Challenges for the Implementation of New Tools to Monitor Treatment Outcome in Miltefosine-treated Kala-azar Patients in India and Nepal

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The oral drug Miltefosine has recently been implemented as first line drug for visceral leishmaniasis (VL) in India and Nepal. Together with rapid diagnosis using recombinant K39-based rapid immunochromatographic test, the provision of free treatment at PHC level should make diagnosis and treatment for VL more rapid and accessible, and is part of the Kala-Azar Elimination Plan. The success of such strategy depends largely on the efficacy of Miltefosine under field conditions, and since treatment failure rates of 6 to 11% have been recorded in phase 4 trials in hospital settings, a surveillance system on treatment outcome for PHC-based management of VL is urgently needed.

We developed surveillance tools to monitor treatment outcomes in health care settings where VL diagnosis and treatment is provided. This requires the implementation of a KA treatment register where all diagnosed cases of VL are recorded and where clinical outcomes are systematically completed at minimum two time points: early treatment outcome at the end of treatment (in case of Miltefosine = 28 days) and late treatment outcome at 6 months after treatment completion. Five health care structures (3PHCs in India, 2 district hospitals in Nepal) were selected based on KA incidence in the previous years to test the tools. Permission and commitment was asked to the medical staff to collaborate, and tools were provided including case definitions for treatment outcome and SOPs for record keeping.

Eight months after the implementation of the register, quality of data collection is poor due to: 1) lack of commitment of the identified staff, 2) poor compliance of the KA treated patients to present at follow-up visits.

Treatment outcome monitoring for VL is necessary but requires important commitment from HC staff and patients. Further efforts are needed including patient education, guidelines and supervision for staff, and positive incentives for both. Use of the existing CHW network to collect data on clinical status 6 months after treatment may provide an alternative but requires strong organization, coordination and commitment from the different health actors at district level. Other methods for monitoring treatment efficacy, e.g. through retrospective surveys, need to be explored.