Background: Data on long-term immuno-virological outcomes and drug toxicity in patients treated with antiretroviral therapy (ART) in resource-limited settings are scarce.

Methods: Cross-sectional evaluation of adults treated with ART for 48 months (M48) in the Médecins Sans Frontières/Ministry of Health programme of Phnom Penh. Antiretroviral (ARV) toxicity was assessed by clinicians and through laboratory testing and adherence through pill counting and visual analogue scale. ARV mutations and resistance patterns were determined for patients with detectable HIV RNA viral load (VL) >250 copies/ml.

Results: At M48 the probability of remaining in care was 0.82. The 349 survey participants (98% of eligible) had a median age of 38 years. At ART initiation 94% were ARV naïve, 83% had been prescribed 3TC-D4T-EFV and the median CD4-count was 16 cells/ml (IQR: 4-71). At M48, 29% remained on a D4T-regimen and 58% received an AZT-regimen (compared to 94% and 3% at ART initiation, respectively); 10% were on second-line therapy. The median CD4-count was 410 cells/ml (IQR: 290-511), with only 10% of patients having <200 cells/ml. 15 patients (4%) had detectable VL and the most frequently observed mutations were M184V and K103N (9 and 5, respectively). 11 patients had reverse transcriptase inhibitor resistance(s) and 1 second-line patient protease inhibitor mutations without resistance. 83% of patients were classified as fully adherent to ART. 97% were diagnosed with ARV-related toxicity but this was severe only in 19% of patients. Most frequent diagnoses were: lipodystrophy (63%), hypertriglyceridemia (41%), asthenia (32%) and increased liver enzymes (27%). Only 1% of patients had anemia.

Conclusions: Despite of a severe immuno-compromised status at ART initiation, 90% of the patients remained on a first-line regimen after 48 months of treatment, and only 4% had virological failure. A severe ARV-toxicity was seen in one fifth of patients and mild and moderate lipodystrophy was common.

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