ART Treatment- Current trends in Myanmar

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National AIDS Programme

GreenShoots FOUNDATION

“Support needing populations through medical assistance and the transfer of knowledge to local medical practitioners.”

Our vision for the

Medical Assistance & Medical Education (MAME) Programs

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ART Treatment- Current trends in Myanmar

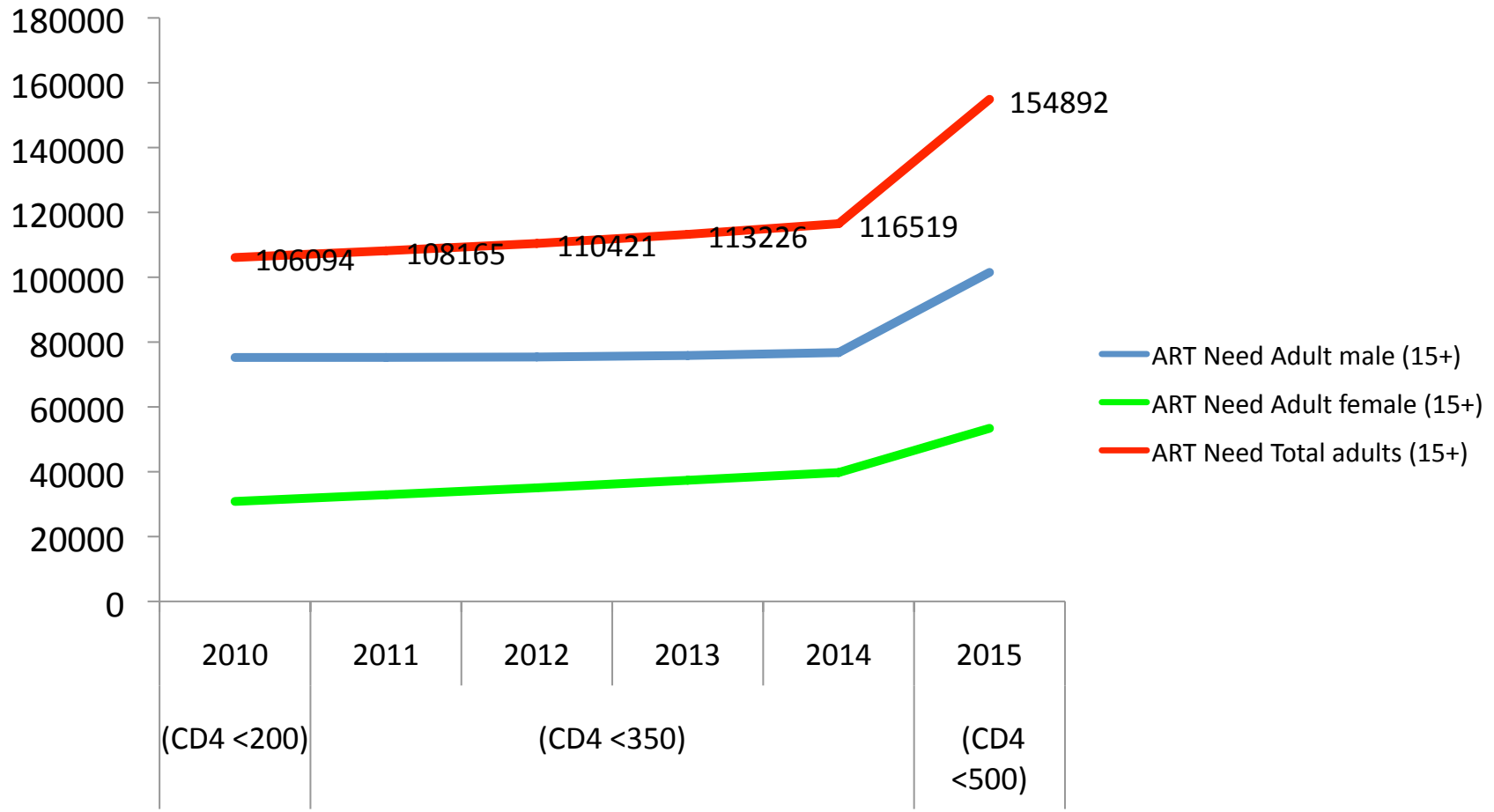
Background

- Three years have passed since the last National guidelines for HIV treatment and prevention (2011) were updated in the Myanmar context.
- During that time period, the WHO has published the CONSOLIDATED GUIDELINES in June, 2013
- In the meantime, Myanmar's concerted efforts against HIV/AIDS with the unwavering help of the UN Agencies, National and International NGO
- The new Myanmar national guideline (2014) will both augment and complement the 2011 Guidelines and will cover a wide range of areas in the fight against HIV/AIDS including:
  - new developments and implementation concerns regarding drug optimization,
  - HIV testing, laboratory monitoring, toxicity and drug resistance surveillance, supply chain management and
  - community delivery of antiretroviral therapy services.

Background (Cont;)

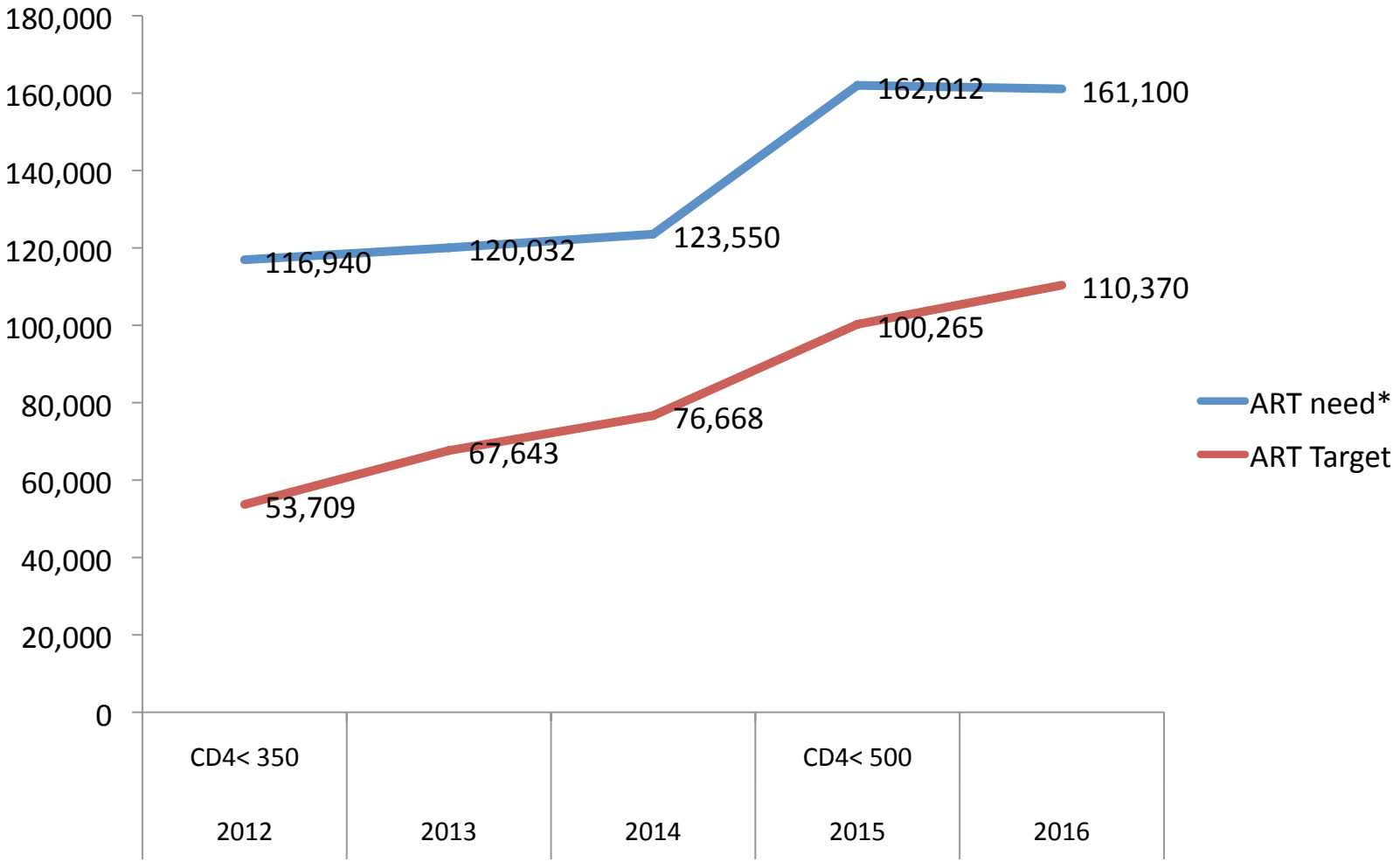
- In Myanmar, a country with limited resources and capacity, the available resources must be best employed to achieve the best possible solutions for People Living With HIV.
- A balance between the best possible treatment and available resources which can be implemented for the largest number of people possible – cost effective
- The new guidelines will provide flexibility and versatility for all healthcare providers and accommodate the decentralized approach being undertaken by the National Programme (NAP).
- The notable changes include:
  - Updates on the Initiation of ART
  - New drugs/ regimens
  - New recommendations on PMTCT
  - Considerations for co-infection with TB and HBV

Total number of ART need (AEM 2014)



ART targets to be provided with MOH & GF new funding

Increasing availability of ART



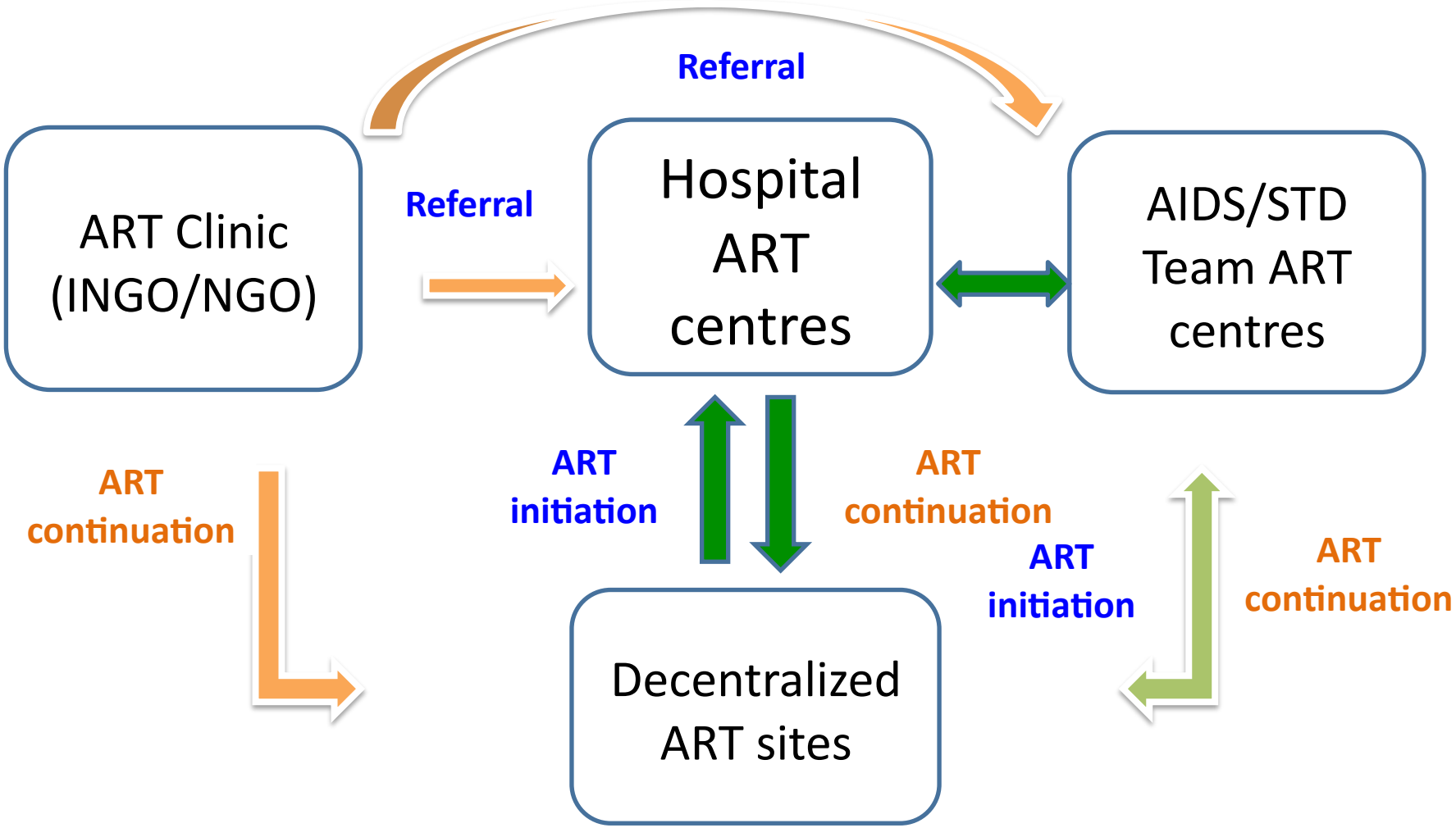
Antiretroviral Therapy in Myanmar

HIV is now a treatable condition and the majority of people who have HIV remain fit and well on treatment.

As part of the Department of Health,

- NAP linked to public health hospitals at the regions/state nad district level, which provide specialized clinical services such as ART provision, and hospital based Prevention of Mother to Child Transmission sine 2005
- Nationwide ART Provision at Partner's clinics also started in 2005
- Moreover, Decentralization at the township level has been practiced by NAP with reducing the barriers for individuals seeking HIV testing and treatment in 2013.
- Initiation will be done at a ART center- maintenance and referral at decentralized sites
- Future interventions are with more focus on the KAP with high prevalence, PWID, FSWs and MSMs especially. Increasing access for the marginalized pop;
- Explore new service models for
  - collaborations with partners undertaking prevention packages for key populations
  - modified decentralization : ART maintenance and continuation site to enhance adherence to ART and strengthen community involvement and referral

ART Decentralization concept.



Decentralized sites will not be initiating ART but will maintain stable patients on ART. However, as they gain experience and the patient load increases, they can be graduated to an ART prescribing site after assessment by NAP.

Special Intervention: TB/HIV collaboration

- The interactions between tuberculosis (TB) and HIV adversely affect outcomes for both diseases.
- As TB is one of the key entry points for HIV-related care, the National AIDS and TB Programmes aim to integrate diagnosis, care, and treatment services for TB and HIV.
- The TB/HIV interventions proposed are in line with the minimum package of TB/HIV services at township level as discussed and agreed upon by the National AIDS Programme (NAP)/National Tuberculosis Programme (NTP) and partners in 2008.
- The joint strategy of the two national programmes includes:
  - intensified case finding of TB among HIV-infected individuals,
  - VCCT services for TB patients,
  - improved TB/HIV awareness and health education,
  - IPT and Cotrimoxazole prophylaxis, and
  - referral to HIV care and treatment including ART.
- At present, integrated TB and HIV services are implemented 130 TB/HIV sites at the end of 2013. In 2015 over 160 sites will expand integrated TB/HIV services (total 300).

Summary of key recommendations for ART in the new guidelines 2014

Summary of key recommendations for ART in the new guidelines

Adults and Adolescents

- **HIV positive individuals** – CD4 ≤ 500 cells/mm3 ; priority to those with CD4 less than 350/cmm
- **HIV positive symptomatic ARV naïve individuals**- WHO clinical stage 2 if CD4 ≤ 500 cells/mm3 *OR* WHO clinical stage 3 or 4 irrespective of CD4 cell count
- **HIV positive pregnant women** – CD4 ≤ 500 cells/mm3 irrespective of clinical symptoms *OR* WHO clinical stage 3 or 4 irrespective of CD4 cell count

Children

- Initiate ART in all HIV infected children < 5 years
- For children > 5 years, follow same criteria as adults.

When to Start ART in Children

- Infants and young children have an exceptionally high risk of poor outcomes from HIV infection.
- Up to 52% of children die before the age of two in the absence of any intervention.
- By five years of age, the risk of mortality and disease progression in the absence of treatment falls to rates similar to those of young adults.

It is therefore recommended that

- ART should be initiated in all children infected with HIV below five years of age, regardless of WHO clinical stage or CD4 cell count
  - Infants diagnosed in the first year of life
  - Children infected with HIV one year to less than 5

Summary of key recommendations for ART in the new guidelines

- Special Populations
- HIV/TB coinfection – Treat all HIV/TB coinfected individuals irrespective of CD4 count
- HIV/HBV coinfection – Provide ART to HBV/HIV coinfected if ALT level more than 2.5 times the normal
- Sero discordant couples – Treat all sero discordant couples irrespective of CD4 count.
- Key populations (FSWs, MSMs and PWIDs) – Treat all irrespective of CD4 count.

What ART to start?

Adults and Adolescent

Already adapted the single preferred regimen as TDF + 3TC/EFV from 2014

- HIV positive ARV naïve adults and adolescents – TDF+3TC (FTC)+EFV is the preferred first line regimen, until there is any contraindication.
- If the preferred first line cannot be used, the alternate first line regimen, in order of preference are: AZT+3TC+EFV; AZT+3TC+NVP: ABC +3TC+EFV

Co-infections

- HIV/TB coinfection – Same as above ; ART to be started 2 to 8 weeks after start of TB treatment ;
- HIV/HBV coinfection – NNRTI regimens that contain both TDF+3TC (or FTC)

** ABC can be kept as backup option if AZT or TDF cannot be used.*

Summary of first-line ART regimens

Adults and adolescents (including pregnant and breastfeeding women and adults with TB coinfection and HBV coinfection)

- TDF+3TC (or FTC)+EFV — **- Preferred first-line regimens**
- AZT + 3TC + EFV — **-Alternative first-line regimens**
- AZT + 3TC + NVP
- ABC + 3TC + EFV[a]

Children ≥3 years

- ABC + 3TC + EFV — **- Preferred first-line regimens**
- ABC + 3TC + NVP — **- Alternative first-line regimens**
- AZT + 3TC + EFV
- AZT + 3TC + NVP
- TDF + 3TC (or FTC) + EFV
- TDF + 3TC (or FTC) + NVP

Children <3 years

- ABC (or AZT) +3TC + LPV/r — **- Preferred first-line regimens**
- ABC + 3TC + NVP — **-Alternative first-line regimens**
- AZT + 3TC + NVP

Prevention of mother-to-child transmission (PMTCT)

WHO recommends a four-pronged approach to a comprehensive PMTCT strategy,:

- 1. Primary prevention of HIV infection among women of childbearing age
- 2. Preventing unintended pregnancies among women living with HIV
- 3. Preventing HIV transmission from women living with HIV to their infants
- 4. Providing appropriate treatment, care, and support to mothers living with HIV, their children and families

Deciding on Duration of ART started to pregnant women:

- If the CD4 count of the pregnant women < 500/cmm or if she has WHO stage 3 or 4 illness,
  - the ART started should be continued as the pregnant women is eligible for it like any other HIV positive individual.
- However, if the CD4 count > 500/cmm,
  - the ART should be continued and stopped after 1 week of cessation of breast feeding. This is same as the **Option B** that was recommended.
  - In certain conditions, continue the ART started in a pregnant women even if the CD4 count is more than 500/cmm at the time of initiation **(Option B +)**.

Major issue now is not "when to start" or "what to start" but "whether to stop"

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ART Recommendations for special populations

HIV/TB coinfection

- Start ART in HIV infected individuals with active TB irrespective of CD4 count.
- Start TB treatment first followed by ART as early as 2 weeks and not later than 8 weeks.
- Use EFV as the preferred NNRTI in patients started on ART while on TB treatment.

HIV and Hepatitis B coinfection

- HIV and hepatitis B co-infection (irrespective of CD4 count) if the ALT level is > 2.5 times the normal.
- Individuals with HIV/HBV coinfection have an increased risk of developing
  - chronic HBV infection;
  - an increased risk of fibrosis and
  - increased risk of death compared to HBV infected individuals without HIV infection.
- It is recommended to initiate ART in all HIV/HBV coinfected patients irrespective of CD4 count if the serum ALT level is more than 2.5 times the normal.

Pre-ART Care

i. WHO clinical staging of HIV disease

ii. TB screening: Screen for TB with any one of the following symptoms;
   - Current cough
   - Fever
   - Weight loss
   - Night sweats
   - Lymph node enlargement

v. Management of Opportunistic Infections and Prophylaxis

vi. *Laboratory Assessment

*Laboratory Assessment

Laboratory assessment for pre- ART

• Hb %	Baseline
• CD4 count	Baseline
• Fasting blood sugar	Baseline
• ALT, AST	Baseline Desirable
• Creatinine (for Cr clearance)	Baseline Desirable
• Urinalysis (proteinuria, glucosuria)	Baseline
• Chest X- rays	Initially and when indicated

Goals of antiretroviral therapy

1. Improvement in quality of life and prolongation of life
2. Reduction of HIV related morbidity and mortality
3. Greatest possible reduction in viral load (<50 copies/ml) for as long as possible
4. Restoration and preservation of immune function
5. Minimize side effects of drugs
6. Reduce HIV transmission

Monitoring response to ART, the diagnosis of treatment failure and Second Line ART

Clinical assessment and laboratory tests play a key role

ART initiation

- CD4 -Recommended
- Haemoglobin test for AZT - Desirable (If feasible)
- Pregnancy test - Desirable (If feasible)
- Blood pressure measurement - Desirable (If feasible)
- Urine dipsticks for glycosuria and estimated glomerular filtration rate and serum creatinine for TDF[e] - Desirable (If feasible)
- Alanine aminotransferase for NVP -- Desirable (If feasible)

Receiving ART

- CD4 (every 6 months) -Recommended
- HIV viral load (6-12 months after ART initiation/ targeted) -Recommended
- Urine dipstick for glycosuria and serum creatinine - Desirable (If feasible)
- for TDF

Treatment failure

- CD4 -Recommended
- HIV viral load -Recommended
- HBV (HBsAg) serology[a] (before switching ART regimen if this testing was not done or if the result was negative at baseline) - Desirable (If feasible)
-

When to switch to second line ART

- When the first line ART regimen fails it becomes necessary to switch to second line ART.
- Second line regimens are expensive (mostly patented)
- Therefore utmost attempt must be made to optimize adherence and prevent resistance to first line regimens.

ART switching-

- Where available , use viral load (VL) to confirm treatment failure
- A persistent VL of > 1000 copies/ml confirms treatment failure
- Where VL is not available, use immunological criteria (CD4 count) to confirm clinical failure.

Second-line ART Regimens

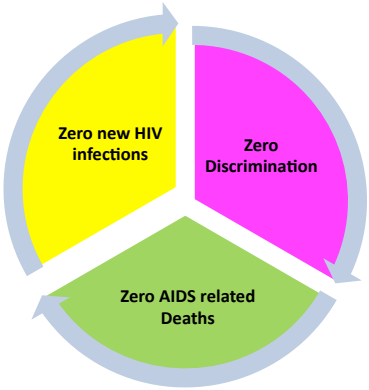
A boosted protease inhibitor (bPI) plus two NRTIs are used for second line ART for adults, adolescent and also for children when NNRTI-containing regimen were used in first line ART.

In children using a PI-based regimen for first-line ART, switching to NNRTI or maintaining the PI regimen is recommended according with age.

A simplified second line ART is recommended –

- If d4T or AZT has been used in first line therapy, use TDF + 3TC (or FTC) plus a boosted PI (LPV/r)
- If TDF has been used in first line therapy, use AZT + 3TC plus a boosted PI (LPV/r) should be used as second line therapy.
- If LPV/r cannot be used, atazanavir/r is the alternate bPI

Conclusion



Key to success will be…

- Scaling up HIV counseling and testing
- Decentralization of testing and treatment services
- Scaling up ART centers/sites
- Coordination amongst service providers
- Linkages between components and other programs (MCH/ OST/TB) and community involvement
- Improved and harmonized recording and reporting system with partners for ART services


Thank you very much for your kind attention

Thank you

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