

Patient Follow-up and Monitoring ARV Therapy

Objectives



1. Discuss clinical monitoring including clinical and laboratory parameters to follow.
2. Describe how to monitor tolerability, efficacy, and toxicity of ARV therapy.
3. Mention viral load and resistance testing
4. Discuss recommended protocol for clinical monitoring in Nigeria.

Monitoring ARV therapy



Clinical Information

- Gather a detailed past and present history
 - Other medical problems
 - Other drugs, including herbs
- Conduct a thorough physical examination
- Provide ongoing patient education and adherence counseling

How to monitor



For clinical and efficacy monitoring, it is very important to examine the patient at every visit.

- Suggested schedule for patient visits for monitoring:
 - First follow ups at two weeks and four weeks, or earlier if needed
 - Monthly visits thereafter, or more if needed
 - Can the patient follow-up every 3 months?
- At each visit
 - ask about symptoms, *adherence*, HIV and non-HIV related problems, quality of life
 - conduct a physical examination and check weight

Monitoring ARV therapy



Laboratory data

- Absolute minimum tests per WHO
 - HIV test
 - hemoglobin or hematocrit level

- Basic tests
 - FBC
 - Total lymphocyte count
 - Liver function tests (LFTs)
 - Renal function tests (RFTs)
 - Blood sugar
 - Pregnancy test
 - Sputum AFB smear

- Optional tests
 - CD4
 - Amylase
 - Bilirubin
 - Lipid panel

- Desirable Viral load

Laboratory Monitoring Recommended by Nigerian Guidelines



Laboratory tests

Baseline

Week 12

Every 24 Weeks

CD4
Viral Load (when/if available)
Hemogram
E&U
LFT
FBS
Lipids
Blood glucose
Amylase
Sputum smear TB
CXR
Pregnancy test



Laboratory monitoring for tolerance/toxicities of ART: Tests to Focus On



Laboratory tests

NRTI

NNRTI

Protease inhibitor

Complete blood count



Serum transaminases



Serum creatinine/urea



Serum bicarbonate



Serum triglycerides



Serum cholesterol

Blood glucose

Serum amylase (lipase)



Urinalysis



Serum bilirubin



Special Cases



- For patient on NVP
 - ALT at baseline, 2 weeks and at 1 month
- For patient on ZDV
 - Hemoglobin at baseline, week 4-6, then every 3 months, or more frequently if clinically indicated
- For patient on PIs
 - Blood sugar, Lipid panel, every ???
- For patient on Tenofovir
 - Renal function at baseline, every ???

Clinical Judgment



- ALWAYS USE CLINICAL JUDGMENT
- For example, regardless of the schedule, don't hesitate to check the amylase in a patient with severe abdominal pain or the blood sugar in a patient with polyuria.

Quantification of HIV



- How to determine who is infected - rapid testing, ELISA
- How much virus is in the infected individual
 - Meaning of viral load (prognostic value)
 - Monitoring of success of therapy most directly
 - Roche monitor v1.5
 - Real- time PCR technology
- CD4 determinations - how sick is the infected person

Desired viral load changes during ART



- Viral load decline of 1.5-2.0 logs in first month
- Viral load decline to <400 (<50) copies/ml at 16-24 weeks

Failure to reduce viral load by at least 1 log₁₀ in the first month of therapy suggests

non-adherence

viral resistance

or poor drug exposure

Health of Patient



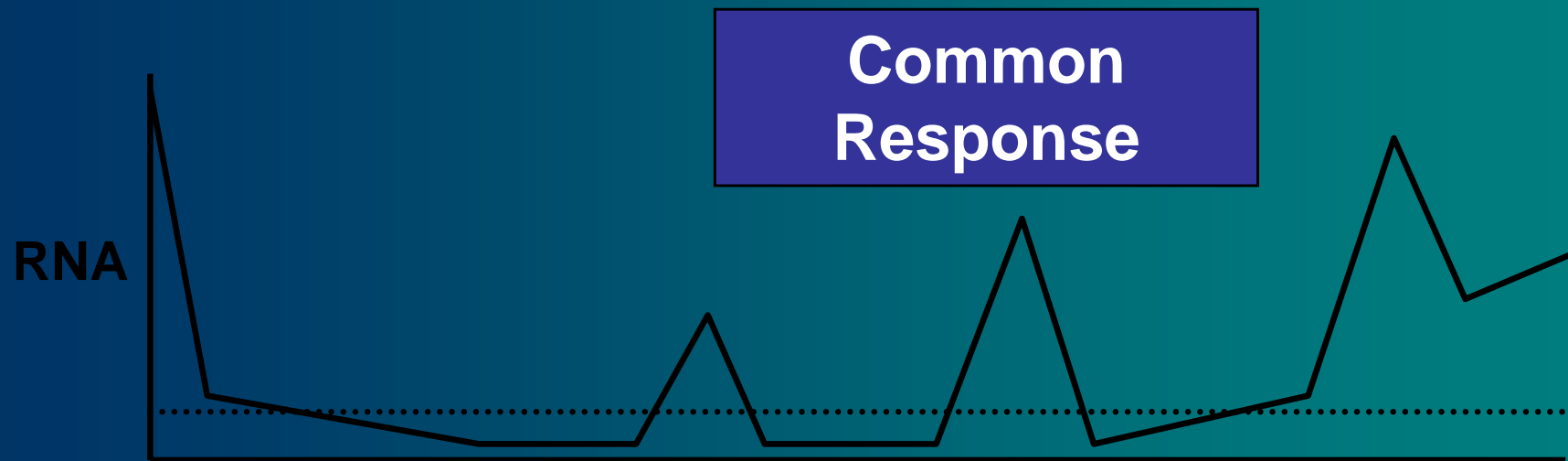
- How to determine who is infected
- How much virus is in the infected individual
- How sick is the infected person
 - Limitations of CD4 counting
 - Prognostic value of CD4 counting
 - Flow cytometry for CD4

CD4 Testing



- 95% confidence range for a true count of 200 cells/cu mm is 118-337 cells/cu mm (JAIDS 1993)
- Diurnal and concurrent illness-related variation in CD4 count
- A trend is more valuable than a single value
- Rise in CD4 with therapy can be extremely variable (50 cells/cu mm in first 4-8 weeks, 50-100/year thereafter)
- A low CD4 nadir results in poorer quantitative response

Response to HAART



Resistance Tests: Relative Advantages



Genotype

- Fastest
- Least expensive
- Offered by many commercial laboratories
- Sensitive for emerging resistance (mixtures)

Phenotype

- Easier interpretation
- Quantitative (indicates *degree* of resistance)
- Assess interactions between mutations
- Does not require understanding of genotypic correlates of resistance

Cost of Laboratory Testing



- At PEPFAR sites under the ACTION and GHAIN projects, laboratory testing required for ARV monitoring is provided at no charge to the patient.

PEPFAR Supported Laboratory Capabilities



- Rapid HIV Ab testing (3 tests)
- (Refer indeterminate specimens)
- FBC and differential (automated)
- Chemistries (automated)
- CD4 (manual, some labs automated)
- Pregnancy testing
- Sputum smear for TB
- Malaria smear
- Chest x-ray at baseline
- Viral load capacity will be developed over time as capacity and resources allow