

# INTENSIFIED MONITORING STRATEGY

ITREMA STANDARD OPERATING PROCEDURE  
FOR THE INTENSIFIED MONITORING STRATEGY

VI.0 (29 JUNE 2015)



UMC Utrecht



ZonMw



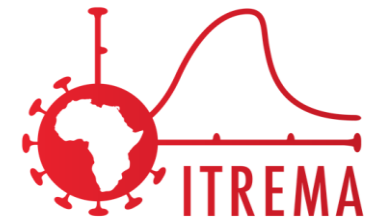
'S REPRODUCTIVE HEALTH & HIV INSTITUTE



Universiteit Utrecht

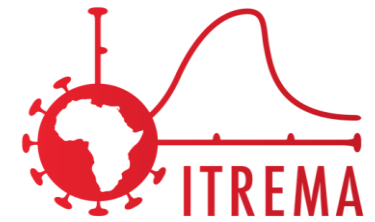
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# ANTIRETROVIRAL TREATMENT MONITORING



- Antiretroviral treatment (ART) is being rapidly rolled out in low- and middle-income countries
- Laboratory tools for monitoring of treatment are required to:
  - Detect viral rebound
  - Confirm virological failure
  - Confirm the presence of drug resistance
  - Obtain insight in adherence to treatment
  - Guide adequate selection of new (second-line) ART
- Effectivity and cost-efficiency of different strategies for monitoring of treatment is largely unknown

# COMPONENTS OF ART MONITORING



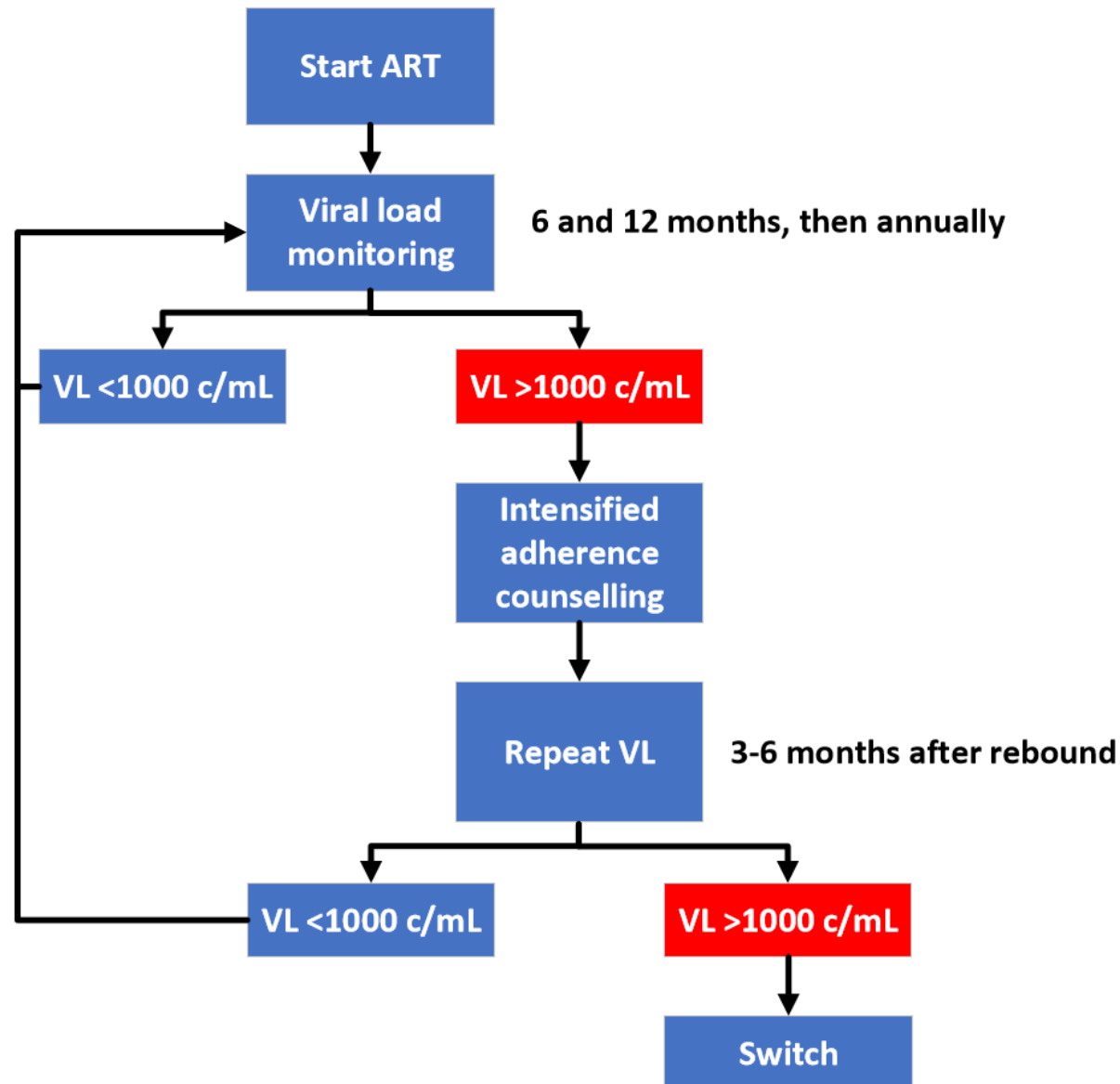
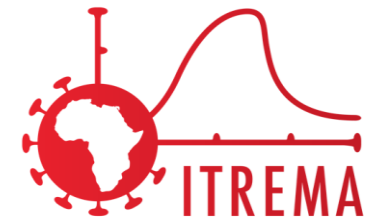
- Clinical monitoring
    - Symptoms
    - Disease staging
    - Toxicity monitoring (chemistry)

→ Clinical failure
  
  - Immunological monitoring
    - CD4 count

→ Immunological failure
  
  - Virological monitoring
    - Viral load (targeted/routine)

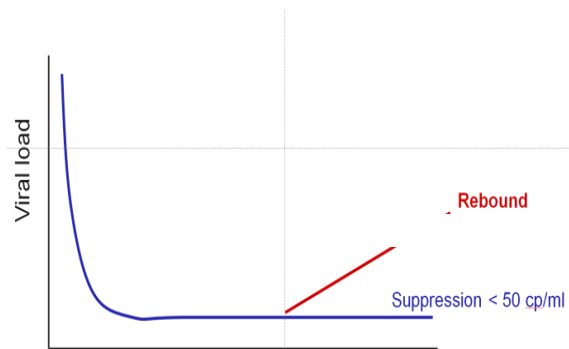
→ Virological failure
  
  - Resistance monitoring
  - Pharmacological monitoring
- Drug resistance
- Drug plasma levels

# WHO GUIDELINE RECOMMENDATIONS FOR ART MONITORING

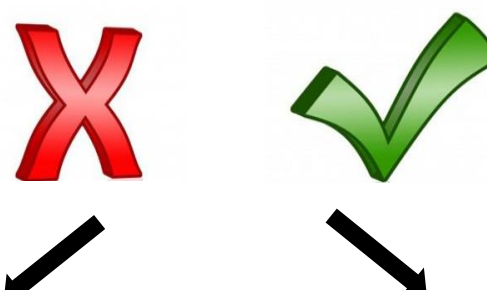


\*World Health Organisation, Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. 2016

# THE INTENSIFIED MONITORING STRATEGY (AS PROPOSED BY ITREMA)



Point-of-care drug level assessment



Drug level informed adherence counselling



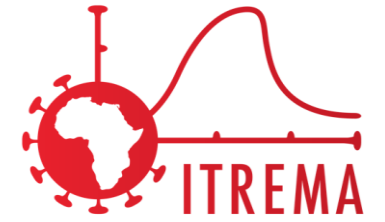
NRTI	GRADE B10217			NVI02 0.4			Final Rating
	Mutation List	Algorithm Result	SR	Mutation List	Algorithm Result	SR	
RPV	None	Susceptible	1.0	None	Susceptible	1.0	1.0
ETR	None	Susceptible	1.0	None	Susceptible	1.0	1.0
RPV	None	Susceptible	1.0	None	Susceptible	1.0	1.0

NRTI	GRADE B10217			NVI02 0.4			Final Rating
	Mutation List	Algorithm Result	SR	Mutation List	Algorithm Result	SR	
RPV	None	Resistance	0.5	None	High Level Resistance	0.5	0.5
ETR	None	Intermediate	0.5	None	Intermediate Resistance	0.5	0.5
RPV	None	Resistance	0.5	None	High Level Resistance	0.5	0.5
RPV	None	Intermediate	0.5	None	Intermediate Resistance	0.5	0.5

Resistance testing



# PRACTICAL PROCEDURE



## VIRAL LOAD MONITORING VISITS

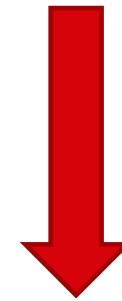
Viral load monitoring is performed at 6 months of ART, and from then every three months



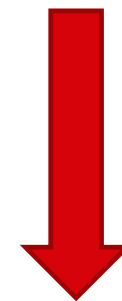
VL < 1000 copies/mL



Continue regular monitoring



VL ≥ 1000 copies/mL



Flag patient and ensure return visit within two months

# PRACTICAL PROCEDURE



## **FIRST VISIT AFTER HIGH VIRAL LOAD**

In case of a VL  $\geq$  1000 copies/mL at the previous visit:

- Draw blood for repeat VL (EDTA/PPT)
- Draw blood for drug level testing (EDTA)



Drug detected



Intensified counselling

Prepare DBS for drug  
resistance testing

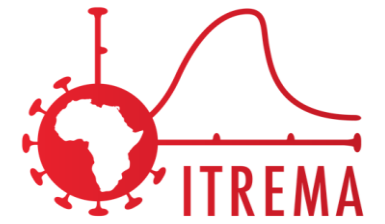


Drug not detected

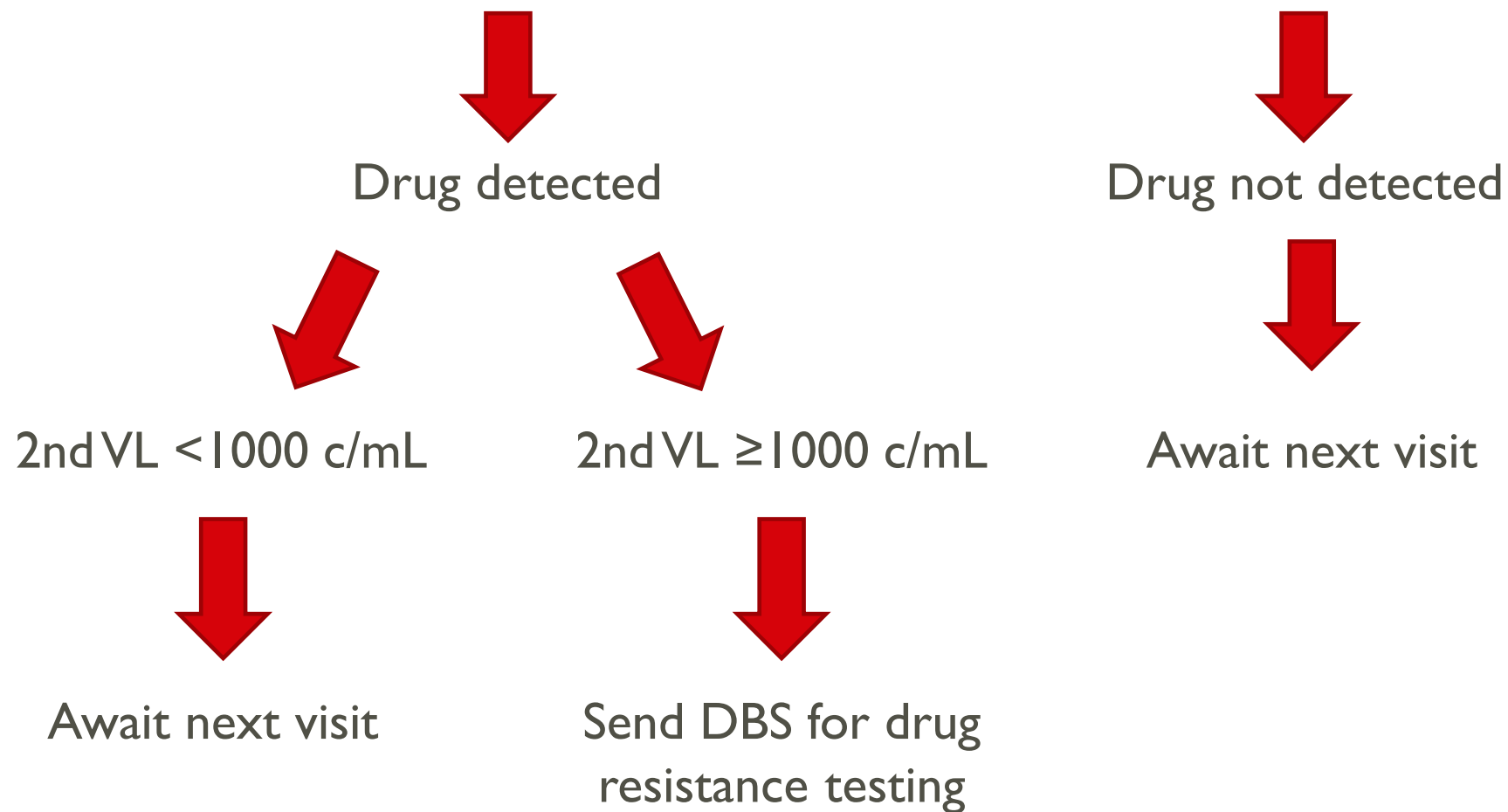


Intensified counselling

# PRACTICAL PROCEDURE

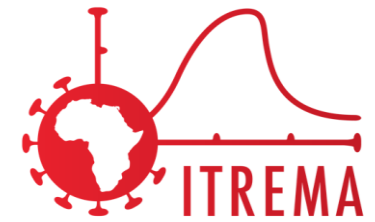


## AFTER FIRST VISIT AFTER HIGH VIRAL LOAD





# PRACTICAL PROCEDURE



## SECOND VISIT AFTER HIGH VIRAL LOAD

2nd VL < 1000 c/mL



Drug level  
positive/negative



Patient resuppressed,

Support ongoing  
adherence

**Keep on 1st line ART**

2nd VL ≥ 1000 c/mL



Drug resistance  
not detected



Patient is viremic!

Strong evidence of poor  
adherence.

Adherence intervention

**Keep on 1st line ART**

Drug level  
negative



Support ongoing adherence

**Switch to 2nd line ART**

Drug resistance  
detected

