Evaluation of Simplified HCV Diagnostics in HIV/HCV Co-infected Patients in Myanmar (Simplified Monitoring Myanmar SM^2 study)

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Background: Simplification and decentralisation of treatment of hepatitis C virus (HCV) infection is crucial for treatment scale up in low- and middle-income countries (LMIC). Different models of care may need to be utilised depending on the local framework for linkage to care.

Methods: This prospective, observational study recruited human immunodeficiency virus (HIV)-HCV co-infected outpatients receiving sofosbuvir/daclatasvir at two hospitals in Yangon, Myanmar. The study examined outcomes using a simplified model of care and factors associated with sustained virological remission (SVR). The study evaluated the utility of a decentralized “hub-and-spoke” testing model to facilitate HCV RNA testing, with blood collected by fingerstick capillary, transported by taxi, and processed centrally. Finally, the study compared the performance of the Xpert® HCV VL Fingerstick Assay in detecting HCV RNA in whole blood samples collected by fingerstick capillary to the current standard of care (Plasma HCV RNA *collected by venepuncture*).

Results: Between January 2019 and February 2020, 162 HCV RNA positive individuals were identified; 154/162 (95%) initiated treatment, 128/154 (84%) returned for their SVR12 visit. SVR was achieved in 119/128 (93%) participants in the *modified-intent-to-treat* population excluding those lost to follow-up (predominantly due to COVID-19 lockdown). In multivariate analysis, individuals receiving antiretroviral therapy were more likely to achieve SVR (odds ratio (OR) 7.16, 95% confidence interval (CI) 1.03-49.50), while individuals with cirrhosis were less likely (OR: 0.26, (95%CI) 0.07-0.88). The sensitivity of the Xpert® HCV VL Fingerstick Assay for was 99.4% (95% CI 96.7–100.0), and the specificity was 99.2% (95% CI 95.9–99.9).

Conclusion: A simplified treatment protocol, using a hub-and-spoke testing model of fingerstick capillary specimens can achieve an SVR rate in LMIC comparable to well-resourced high-income settings. The model has the potential to improve testing, diagnosis, linkage to care and treatment initiation in difficult-to-reach populations living with HCV globally.

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