

WHAT'S NEW IN MONITORING

NOVEMBER 2015



Monitoring of individuals on ART is important to ensure treatment efficacy and improved health outcomes.

Updated WHO Consolidated ARV Guidelines will be available in December 2015 and include recommendations on routine monitoring and the diagnosis of treatment failure.

Viral load for monitoring treatment

- Monitoring people on antiretroviral therapy (ART) is important to ensure successful treatment, identify adherence problems and determine whether ART regimens should be switched in case of treatment failure.
- Viral load is recommended as the preferred monitoring approach to diagnose and confirm treatment failure. Measuring viral load can help to discriminate between treatment failure and non-adherence.
- Viral load gives clients a measure of understanding, control and motivation to adhere to treatment and understand their HIV¹. Adherence counselling needs to address the implications of a detectable or undetectable viral load.
- Routine viral load testing should be conducted at 6 months after initiation and can be repeated at 12 months and every 12 months thereafter to synchronise with routine monitoring.
- Dried Blood Spot (DBS) specimens provide a way to improve coverage and reach of viral load testing, particularly in remote and rural areas.

Monitoring for drug resistance

- WHO recommends HIV drug resistance prevention to be integrated into national HIV programmes through annual monitoring of five early warning indicators (EWIs):
 1. on time ARV drug pick up
 2. retention on ART at 12 months
 3. ARV drug stock outs
 4. viral suppression at 12 months after ART initiation
 5. viral load testing coverage
- Routine programme data should be used to evaluate these indicators.²

Definitions of clinical, immunological and virological failure

FAILURE

CLINICAL FAILURE

Adults and adolescents

New or recurrent clinical event indicating severe immunodeficiency after 6 months of effective treatment

Children

New or recurrent clinical event indicating advanced or severe immunodeficiency (WHO clinical stage 3 or 4 with exception of TB) after 6 months of effective treatment.

IMMUNOLOGICAL FAILURE

Adults and adolescents

CD4 count 250 cells/mm³ following clinical failure or persistent CD4 levels below 100 cells/mm³

Children

Younger than 5 years

Persistent CD4 levels below 200 cells/mm³

Older than 5 years

Persistent CD4 levels below 100 cells/mm³

VIROLOGICAL FAILURE

Viral load above 1000 copies/ml based on 2 consecutive viral load measurements within 3–6 months, with adherence support following the first viral load test.



Photo: WHO/Gary Hampton

Stopping the use of CD4 where viral load is available

- Evidence suggests that for individuals stable on ART who are monitored virologically, routine CD4 can be stopped.³ Long term CD4 monitoring adds little value in these circumstances and stopping CD4 testing can be cost saving.
- CD4 still has an important role to play in assessing baseline risk of disease progression, decisions for starting and stopping prophylaxis for opportunistic infections and prioritising ART initiation in settings where universal treatment is not possible.

Settings with limited access to viral load testing

- While scale up continues, reliable access to routine viral load monitoring remains limited.
- In settings with limited access to viral load testing, a targeted viral load strategy to confirm suspected treatment failure based on immunological or clinical criteria should be used to avoid unnecessary switching to second-line regimens.
- Where viral load is not available, clinical monitoring and CD4 monitoring can be used to identify those at highest risk of disease progression and mortality.

Appropriate use of CD4 testing as viral load access increases

- As access to routine viral load increases, reductions in CD4 testing capacity can be staged through strategies based on site-level demand age of instrument and failure rates.
- Programmes need to ensure adequate sample referral network capability for viral load testing prior to scaling down CD4 testing.
- Planning should include realistic transition of financial support from CD4 testing to viral load monitoring.

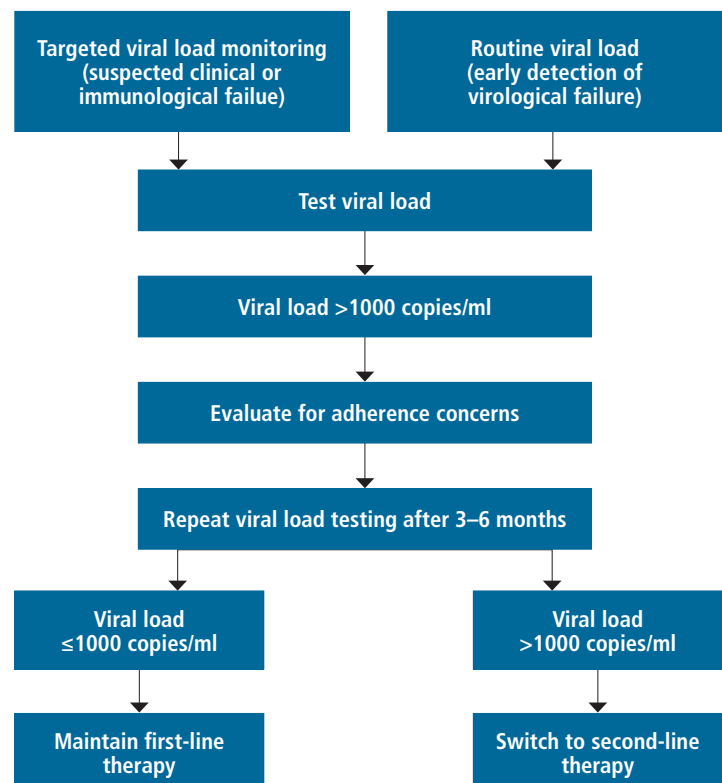
- CD4 cell testing will need to continue for baseline risk and other clinical assessment; programmes may decide centralise the continued use of CD4, depending on the context.

1 Pangaea Global AIDS Foundation. Preliminary report of the community led consultations for WHO 2015 consolidated treatment guidelines update. Acceptability of early initiation of antiretroviral therapy (ART) and viral load monitoring: Values and preferences of service users and providers. 2015. Annex 2 available at <http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/>, accessed 24 November 2015.

2 World Health Organization Consolidated guidelines on strategic information for HIV in the health sector. Geneva World Health Organization 2015. <http://www.who.int/hiv/pub/guidelines/strategic-information-guidelines/en/> accessed 11 November 2015.

3 Ford N, Stinson K, Gale H, Mills E, Stevens W, Perez Gonzalez M et al. CD4 changes among virologically suppressed patients on antiretroviral therapy: a systematic review and meta-analysis. *Journal of International AIDS Society* 2015. 18:200061.

Fig. Viral load testing strategy



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