020, 90% of all people receiving antiretroviral therapy will have viral suppression.

Introduction

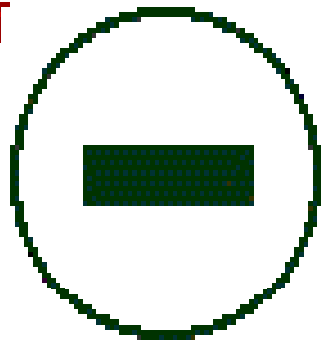
- Nigeria is a long way off meeting the global target of enrolling 90% of people diagnosed with HIV on antiretroviral treatment.
- Just 30% of all people living with HIV were receiving treatment in 2016. Amongst children this was even lower, with just 21% on ART.
- Of the people on HIV treatment, only 24% had achieved viral suppression in 2016.

Modes of HIV/AIDS Transmission

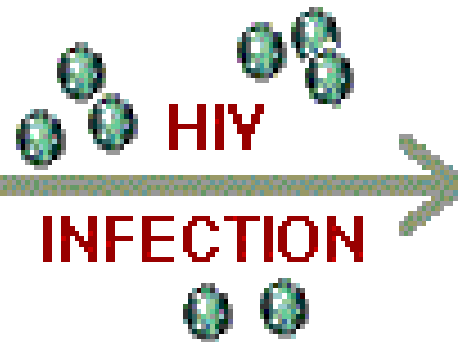


Stages of HIV Infection

START



**HIV
NEGATIVE**



**SEROCONVERSION
ILLNESS**

SYMPTOMATIC

What is Antiretroviral therapy?

- Antiretroviral therapy (ART) is the treatment of HIV infection using a combination of antiretroviral drugs (ARVs)
- ART should be offered in a comprehensive manner that includes access to on-going adherence counseling, baseline and routine/periodic laboratory investigations, prevention and management of opportunistic infections(OIs), treatment monitoring and follow-up.
- Standard antiretroviral therapy (ART) consists of the combination of at least 3 ARV drugs that suppress HIV replication at different stages of the lifecycle of the virus.

Goals of ART

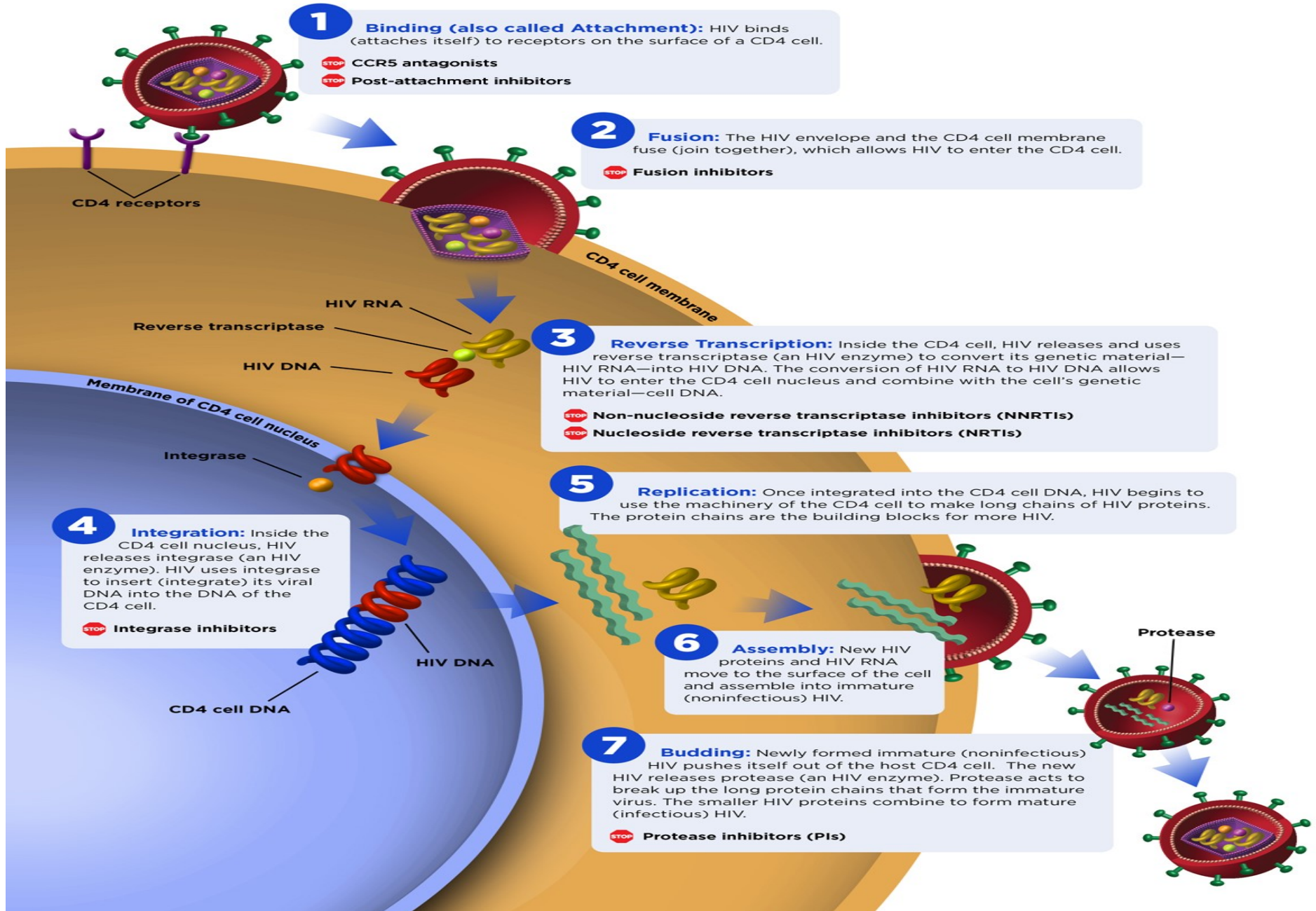
- **Virological:** Reduction in viral load to undetectable levels. <400 copies /ml after 24 weeks and <50 copies/ml after 48 weeks of initiation of therapy.
- **Immunologic:** Quantitative and qualitative immune reconstitution with improved immune function with a progressive increase in CD4+ cell count at a rate of 50 to 100 cells/ μ l /year.
- **Clinical:** Prolongation and improved quality of life by reducing HIV-associated morbidity and mortality
- **Therapeutic:** Appropriate choice of ARV regimen to achieve the goals of therapy while preserving future therapeutic options, minimising ARV toxicities and promoting excellent adherence
- **Epidemiologic:** Reduce transmission of HIV

Classes of Antiretroviral Drugs

- Antiretroviral drugs are classified according to their modes of antiviral action. Each class targets a different step in the viral life cycle.
- The classes of antiretroviral drugs are:
 - ☐ Nucleoside and nucleotide reverse transcriptase inhibitors (NRTI)
 - ☐ Non-nucleoside reverse transcriptase inhibitors (NNRTI).
 - ☐ Protease inhibitors (PIs)
 - ☐ Integrase inhibitors
 - ☐ Entry inhibitors (or fusion inhibitors)
 - ☐ Maturation inhibitors

The HIV Life Cycle

HIV medicines in seven drug classes stop  HIV at different stages in the HIV life cycle.



EXAMPLES OF ARVs

NRTIs

- Lamivudine (3TC)
- Zidovudine (ZDV)
- Abacavir (ABC)
- Emtricitabin(FTC)
- Stavudine (D4T)
- Tenofovir (TDF)

NNRTIs

- Efavirenz
- Etravirine
- Nevirapine
- Rilpivirine

EXAMPLES OF ARVs

PROTEASE INHIBITORS

- Lopinavir
- Saquinavir
- Atazanavir
- Darunavir
- Ritonavir,
- Fosamprenavir
- Indinavir
- Nelfinavir

INTEGRASE INHIBITORS

- Raltegravir
- Dolutegravir (DTG)
- Elvitegravir(EVG)

ENTRY INHIBITORS

- Maraviroc (entry inhibitor)
 - Enfuvirtide(fusion inhibitor)
- are the two currently available agents in this class

To note.....

- Pharmacokinetic enhancers are drugs used in HIV treatment to increase the effectiveness of certain classes of ARV drugs.eg Ritonavir for PIs.
- Typically, a backbone of 2 NRTIs combined with an NNRTI or a PI is used.
- Monotherapy or dual ARV therapy for HIV infection is not recommended for treatment because of the increased risk of development of drug resistance.

INITIATION OF ART-2016 guidelines

- Early initiation of ART is associated with improved survival for patients and reduction of the incidence of HIV infection in the community.
- THE NEW GUIDELINES STIPULATE THAT ART SHOULD BE INITIATED IN ALL ADULTS, ADOLESCENTS AND CHILDREN WITH A DIAGNOSIS OF HIV. THIS IS REGARDLESS OF THE CLINICAL STAGE OF THE DISEASE AND ALSO REGARDLESS OF CD4+ CELL COUNT !!! (TEST AND TREAT APPROACH).
- However, patient's informed consent should be established before starting ART.

INITIATION OF ART-2016 guidelines

- 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
- Dolutegravir (DTG) and Efavirenz (EFV) 400mg are new alternative options in first line ART regimens
- Initiation of ART for all HIV-positive and pregnant, post-partum and breast-feeding women, regardless of CD4+ cell count. This ART treatment is for life.
- Repeat HIV testing for HIV-negative pregnant women in the last trimester
- Viral load testing for pregnant women in the last trimester of pregnancy

INITIATION OF ART-2016 guidelines

- 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
- 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).
- Pre-exposure prophylaxis is recommended for most at risk persons with special emphasis on sero-discordant couples and key populations.

Priorities for initiation of ART

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

Priorities for initiation of ART

- In conditions such as pregnancy, labour and serious ill health, treatment should be initiated with an increased sense of urgency as delay may lead to poor outcomes.
- HCWs are encouraged to support positive decision-making by clients and implement interventions that remove barriers to early initiation of ART.
- In patients with dual TB/HIV disease TB treatment should be initiated first, followed by ART as soon as possible thereafter (within the first two weeks of initiating TB treatment).
- For most HIV/HCV co-infected people, including those with cirrhosis, the benefits of ART outweigh concerns regarding drug-induced liver injury.

Pre-Treatment Evaluation

- Baseline assessment:
 - ☐ Retesting to verify HIV status
 - ☐ Assessment of readiness for therapy
 - ☐ Development of patient-specific adherence strategy
- Further baseline assessment
 - ☐ Complete history and physical examination
 - ☐ WHO staging of the disease.
 - ☐ Baseline investigations: CD4 cell count, screening for OIs(TB, HCV, HBV, Cragg),FBC, ALT, E/U/Cr, FLP, FBG, PGT,
 - ☐ Rectal and vaginal examination (VIA or/and PAP smear)
 - ☐ Family planning and counseling services, where required
 - ☐ Evaluation of nutritional(Anthropometry) and psychosocial and immunization status

First line ART for adults/adolescents

Preferred first line regimen:

- TDF +3TC(or FTC) + EFV

Alternative first line regimens

- TDF +3TC (or FTC)+DTG
- AZT+3TC+EFV
- TDF +3TC (or FTC)+EFV 400
- AZT+3TC + NVP
- TDF+ 3TC (or FTC)+NVP
- ABC +3TC +EFV

First line ART for children

3-10 YEARS OLD

PREFERRED 1ST LINE REGIMEN:

- ABC + 3TC + EFV

ALTERNAT 1ST LINE REGIMENS

- ABC + 3TC + NVP
- AZT + 3TC + EFV
- AZT + 3TC + NVP
- TDF + 3TC (or FTC) + EFV
- TDF + 3TC (or FTC) + NVP

LESS THAN 3 YEARS OLD

PREFERRED 1ST LINE REGIMEN:

- ABC + 3TC + LPV/r or AZT + 3TC + LPV/r 46

ALTERNATE 1ST LINE REGIMENS

- ABC+ 3TC + NVP
- AZT + 3TC + NVP
- ABC +3TC + RAL
- AZT+3TC+RAL

First line ART for pregnant women

Preferred first line regimen:

- TDF + 3TC (or FTC)+ EFV

Alternative first line regimen:

- AZT + 3TC + EFV (or NVP)
- TDF + 3TC (or FTC)+ NVP

Things to note.....

- TDF based regimens should be used with caution in individuals with HTN and DM.
- TDF is contraindicated in patients with CKD
- AZT should be avoided in individuals with severe anaemia (Hb <8g/dl).
- Where TDF and AZT are contraindicated as in chronic kidney disease, ABC can be used as a substitute. However provision should be made for dose adjustment of 3TC in cases of renal impairment.
- Review of available data has not confirmed occurrence of teratogenicity with use of EFV in 1st trimester of pregnancy.
- NVP should not be used when treating for TB with Rifampicin based regimen

Monitoring patients on ART

- Once ART is initiated, assessment should look out for:
 - ☐ Persisting or new signs/symptoms of HIV related dx
 - ☐ Potential drug toxicities.
 - ☐ Medication Adherence
 - ☐ Response to therapy (Clinical, Immunological and Virologic).
 - ☐ Weight changes, growth and development including height in children
 - ☐ Abnormal Laboratory parameters

RECOMMENDED SCHEDULE FOR MONITORING OF LABORATORY PARAMETERS

[illegible]

ARV medication Adherence

- Term used to describe the patients' behaviour of taking drugs correctly based on mutual agreement between the patient and health care provider. It involves taking
 - the right drugs, the right dose
 - At the right frequency
 - at the right time
- Adherence also means patients attending all scheduled clinic visits, conducting required investigations and adhering to treatment plans.
- Failure to adhere results in treatment failure

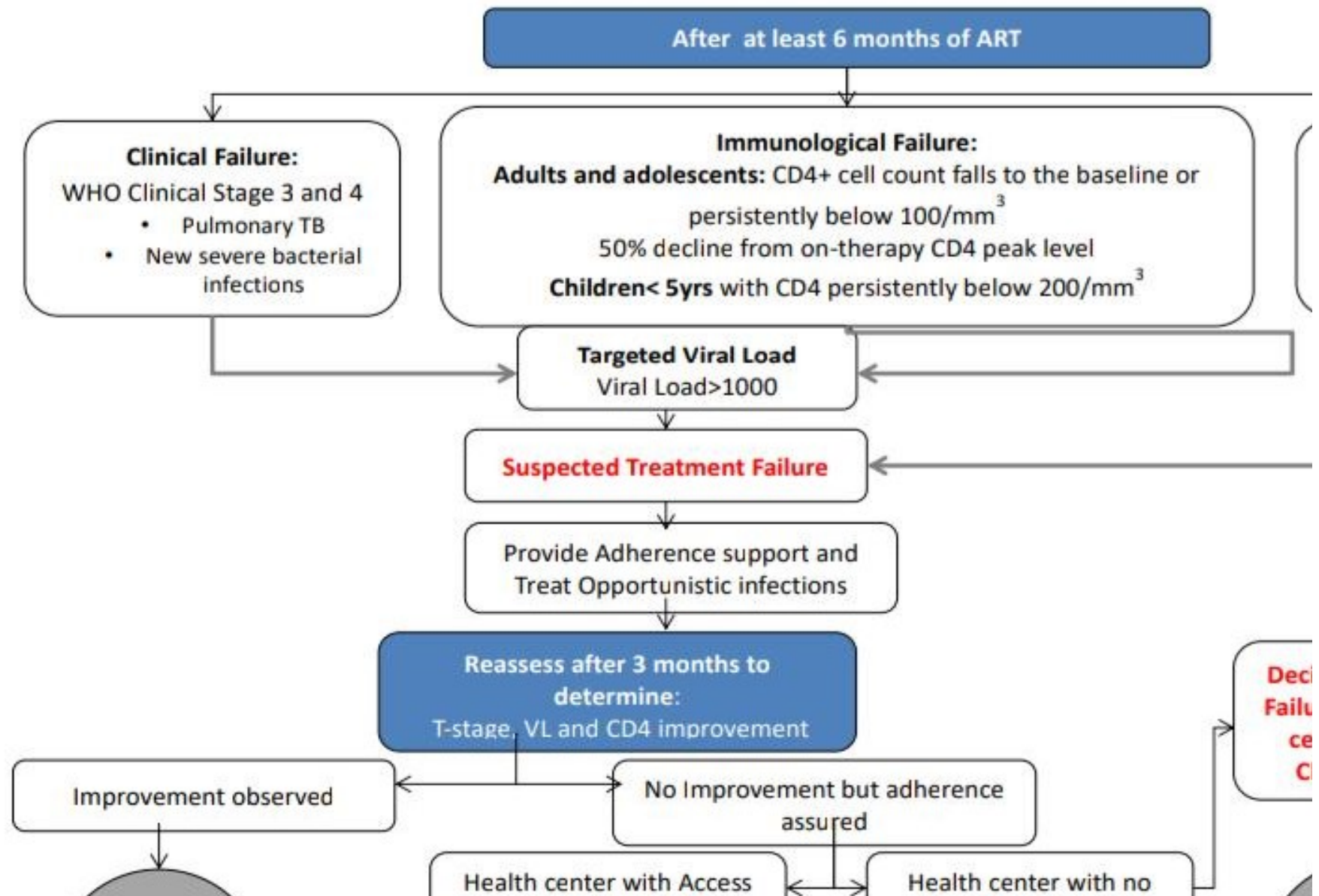
Strategies for Improving Adherence

- Free treatment
- Treatment education for patients and treatment partners
- Treatment-supporter involvement eg family
- Peer health education
- Routine assessment and reinforcement of adherence during follow up
- Directly Observed Therapy if possible
- Fixed dose combination (FDC)
- Adapting therapy to patient's lifestyle
- Reminders (e.g. a cell phone, alarm clock)
- Convenient monthly packs (or using pill storage boxes)

What is Treatment Failure?

- **Clinical** treatment failure
 - New or recurrent OI, WHO stage 4
- **Immunological** treatment failure
 - Fall of CD4 count to pre-therapy baseline (or below) OR
 - >50% fall from on-treatment peak value (if known)
 - Persistent CD4 levels below 100 cells/ml
- **Virological** treatment failure
 - Incomplete viral suppression after 3 – 6 months
 - Repeated, continual detectable viraemia
 - Reappearance of a detectable viral load

Figure 3.1: Algorithm for Treatment Failure Evaluation in Adults, Adolescents and Children



Second line ART regimens

Recommended second-line for patients failing first line therapy

First-line	Second-line
TDF + 3TC + EFV or NVP	AZT + 3TC + LPV/r or ATV/r
AZT + 3TC + EFV or NVP	TDF + 3TC + LPV/r or ATV/r

SRH and HIV services integration

- There is broad international consensus that linking family planning (FP) and HIV services is essential for meeting international development goals and targets, including the United Nations Millennium Development Goals.
- Family planning reduces the number of unintended pregnancies and abortions, improves maternal and infant health and also prevents vertical transmission of HIV.
- Integrating services also provides the opportunity to increase male and youth involvement in reproductive health and HIV services.

SRH and HIV services integration

- As access to ART has substantially increased, HIV infected clients are living longer and feeling better.
- HIV providers are finding repeat unintended pregnancies among PMTCT clients and ART clients in their programs.
- The integration of FP and HIV services is an evidence-based approach to averting unintended pregnancies of HIV clients .
- HIV providers should be equipped with the skills and knowledge to discuss fertility desires and contraceptive methods for women and couples with HIV.
- Linking FP with HTS services expands access to FP to both HIV positive and negative clients, reaching a segment of the population that may not attend traditional FP services, such as men or sex workers

SRH and HIV services Integration

- Prior to integration efforts in Nigeria, HIV and FP services have been provided separately in the same facility.
- HIV services were provided in one unit by a set of providers and FP services were provided in a separate unit by a different set of providers.
- However, it was not uncommon for the same providers to multi-task in several units such as provide ANC, PMTCT and FP services.
- Drawing from results of the programmatic assessment in the integration of FP into HTS in Kenya, the FMOH developed national guidelines for reproductive health and HIV service integration.

Benefits of integrating HIV and SRH

- Increased access to SRH services among those living with HIV/AIDS can protect against unwanted pregnancy and therefore reduce the number of HIV-infected babies.
- Increased access to information about HIV among those receiving SRH services can help to curb sexually transmitted HIV infection.
- Reduction of HIV associated stigma and discrimination
- Improved quality of care
- Overall, integration makes for more efficient and effective use of resources to address clients' health needs and increases access to both types of services.

Common SRH-HIV Integration strategies

- ONE-STOP SHOP
 - Hospitals in Kenya integrate HIV services into family planning services. Within a family planning context, HIV counseling and testing, STI screening and management, HIV care and treatment.
 - In Kenya and Swaziland, HIV services are also integrated into post natal care and family planning. Services offered include HTS, which includes repeat testing for mother and infants and HIV care and treatment, as well as referrals for HIV positive clients.

Common SRH-HIV Integration strategies

- IMPROVE THE CAPACITY OF HCWS TO PROVIDE INTEGRATED RH AND HIV SERVICES.
 - IN Nigeria, FHI ensured capacity building of the staff in their 141 project sites across the country in order to enable them provide these services in an integrated manner.
 - By the end of the project, 36% of sites operated as one-stop shops, while the remaining sites (n=90) implemented the referral-based model

Common SRH-HIV Integration strategies

- **STRENGTHEN REFERRAL PROCESSES**
 - Within a facility, referral of people discovered to be HIV positive should be strengthened so that patients are not lost.
 - This was done in the Kenya, Swaziland and FHI Nigeria examples

Common SRH-HIV Integration strategies

- INTEGRATED TOOL FOR MONITORING
 - In Ghana, multidisciplinary teams were dispatched to monitor programmes with an integrated tool that addressed all health services. This involved the use of multidisciplinary teams to monitor the implementation of all programmes using a newly developed integrated monitoring tool.

Common SRH-HIV Integration strategies

- INTEGRATED MONITORING SYSTEMS FOR IMPROVED FOLLOW-UP CARE FOR MOTHERS AND INFANTS
 - In Lesotho, ALL patients who did not return for follow up were tracked regardless of their diagnosis. This practice reduced HIV-related stigma by offering anonymity that counteracted the common perception that VHWs only provided follow-up care and home visits to people living with HIV.

Common SRH-HIV Integration strategies

- IMPLEMENTATION OF LIFELONG ART FOR ALL PREGNANT AND BREASTFEEDING WOMEN THROUGH INTEGRATION INTO THE MNCH PLATFORM,
 - In Malawi, transitioning to option B+ was grounded in the integration of SRH and HIV services delivering long-term ART within MNCH settings.
 - This was only possible through task-shifting i.e the initiation of and management of ART to nurses and other cadres of health workers. As a result, MNCH facilities provided HTC to all pregnant women; initiated pregnant and breastfeeding women living with HIV on ART; provided routine follow-up; provided EID to HIV-exposed infants; and offered HTC during family planning consultations and FP services in ART clinics

Key Points

- ART has multiple goals, which are virological, immunologic, clinical, therapeutic, and epidemiologic
- The 2016 guidelines recommend that all those diagnosed with HIV commence ART as soon as possible.
- The benefits of SRH-HIV services Integration cannot be overemphasized. The onus is on us to push for its implementation in our various centers to ensure adequate patient outcome.

THANK

YOU



References

- EngenderHealth, GNP+, ICW, IPPF, UNAIDS, Young Positives. Advancing the Sexual and Reproductive Health and Human Rights of People Living With HIV: A Guidance Package. Amsterdam: The Global Network of People Living with HIV/AIDS (GNP+); 2009. Available from:http://www.who.int/reproductivehealth/topics/linkages/guidance_package.pdf?ua=1
- FMOH. Technical Report: 2010 National Sentinel Seroprevalence Survey: Department of Public Health: National AIDS/STI Control Programme 2010.
- Kennedy CE, Spaulding AB, Brickley DB, Almers L, Mirjahangir J, Packel L, Kennedy GE, Mbizvo M, Collins L, Osborne K. Linking sexual and reproductive health and HIV interventions: a systematic review. *Journal of the International AIDS Society* 2010, 13:26.
- National Population Commission(NPC), ICF M. Nigeria Demographic and Health Survey 2008. Abuja: National Population Commission(NPC) and ICF Macro 2009.
- O. Chabikuli, D. Awi, O Chukwujekwu, Z. Abubakar, U Gwarzo, M Ibrahim, M Merrigan, C Hammelman. The use of routine monitoring and evaluation systems to assess a referral model of family planning and HIV service integration in Nigeria. *AIDS* 2009, 23(suppl 1):S97-S103
- O. Chukwujekwu, O. Chabikuli, M. Merrigan, D. Awi and C. Hamelmann. Integrating reproductive health and HIV indicators into the Nigerian health system--building an evidence base for action. *African Journal of Reproductive Health* 2010, 14(1):109-16
- M. Saleh, Z. Abubakar, H. Khamofu, J. Kwakfut, T. Badru, I. Mogaba, D. Ajagun, K. Torpey, O. Chabikuli: The uptake of HIV counseling and testing services at FP clinics implementing two FP-HIV integration models in Nigeria. 2011 unpublished article.