

FOLLOW UP PROCEDURES FOR POSITIVE CASES

1. PURPOSE

This document describes the follow up procedures for treating individuals in control clusters identified during the longitudinal monitoring survey as positive cases (children with any intensity of STH infection and adults with moderate to high intensity STH infection). This SOP lays out the key steps that all sites are expected to carry out during this process.

2. INTENDED USERS

The intended users of this SOP are trial coordinators, data managers, field supervisors, site medical teams and all other DeWorm3 team members and other stakeholders involved in the follow up procedures for treating positive cases.

3. RESPONSIBILITIES

All DeWorm3 study staff and individuals involved in the treatment of positive cases in control clusters should understand and follow this SOP. It is the responsibility of the site's Principal Investigator (PI) to ensure that all relevant staff comply with this SOP during relevant activities.

4. DEFINITIONS

4.1. Longitudinal Monitoring Cohort (LMC) is a follow-up study of an age-stratified cohort of residents in each cluster of the DeWorm3 study, identified at baseline and followed until the endline of the study. Its purpose is to track STH prevalence and reinfection patterns over time.

4.2. Moderate to high intensity infection: Defined by the estimated number of eggs per gram (epg) enumerated following analysis of a stool sample using the Kato-Katz technique. The threshold is ≥ 2000 epg for hookworm, ≥ 1000 epg for *T. trichiura* and ≥ 5000 epg for *A. lumbricoides*.

4.3. Positive cases: (1) All children (2-14 years) in control clusters in Benin and Malawi, identified as having an STH infection through Kato-Katz performed during the LMC surveys (2) All adults in control clusters (at all sites) identified as having a moderate to high intensity STH infection.

4.4. LM Cases treatment list: A list of the positive cases that require treatment with albendazole

5. REQUIRED MATERIALS

5.1. LM Cases paper log forms in required quantities

5.2. Albendazole drugs in required quantities with valid expiry dates

5.3. LM Cases treatment list

5.4. DeWorm3 adverse event reporting form

5.5. Materials for DeWorm3 identification including CDD ID tags, t-shirts, bags etc.

5.6. Treatment summary forms

6. PROCEDURE

6.1. Treatment preparation

a. Following analysis of LMC stool samples using the Kato-Katz technique, all positive cases should be visited and treated with albendazole.

b. Treatment of positive cases should take place within three months of diagnosis and **should not take place concurrently with MDA activities.**

c. Treatment exclusion criteria include: (a) pregnant women in their first trimester, (b) seriously ill individuals (people with an acute medical condition that warrants medical

consultation and renders the individual unable to engage in the normal activities of daily living without assistance because of their illnesses), (c) those with a known history of adverse reaction to Benzimidazoles and (d) individuals who are intoxicated with drugs or alcohol.

- d. Treatment of positive cases should be carried out by site medical teams accompanied by field supervisors/workers to record the treatment. Individuals should be given a single dose of 400mg of albendazole.
- e. In advance of the treatment of positive cases, the site coordination team should conduct a sensitization visit or phone call to village leaders to ensure that they are aware of the treatment in advance of the survey team's visit and understand why the individuals are being treated.
- f. The trial coordinator should ensure that they have a copy of the LM Cases treatment list and that this has been shared with field supervisors and medical teams.
- g. Field supervisors should ensure that they have sufficient quantities of the LM cases paper log forms to record all treatment taking place.

6.2. Delivery of albendazole and recording of treatment

- a. Upon arrival at the household record the cluster village on the LM cases log form.
- b. Record the name and ID of the individual, confirm that their details are correct and then navigate to the household. If necessary, use the Google map functionality to help navigate to the household.
- c. Upon arrival at the household enquire which individual(s) provided a stool sample in the recent survey. Confirm that the named individual you have on the LM case list is one of the surveyed individuals and that they are present at the time of the visit.
- d. If the individual confirms they provided a stool sample and they are present, explain that they are being followed up for treatment due to identification of a moderate to high intensity of infection in their stool sample which was previously collected during the LMC survey.
- e. Emphasize that this treatment is a one-off activity due to their current infection status and does not mean that they will be treated during the next round of MDA.
- f. If the individual on the LM cases treatment list did not provide a stool sample and it was another household member in their place, contact the trial coordinator.
- g. Before proceeding to treatment, confirm that the individual does not meet any of the exclusion criteria (pregnant in first trimester, seriously ill, intoxicated or has a known history of adverse reaction to benzimidazoles). For intoxicated individuals a return visit should be made to treat them when they are no longer intoxicated.
- h. If the individual is not eligible for treatment thank them for their time and then proceed through to select the reason for ineligibility before saving and finalizing the form.
- i. If the individual is eligible and consents to treatment, DeWorm3 staff should directly observe compliance and record when a tablet has been ingested. If the tablet is spat out or vomited within 30 minutes the tablet should be re-administered.
- j. Tablets should not be left at the house for absent household members. A call-back visit should be arranged with the household to treat the absent members. Study staff should return at least 3 times to try to reach individuals who were absent at the time of the visit.
- k. Once treatment has been observed thank the individual for their time and answer any questions they may have about the treatment.

- I. Following this, proceed to save and finalise the form, recording any notes or observations you may have

6.3. Side effects and adverse events

- a. Ingestion of albendazole is rarely associated with side effects. There may be some mild side effects like dizziness, nausea, headache, and vomiting. Side effects are most commonly experienced by individuals with heavy infections but these side effects disappear after some time.
- b. Record any immediate side effects on the notes section at the end of the LM cases log form.
- c. Ensure that a system of passive AE monitoring is in place similar to that employed during the community-wide MDA. Record any AEs/SAEs as per **SOP_511. Surveillance and reporting of AEs/SAEs**. All AEs/SAEs should be followed up by the study medical team.
- d. Any experience reported by a participant that the investigator regards as serious or that would suggest any significant hazard, contraindication, side-effect, or precaution that may be associated with the use of the drug should be recorded on a serious adverse event reporting form.

6.4. Treatment of non-STH infections detected through Kato-Katz

- a. During the Kato-Katz procedure, it is possible that other infections were also picked up and recorded on the LM cases log form (these include *Strongyloides* spp, *E. vermicularis*, *Taenia* spp, *H. nana*, *H diminuta*, *S. haematobium*, *S. mansoni* and *F. hepatica*)
- b. The LM cases treatment list will contain primarily the individuals with STH infections for treatment with albendazole. However, individuals identified to as having one of the infections outlined in *section 6.4.a.* can also be added to the list for treatment. Where these infections are identified and added to the treatment list the site should take necessary steps to ensure that the required drugs for treatment have been sourced in advance of the activity.
- c. Cases of specified enteric infections outside of those mentioned in *section 6.4.a.* will be treated by the site medical team independently.