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A study of outcomes of seven years' viral load testing at the National Public Health Laboratory, Nepal

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The benefits of antiretroviral therapy (ART) in patients living with HIV (PLWH) in Nepal have been obvious. However, their viral load (VL) and the effects of VL testing scale-up on the outcomes of HIV treatment have not been adequately investigated. In Nepal, VL tests were performed since 2009 at National Public Health laboratory. VL testing for monitoring scale up was introduced in 2014. The present study was undertaken to find out the virological failure (VF) and virological suppression (VS) rates in PLWH on ART in Nepal and to assess the effect of VL testing coverage on ART outcomes. A total of 8,230 blood/plasma samples were collected from among 11,922 patients on ART during 2009 to 2015. The VL testing coverage in 2009 was 2.9% which increased to 48.3% in 2015. VF was 35.9% in 2009 (mean for 2009-2013 was 27.5% and for 2014-2015 the mean VF was 10.2%). Decrease in VF to nearly one third in 2015 coincided with the rise in VL testing coverage (from 2.9 to 48.3%). Improvement in VL testing coverage for ART monitoring coincided with decline in VF, indicative of ART optimization. VL testing of ART treatment failure cases only in the first segment of the study (2009-2013), accounted for initial low VL coverage. However, 48.3% coverage in the last year of scale-up period, with a mean VF of 10.2% and nearly 90% of all those receiving ART having VS, was very encouraging.

Key words: Viral load testing, Nepal, outcomes.

INTRODUCTION

The quantity of human immunodeficiency virus (HIV) RNA in plasma can be measured accurately by plasma viral load testing (Mylonakis et al., 2001), which is the gold standard practice in resource-rich countries for detecting treatment failure among people receiving ART (World Health Organization, 2014). It has been recommended by World Health Organization (WHO, 2014) as a preferred tool for diagnosing and confirming the failure of antiretroviral therapy (ART) (World Health Organization, 2013a) and has become the cornerstone of HIV disease management. Viral load (VL) testing facility has been available at the National Public Health

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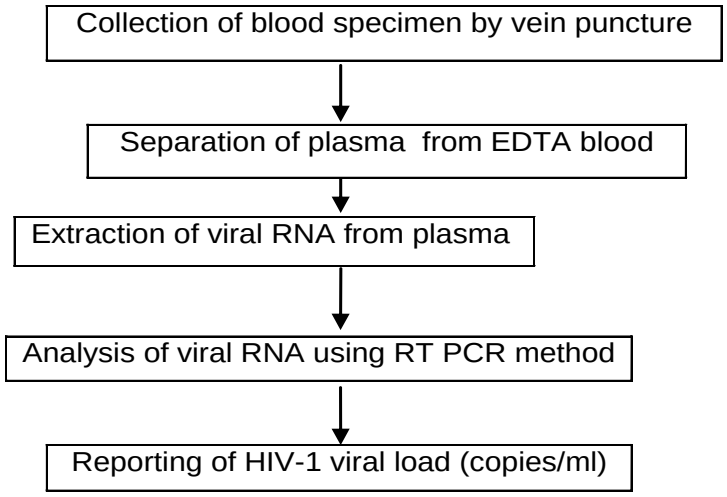

Figure 1. Procedural steps of sample processing

laboratory (NPHL), Kathmandu, Nepal since 2009 and contributing since then to the control of HIV, including the scale-up viral load plan 2014-2018 of the government of Nepal.

Twenty-five (25) ART centers located at various parts of the country provided treatment to patients living with HIV (PLWH) in Nepal, following the National Centre for AIDS and STD Control and National ART Guidelines (2009) and National consolidated Guideline for Treating and Preventing HIV in Nepal (Government of Nepal Ministry of Health and Population, 2014). VL testing of patients referred as clinical treatment failure cases was done since 2009 to 2013. VL testing for monitoring scale-up was introduced in 2014 and thereafter; VL testing was done after completion of the first six months of ART treatment and subsequently when indicated.

The present study was carried out with the objective of finding out the prevalence of viral suppression (VS) and viral failure (VF) in PLWH on ART in Nepal and to assess the effect of VL testing coverage on ART outcomes in patients treated according to the National ART Guidelines (2009) and National consolidated Guideline for Treating and Preventing HIV in Nepal (2014).

MATERIALS AND METHODS

All cases referred to the NPHL for VL testing from the peripheral ART centers during 2009 to 2015 were included in the study. During 2009-2013 (pre scale-up period, PSuP), VL testing was done for ART treatment monitoring as on-request testing for referred (ART treatment failure) cases whereas, from 2014 (scale up period, SuP), testing was done as part of scale up VL testing program after completion of first six months of ART, for treatment monitoring, as recommended in the National consolidated Guideline for Treating and Preventing HIV in Nepal (2014).

After recording the demographic and treatment history and obtaining informed consent, blood specimens were collected by venepuncture, taking all biosafety precautions. Plasma was separated for laboratory analysis. In the case of patients who could not travel to the NPHL, plasma specimens were collected at the ART centers and received at the NPHL within 6 h of collection. Specimens were transported in ice-box at temperature between 2 to 8°C, along with VL database, as per guideline.

HIV viral load testing was done at the HIV reference laboratory unit of the National Public Health Laboratory (NPHL), Teku, Kathmandu, Nepal. Viral RNA samples were extracted by QIAamp Viral RNA Mini Kit or Roche's High Pure Viral Nucleic Acid Kit and extracted RNA were analyzed in reverse transcription polymerase chain reaction (RT PCR) Corbett Rotor-Gene 6000, COBAS®TaqMan® 48 Analyzer according to procedural steps, shown in Figure 1. The VL values obtained were recorded, tabulated and analyzed using appropriate statistical methods. Virological failure was defined as a viral load of > 1000 copies of viral ribonucleic acid (RNA) per ml (World Health Organization, 2013a) and a viral load of < 1000 RNA copies per ml was defined as viral suppression (Bennett et al., 2008).

RESULTS

Total number of patients on antiretroviral therapy (ART) during the study period was 11,922 and the number of samples tested for viral load (VL) during the same period was 8,230, (2474+5756) which comprised samples tested during both (PSuP and SuP) periods (Table 1). The year wise scatter of number of patients receiving ART along with VL test coverage during the same period is shown in Table 2. Table 3 shows the year wise (2009-15) rate of virological failure (VF) and virological suppression (VS). The VF rate (with exception in 2013) showed progressive fall with the declining trend continuing into the SuP. Virological failure (VF) rate during PSuP and SuP periods is shown in Table 4.

DISCUSSION

A total of 11,922 patients were on ART treatment during the study period in which 8,230 samples were tested for

Table 1. Number of blood/plasma samples collected.

Duration of sample collection	Number of samples
Pre scale-up (2009-13)	1528
Scale-up (2014-15)	6702
Total: (PSuP+SuP), (2009-15)	8230

Table 2. Year wise scatter of patient number on ART and viral load (VL) test coverage.

Year	Number of patients on ART	Number of VL tested	VL test coverage (%)
Pre scale-up (2009-13)			
2009	3550	103	2.9
2010	4867	297	6.2
2011	6483	366	5.6
2012	7719	428	5.5
2013	8866	334	3.8
Scale-up (2014-15)			
2014	10407	946	9.1
2015	11922	5756	48.3

Table 3. Virologic failure (VF) rate during pre-scale-up (PSuP) and scale-up period (SuP).

Study period	PSuP	SuP	Total (SuP+SuP)
Number of samples tested for VL	2474	5756	8232
VF rate: Number (%)	680 (27.5)	583 (10.2)	1263

Table 4. Year wise rate of virological failure (VF) and virological supression (VS).

Year	Number of VL tested	VS (%)	VF (%)
2009	103	66(64.1)	37(35.9)
2010	297	208(70.1)	89(29.9)
2011	366	274(74.8)	92(25.2)
2012	428	339(79.2)	89(20.8)
2013	334	221(66.1)	113(33.9)
2014	946	764(80.7)	182(19.3)
2015	5756	5,173(89.8)	583(10.2)

VL, and VL testing coverage steadily increased from 2.9 (in 2009) to 48.3% (in 2015). This led to an important impact on the treatment outcome and prognosis. The mean virological failure rate (VF) dropped from 27% (680/2474) in 2009 to 10.2% (583/5756) in 2015, with corresponding increase in virological suppression (VS) rates. This is comparable with the overall VF rate of 10.44% (232/2223) reported from Jiangsu province in Eastern China (Zhou et al., 2016). On the other hand, a higher overall rate of VF (41.3%, 36.4 to 46.4) was reported from Gabon, Africa (Liégeois´et al., 2012).

In the Resource-Poor Settings (RPS), like in Nepal, increasing the availability of ART has improved the survival rates and quality of life for HIV/AIDS patients (Ojha et al., 2016). However, adherence to the WHO guidelines (World Health Organization, 2013b, 2014) is necessary for continued success. The 90–90–90-UNAIDS treatment target to help end the AIDS epidemic (UN:UNAIDS, 2014) has been a source of great zeal and inspiration in this regard. Despite only 48.3% VL test coverage in the last year of the second segment with a mean VF of 10.2 and 89.8% of all those receiving ART

had VS which is very encouraging for achieving the target in the near future.

WHO recommended the use of viral load testing as the preferred method of monitoring response to ART and detecting treatment failure (World Health Organization, 2013b, 2014). Although in the past, VL monitoring in the RLS was a topic for much debate (Calmy et al., 2007), VL testing has been increasingly incorporated in the newer national guidelines for HIV management (Stevens and Marshall, 2010; Ministry of Health Government of Lesotho, 2014; Policy Brief, 2015). Results of the present study document that VL monitoring of ART of PLWH in the RLS improves and optimizes HIV Treatment. This further emphasizes the need to refocus the attention from only increasing access to drugs to VL monitoring to provide optimal treatment to PLWH.

Conclusion

VF failure rate dropped from 27 to 10.2% with increasing VL testing coverage during the period of seven years. VL monitoring improves and optimizes ART of people living with HIV (PLWH).

CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

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