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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INTRODUCTION

- From Kala Azar Elimination Plan : make diagnosis and treatment for VL more rapid and accessible
  - Rapid diagnosis (rK39-based rapid test)
  - Free diagnosis & treatment
  - Oral treatment (Miltefosine tablets, 50mg, 10 mg)

  } at PHC level

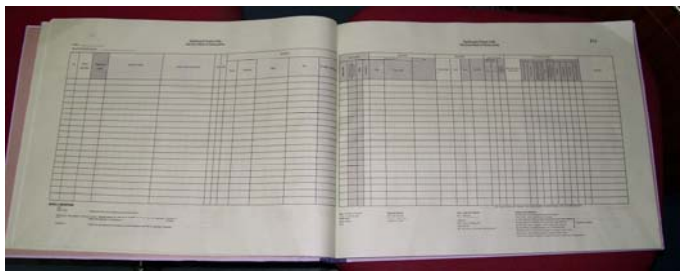
- The oral drug Miltefosine : recently implemented as 1st-line drug for visceral leishmaniasis (VL) in India and Nepal.

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

1. A new **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.
2. Methodological analysis of the data by Retrospective Cohort Analysis method (as done in TB programs)



KA treatment register book

Five health care structures (3 PHCs 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.

RESULTS

Eight months after the implementation of the register books, quality of data collection is gradually improving.

Lessons learnt from implementation process:

- Long-term follow-up in PHC setting is difficult due to:
  a) Poor motivation of PHC staff for new initiatives
  b) Poor compliance of the KA treated patients to present at follow-up visits (as most of them are no longer sick).
- Retrospective Cohort Analysis (as applied in TB programs) is complicated because of multiplicity of cohorts: new KA cases versus relapse KA cases, presence of different treatment options (MIL, Ampho B, etc.)

INDIA

1) Cohort > 7 months since treatment start

total number treated	DRUG		type of patient (NC= New case; RC= relapse or re-treatment)		EARLY TREATMENT OUTCOME: early cure	default	Trtmt Failure	death	Treatment switch for SAE	transfer out / treated elsewhere	FINAL TREATMENT OUTCOME: Def. Cure	Defaulter	Trtmt Failure	death	Treatment switch for SAE	transfer out / treated elsewhere	relapse	lost to follow up
27	MIL	21	NC	20	18	1	0	0		1	12	1	0	0		1	3	3
			RC	1	1	0	0	0		0	1	0	0	0		0	0	0
	SAG	6	NC	6	6						6							
			RC															

2) Cohort < 7 months since treatment start

# total	DRUG		type		EC	DEF	FAIL.	DEATH	SAE RS	TF Out	FC	DEF	FAIL.	DEATH	SAE RS	TF Out	REL	LTFU
111	MIL	110	NC	102	85	5	0	1		11								
			RC	8	8	0	0	0		0								
	SAG	1	NC	1	1													
			RC															

NEPAL

All < 7 months since treatment start

# total	DRUG		type		EC	DEF	FAIL.	DEATH	SAE RS	TF Out	FC	DEF	FAIL.	DEATH	SAE RS	TF Out	REL	LTFU
49	MIL	22	NC	20	15	4	0	0	1	0								
			RC	2	1	0	0	0	1	0								
			RT	0	0	0	0	0	0	0								
	AMPHO-B	27	NC	22	20	0	0	0	2	0								
			RC	3	3	0	0	0	0	0								
			RT	2	2	0	0	0	0	0								

CONCLUSIONS

Treatment outcome monitoring for VL is necessary but requires important commitment from HC staff and patients. Further efforts are needed including patient education, training workshops, 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 (ref. E.Hasker et al. *TMIH* Vol15Suppl.2 pp55-62), need also to be further explored.

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