INTERIM TECHNICAL UPDATE

TECHNICAL AND OPERATIONAL CONSIDERATIONS FOR

IMPLEMENTING HIV VIRAL LOAD TESTING

JULY 2014

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ABBREVIATIONS

ART	antiretroviral therapy
CAP	College of American Pathologists
CD4	cluster of differentiation 4
CE	European conformity
EDTA	ethylenediaminetetraacetic acid
IVD	in vitro diagnostic medical device
PCR	polymerase chain reaction
SLIPTA	Stepwise Laboratory Quality Improvement Process towards Accreditation
SLMTA	Strengthening Laboratory Management towards Accreditation
TB	tuberculosis

EXECUTIVE SUMMARY

This publication provides high-level guidance on implementing and scaling up HIV viral load testing programmes for health ministries and implementation partners, using a three-phased approach: (1) planning; (2) scale-up; and (3) sustainability. The guidelines for managing antiretroviral therapy (ART) issued by WHO have recognized the importance of viral load monitoring since 2003. Routine viral load monitoring is now strongly recommended as the monitoring strategy of choice. In 2013, WHO recommended viral load as the preferred monitoring approach to diagnose and confirm ART failure and using the reduced threshold of viral failure of 1000 copies/ml based on two consecutive viral load measurements using plasma specimens within 12 months, with adherence support between measurements. There are many challenges to implementing viral load monitoring in resource-limited settings, including complex technical requirements to perform the test, the logistics of specimen transport and cost. This publication addresses strategies to plan and implement a logical viral load testing network, including engaging leadership, mapping and forecasting, product and specimen selection, algorithm development, human resources and infrastructure requirements, monitoring and evaluation, maintenance, quality management systems and training. A key inclusion is technical guidance on using dried blood spot specimens. This publication is intended to serve as a reference point for countries, whether they are commencing implementation or scaling up existing viral load testing capacity. Thoughtful consideration and planning of all areas covered in this publication will assist in developing a robust and sustainable HIV viral load testing network.

INTRODUCTION

The 2013 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection *(1)* recommend viral load testing as the preferred monitoring tool for diagnosing and confirming the failure of antiretroviral therapy (ART). In accordance with these guidelines, many countries are investing in viral load testing to monitor people receiving ART (Fig. 1). Viral load monitoring is the gold standard practice in resource-rich countries for detecting treatment failure among people receiving ART; however, its availability in resource-limited settings has been severely restricted because of prohibitively high costs (US$ 40–85 per test solely for reagents and consumables), complex specimen collection and transport requirements and the need for well-established laboratory infrastructure and well-trained personnel. Because of these financial and operational barriers, the WHO treatment guidelines, while recognising viral load as the gold standard for ART monitoring, have historically focused on using clinical and immunological criteria for determining treatment failure. However, numerous studies have demonstrated the poor predictive value of the WHO immunological criteria for identifying viral failure and have shown that delayed detection of treatment failure leads to accumulation of HIV drug resistance *(2,3)*. The 2013 WHO consolidated antiretroviral guidelines *(1)* recommend viral load testing six months after initiating ART and then annually for people receiving ART; for the people with detectable viraemia, targeted adherence support followed by confirmatory viral load testing is recommended to distinguish poor adherence from true treatment failure. Those with treatment failure would then be switched to second-line ART.

This publication provides high-level guidance on implementing and scaling up viral load testing programmes for health ministries and implementing partners. It aims to inform national HIV programme managers and laboratory managers using a three-phased approach: (1) planning; (2) scale-up; and (3) sustainability.

Fig. 1. Phased implementation of viral load testing