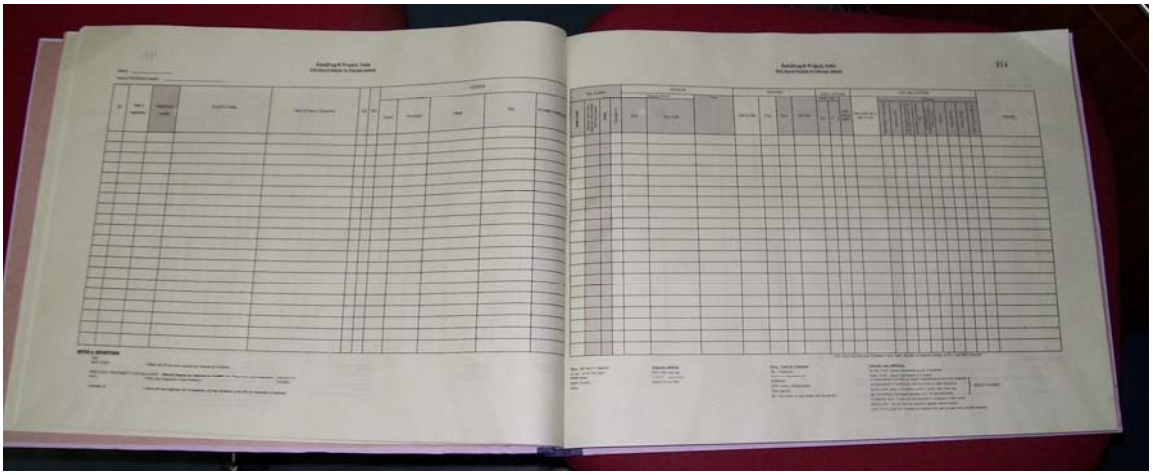
KALADRUG-R: Work Package 2

SOP on the correct use of the Daily Record Register for Kala azar Patients

Feb 2012, Kaladrug-R

To find register, click here



The register is conceived to collect all data on every patient from the start of his/her treatment until the final treatment evaluation (usually 6 months after the last tablet taken, eventually longer) - on one single line (as done with TB).

The tool contains all necessary information for the clinician doing the follow up, for the statistician doing the data collection and reporting, and for the district health office to do program evaluation and organizing preventive activities (e.g. targeted spraying)

PATIENT IDENTIFICATION DATA

SN: serial number in the register

Date of registration: the date on which the patient was included in the register

Registration number (or patient code):

Unique number for each KA patient diagnosed and registered at the treatment center (note: in some cases patients registered may ultimately be referred for treatment to another health center or referral center, i.e. in case a treatment center is nearer by to their home, or if appropriate treatment is not available (contra-indication, stock rupture).

A registration number is composed by (3) letters and (3) numbers:

The three-letter code refers to the health institution and usually already exists, and is attributed by the district health office. (could be chosen based on the first three letters of the name of the health institution, provided the combination doesn't already exists.

Example:

- Motipur in Muzaffarpur district: MOT###

Patient's name (+ Name of Head of Household)

Several lines can/must be used to write relevant information.

Age: age (in years) of the patient

Sex: M (male) ; F (female) ; U (unknown)

Address:

Name of Sub Center: could be relevant to identify the health worker/village volunteer in view of treatment and outcome follow-up.

Panchayat / Village / Tolla : *Several lines can/must be used to write relevant information*.

Tel/Mobile number of contact person:
Given the increasing coverage of mobile telephone facilities, it should be possible to identify a contact number/person (family member, neighbor) so that a patient can easily and efficiently be traced when not attending the clinic (e.g. for follow-up supply for treatment) and for collecting (late) treatment outcomes

TYPE OF PATIENT

Mark one box from the four columns: New Case / Patient who had past history of Kala azar / PKDL / Transfer in.
It is important to clearly separate new cases from others as only the number of new cases should be used to calculate the incidence of VL in a given health district. Patients who start a second (line) treatment after defaulter, treatment switch or relapse should not be included as new cases, as they would be counted twice and falsify the true incidence. Same for patients that were diagnosed and registered in another clinic and transferred in should not be included as new cases as they were already recorded elsewhere.

NEW CASE			= Patient with KA who never received any treatment for KA before (treatment naïve)
PATIENT WHO HAD PAST HISTORY OF KALA AZAR			
The type of patient could be specified in the line(s) below:			
	TAAE	= Treatment after SAE	= Patient who during the course of his treatment, had a treatment switch because a serious adverse event, and now is started on a second line treatment.
	TAF	= Treatment after Failure	= Patient who had a treatment switch because of clinical failure (non-responder) i.e. no clinical improvement noted during or at the end of his KA treatment, and now is started on a second line treatment.
	TAD	= Treatment after Default	= Patient who defaulted during the course of his treatment, and was started up again with a new second line regimen
	REL	= Relapse case	= Patient who already received KA treatment for a previous episode of KA and of which he was "cured".
PKDL		= Post Kala azar Dermal Leihmaniasis	= PKDL case
TRANSFER IN			= Patient who was diagnosed with KA elsewhere, and then transferred to the PHC for continuation of treatment

Remarks:

- In the pilot project (Kaladrug-R) we proposed for TAAE, TAF and TAD cases to start a new line in the KA register, but to keep the same registration number/patient code that was attributed to this patient at the time he was recorded as a new case. This for research purposes, as we kept biological samples (see below). We used the original registration number/patient code, followed by a slash, and the number of months since the start of the initial treatment.
  Example
  - a patient is started on MIL (BPK401) but during the course of the treatment a treatment change to AmphoB is imposed due to SAE: a new line in the

KA register, and a new CRF is started with registration number/patient code = BPK401/1

- another patient is started on MIL (BPK402), there is initial cure at D28, but at his 3-month follow-up visit he presents again with fever and diagnosis of treatment failure is confirmed: a new line in the KA register, and a new CRF is started with registration number/patient code = BPK402/3

The objective of keeping the original ID code of the patient was to be able to follow up the evolution of the parasite (as identified by molecular techniques) in time: Samples taken from a "new patient" BPK402/3 can then be linked to the original parasite isolated from BPK402 before exposure to treatment in order to see if any mutations have occurred under pressure of the drug.

- "Transfers in" i.e. patients who were registered elsewhere, should be recorded using the registration number/patient code used by the referring PHC/hospital.
- The difference between *failure* and *relapse* may not always be clear. Some people may have clinically improved but not recovered completely. Relapse is when after a period (undetermined) of clinical improvement (absence of fever, reduced spleen size, return to physical activity) clinical symptoms reappear.

DIAGNOSIS

Record in the first column the method of diagnosis (e.g. rK39 RDT, parasitology) and the date of the test (can be written on the lines below).
In the second line the place of diagnosis (could be on site = at the PHC itself, in a private facility, a district hospital etc.)

TREATMENT

The columns with regards to the treatment contain:

- *Referral for treatment elsewhere*: if the patient prefers to be treated elsewhere for convenience matters, and this is approved by the doctor in charge (if not this would be LAMA (left against medical advice), in other words *defaulter*). Referral for treatment elsewhere also implies that the patient leaves with a copy of the diagnostic test/diagnosis/referral letter to the health service of his choice. The name of the health service he is referred to should ideally be noted i.e. in the last column "comments".

For all those being treated on the site:

- *Starting date*: date of start of treatment - *Drug*: drug of choice - *Dose*: daily dose	to be filled in at Day 1of the treatment
- *End date*: day of last drug taken	to be filled in on the day of treatment evaluation i.e. after treatment has been completed

EARLY OUTCOME (to be filled in at the day of treatment evaluation/completion)

Tick only one of the proposed outcomes

(case definitions taken from TDR/SEARO document)

- *Initial cure* (IC): the full course of treatment was completed within a reasonable time period (e.g. for MIL: the 28 daily doses were taken within 40 days) AND the patient has clinically improved. Clinical criteria for cure should be assessed as no fever + regression of enlarged spleen + return of appetite and/or gain in body weight.
- *Non-response*: signs and symptoms persist or recur.
- *Side-effect related switch*, whereby the side effects necessitated a change of treatment.
- *Death*: any death, whether or not related to KA[1].
- *Defaulter* (DF): patient did not come to complete treatment and/or does not present for assessment after treatment.

FINAL OUTCOME (to be filled in six months after the last drug taken)

Fill in date of the visit (or the date of the event e.g. relapse, death)

Note that the final outcome can only be reported on those with initial cure. Those who had no initial cure, already had an outcome (Non-response, Side effect related switch, Death and Defaulter) which should just be copied in these columns.

The late outcomes for those initially cured are:

- *RELAPSE* (REL): any reappearance of KA symptoms within a period of six months after the end of the treatment. This relapse is preferably parasitological confirmed (BM or spleen aspiration)
- *FINAL CURE*: no signs of relapse observed since end of treatment.
- *DEATH* (D): any death, whether or not related to KA[1]
- *LOST TO FOLLOW UP* (LFU): patient has not shown up for clinical evaluation, and tracing has been unsuccessful.

[1]Cause of death can be noted in the comments column at the right

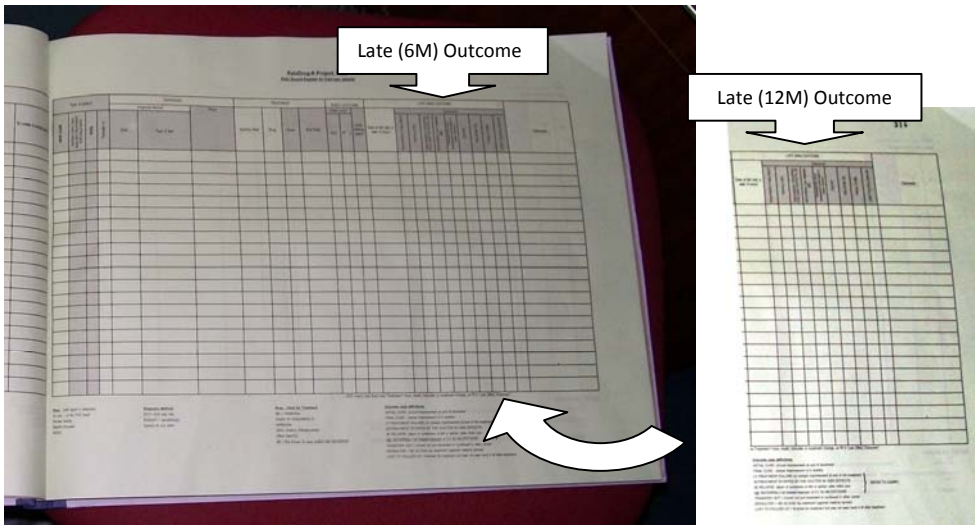
Remark:

FINAL OUTCOME AT 12 MONTHS

In the register, an extra sheet can be added for 12 months outcomes collection e.g. in Nepal after the observation of high frequency of relapses after 6 months. The outcomes are the same as those mentioned above. PKDL can be added.

The same tool can be used for later outcome evaluations (24 months, 36 months).

PKDL: Patient has developed skin disorders suggestive for PKDL (preferably confirmed by dermatologist/anatomopathology (Skin Slip Smear, SSS).



Practical Organization of follow up of KA patients and filling in the KA Register:

- Initial data (start up): can be filled in by the doctor in charge of treatment, a nurse at IPD or a focal person designated for Kala azar related activities (e.g. pharmacist).
  A major task of initiating the treatment is the counseling, on VL and VL transmission, signs and symptoms of cure and treatment failure, on side effects of the drugs and how to deal with these and on the importance of adherence to the treatment and the return visits.
  Therefore, assigning one or two persons for VL case management is mandatory for good clinical practice.
- Follow-up of data during treatment:
  - As VL patients need to return for their provision of MIL, ideally one person should keep an overview of all patients under treatment, and notify whenever a patient does not return (defaulter) so that tracing can be started (all necessary information for tracing is in the register)
  - At the final visit, at the end of treatment: filling in the Early Treatment Outcome
  - The MoH has provided incentives for complete treatment. Payment of (the last part of) this incentive can be kept for this final visit, to incite VL patients

to return even though the treatment has been completed and signs and symptoms have subsided.

- Follow up of Late Treatment Outcome
    - Former VL patients should be seen and evaluated 6 months after the end of the treatment, and the register should be completed with the Late Treatment Outcome.
    - In order to do so, patients should be invited to present themselves 6 months after treatment, but a more realistic alternative is
        - Contact the patient through mobile phone and inquire on his health
        - Make use of the existing network of health volunteers at village level to check on the former VL patient

Conclusion:

This register collects systematically the data on every Kala azar patient identified, (diagnosed and treated) at the health center. These data are needed to complete the epidemiological tools with regards to incidence and outcome.
This contains challenges: While for most of the cases, suspicion, diagnosis and treatment is indeed done at the (local) health institution, however

1) Some cases can not be confirmed on the spot by simple rK39 rapid test and need to be referred to a level 3 or 4 health facility for Bone Marrow or Spleen aspiration, and then yes or no be referred back for treatment & follow-up
2) Some diagnosed locally may not be treated at the health institution (e.g. pregnant women in PHC who need referral for second line treatment)

In one way, the register should be exhaustive (= include all KA patients of the block area), in particular to organize the 6 months follow-up and register the outcome and keep the overview.
On the other hand, double registry (on two different sites) should be avoided, as this would falsify epidemiological data.

The register should be printed, not handmade, in order to assure optimal recording conditions and storage of the registered data. (see also tuberculosis register?)

The register should be the tool to monitor the treatment outcomes: at the start of every month, the KA responsible clinician will check the list of patients that started treatment 6 months earlier, and organize a way of contacting them/inviting them to come to the PHC for a check-up visit.

This daily record register, if filled in properly and systematically, will provide all necessary data to allow the staff to compile the monthly and the quarterly report, without having to consult individual patient files or documents.

Since the register is already very large, the 12 month (and subsequent) outcome evaluations will be registered on a (small) supplementary sheet that can be attached or stapled at the appropriate time to the right side of the register.