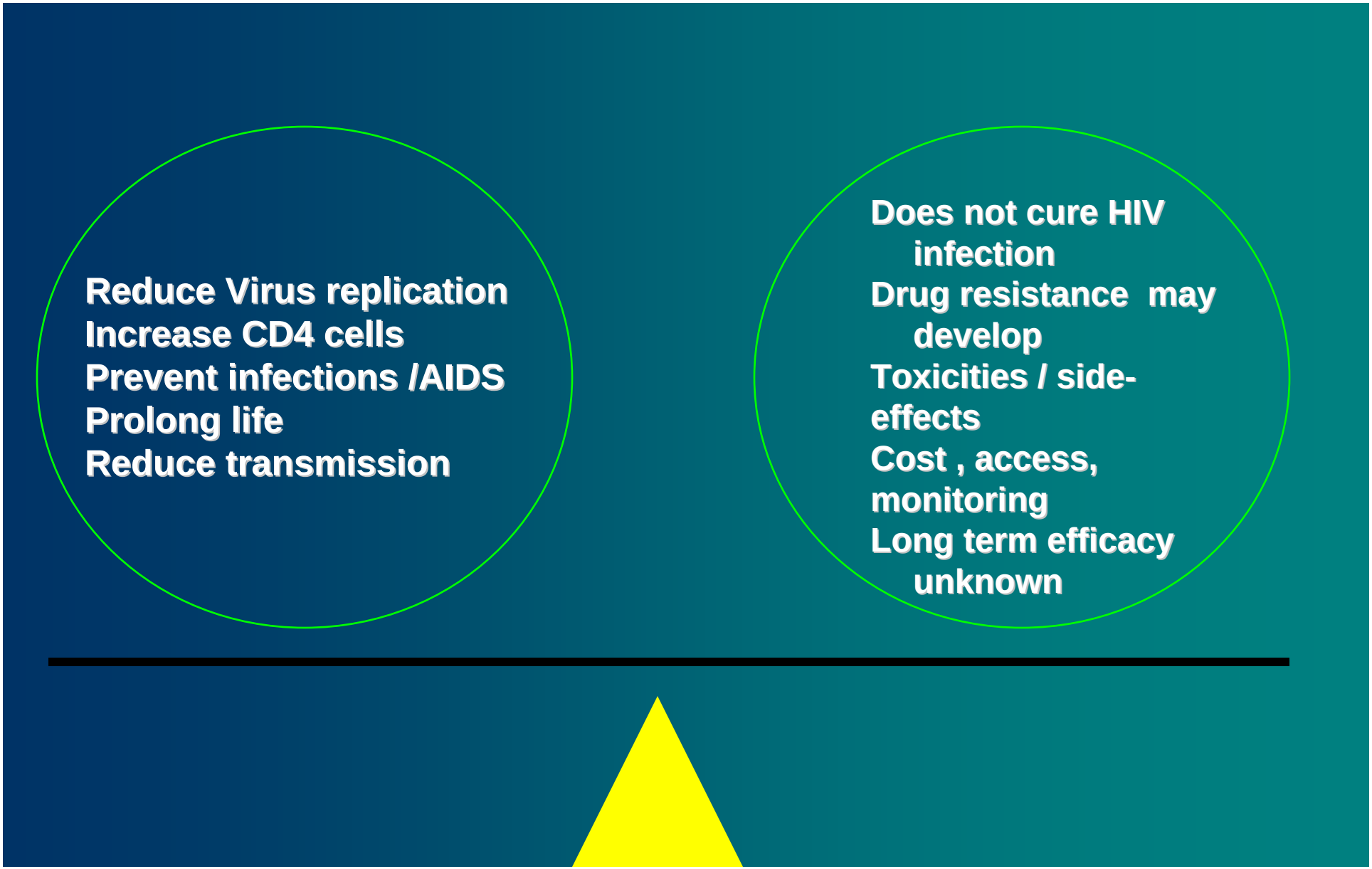
When and How to Start ARV Therapy in Adults

Objectives

1. Discuss the rationale and timing for ARV initiation.
2. Discuss the WHO clinical classification system and its use in deciding when to initiate ARV.
3. Discuss the Nigerian Guidelines criteria for ARV initiation.
4. Describe the essential elements of a clinical patient evaluation prior to ARV initiation.

Antiretroviral Therapy on Balance



When to start HAART? Pros and cons...

ACTION
AIDS Care and Treatment in Nigeria

Earlier

- Prevent CD4 decline
- Prevent infection
- Protect brain & other organs
- Preserve immune response to HIV (HIV immune response does not improve on therapy)
- Viral suppression may be more difficult if ARVs started later
- Less likely to transmit virus

Later

- Reduce toxicity, side-effects, and cost
- Avoid resistance
- Patients generally respond very well to ART
- Patients more likely to be tolerant of side effects
- Saves limited resources to those who need it most

WHO Clinical Staging: a Review

Stage I: Asymptomatic, generalized lymphadenopathy

Stage II: Weight loss <10%, prurigo, fungal nail infection, herpes zoster, recurrent URTIs

Stage III: Weight loss > 10%, chronic diarrhea or fever, oral candidiasis/hairy leukoplakia, pulmonary TB, severe bacterial infections

Stage IV: AIDS-defining illnesses: e.g HIV wasting syndrome, PCP, brain toxoplasmosis, candida oesophagitis, extra-pulmonary TB, CMV retinitis, Kaposi's sarcoma, non-Hodgkins lymphoma and/or performance score 4: bedridden >50% of the day during the last month

Nigerian Guidelines: Criteria for Initiating ARV

- For adults and adolescents, initiation of therapy is dependent on clinical staging and CD4 count
- Nigeria's national guidelines endorses the WHO recommendations for initiating HAART:
  - WHO stage IV disease irrespective of CD4 count
  - WHO Stage III disease with CD4 count <350/mm^3
  - WHO Stages I-II disease with CD4 count <200/mm^3

Clinical and Immunologic Staging

Laboratory axis		Clinical Axis			
	CD4	Stage 1 Asymptomatic PGL	Stage 2 Early HIV	Stage 3 Intermediate	Stage 4 Late AIDS
A	>500	1A	2A	3A	4A
B	200-500	1B	2B	3B**	4B
C	<200	1C	2C	3C	4C

- Shaded area (stages 1C, 2C, 3C, 4A, 4B, 4C) represents those with case definition of AIDS, and these patients should strongly be considered for starting ART

** Patients in this category (3B) should also be considered for starting ART if their CD4 < 350.

Case Vignettes

Do these HIV+ people qualify for starting therapy?

- 32 year old male, asymptomatic, CD4 count of 180
- 22 year old female, pulmonary TB, CD4 count of 400
- 41 year old female, oral candidiasis, CD4 300
- 33 year old male, TB meningitis, CD4 250

Criteria for Starting ARV Are Not Just Clinical

STARTING HAART IS RARELY AN EMERGENCY

- **However, treatment of opportunistic infections may be an emergency**

Strongly consider <u>not</u> starting ARVs:

- **If the patient is not willing or able to return for regular follow-up**
- **When adherence barriers remain**
- **If treatment cannot be continued (patient or drug supply factors)**

When not to start therapy, cont'd

- If patient is asymptomatic and there is no CD4 data
- If laboratory monitoring is not possible
- If there is no access to diagnosis and treatment of OIs
- *during a severe acute opportunistic infection (including TB)*
- In the presence of terminal incurable disease, e.g. cerebral lymphoma, or other major co-morbidities (esp. renal/hepatic)

ARV Pre-Treatment Evaluation

1. Establish presence of HIV infection through VCT (Repeat serologic testing if necessary)
2. Perform history and physical exam (Determine presence of OIs or co-morbidities, especially tuberculosis)
3. Laboratory and diagnostic evaluation
4. Perform clinical and immunologic staging
5. Provide patient counseling including assessment of patient readiness for ARV and development of a patient-specific adherence strategy
6. Provide all supportive measures as indicated (nutrition, psychosocial, OI prophylaxis)

Baseline Laboratory Tests

- Obtain basic laboratory support and establish baseline laboratory test results
- Baseline labs recommended in Nigerian National ARV Guidelines
  - **CD4**
  - **FBC with differential**
  - Electrolytes, **Urea and Creatinine**, FBS
  - **LFTs**
  - Serum lipids if taking PIs
  - Amylase
  - Pregnancy test
  - Chest x-ray +/- sputum smear for TB

ARV Treatment Counselling Must Take Place Prior to Treatment Initiation

A patient should understand:

- The goals of therapy
- ARVs are not a cure
- During ARV the virus can still be transmitted → the need for safe sex practices
- ARV is a life-long treatment
- The cost and consequences for family budget
- The importance of optimal adherence
- Disclosure issues of ARV-use to family members
- The possibilities for psychosocial support
- Drug information to include…

Patient Counselling (cont.): Drug Information

- Type of drugs
- Dose
- Frequency of administration
- Dosing in relation to:
  - meal times/fasting
  - fluid intake
  - timing with other drugs
- Drug timetable
- Drug interactions

Patient Counselling (cont'd): Drug Information

- Storage
- Clinical and laboratory monitoring
- Side effects - management
- Possibility of treatment failure
- Criteria for cessation or changing therapy
- Life style considerations (poor nutrition, alcoholism)

8 Steps to HAART success

1. **Identify** patient for whom benefits outweigh risks (and local guidelines permit therapy)
2. **Assess** prior adherence, all potential adherence barriers
3. **Implement** solutions to adherence barriers
4. **Educate** pt about HIV & HAART
5. **Select** treatment that is **potent, durable, convenient, non-toxic, well-tolerated, and sustainable**
6. **Train** patient on dosing and schedule
7. **Monitor** response and adherence
8. **Respond** promptly to problems

Medical assessment for HAART

- Is diagnosis of HIV confirmed?
- Does patient meet national and local guidelines for HAART?
- Complete history and physical, including neurologic exam
- Assess TB status: Symptoms, CXR, smear & culture as indicated

Medical assessment for HAART (2)

- Labs: Complete blood count; CD4; viral load (if available), pregnancy test, electrolytes, urea or creatinine, LFTs, stool exam, (amylase, glucose, ? lipids)
- Has adherence assessment been completed and all issues addressed?
- Is patient trained and ready to start?
- Treatment partners identified?
- Is medication supply sustainable?

Educating the patient about HAART

- Benefits and risks including side effects and drug interactions
- HIV *will* become resistant and the medication *will* stop working unless all medications taken correctly
- Regular follow up is essential
- *Communicate* any potential problems or questions *immediately*- we are here to help!
- Return to clinic if medications run out before next appointment

Summary: Starting ARV

- Nigerian Guidelines utilize WHO Clinical Staging and CD4 count as criteria for recommending initiation of ARV.
- Baseline evaluation including complete history and physical examination, exclusion of opportunistic infections and other diseases such as TB, pregnancy status, laboratory testing, and patient counseling is essential prior to initiating ARV.