

CONDUCTING COMMUNITY-WIDE MASS DRUG ADMINISTRATION (MDA)

1. PURPOSE

This document describes the processes by which sites will prepare for mass drug administration (MDA) and deliver albendazole in communities in the study clusters randomized to receive community-wide treatment. This SOP lays out the key steps and processes that all sites are expected to carry out during the community-wide treatment.

2. INTENDED USERS

The intended users of this SOP are site DeWorm3 team members and other stakeholders involved in the delivery of community-wide MDA such as cluster leads and community drug distributors (CDDs).

3. RESPONSIBILITIES

All DeWorm3 study staff and individuals involved in the community-wide MDA 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 all MDA campaigns.

4. DEFINITIONS

- 4.1. **Adverse event (AE):** An adverse event (also referred to as an adverse experience) can be any unfavorable and unintended sign, symptom, or disease temporarily associated with the use of a drug, regardless of drug causality or relationship.
- 4.2. **Cluster household roster:** A list of all the households in the cluster complete with village name, household IDs, head of household name, and number of household members.
- 4.3. **Community drug distributor (CDD):** Volunteer drug distributors who will be conducting MDA in intervention (i.e. community-wide MDA) clusters.
- 4.4. **Community-wide mass drug administration (MDA) A:** This refers to the round of community-wide MDA that is delivered in the intervention clusters within the same time frame as the school-age-targeted MDA that is delivered in the control clusters
- 4.5. **Community-wide mass drug administration (MDA) B:** This refers to the additional round of community-wide MDA in the intervention clusters delivered six months apart from community-wide MDA A. Community-wide MDA B is not delivered within the same time frame as the school-age-targeted MDA in the control clusters
- 4.6. **Drug distribution channel:** The mechanism through which anthelmintic drugs are provided to target communities or population groups.
- 4.7. **Exclusion criteria:** Characteristics that preclude certain individuals from treatment and render them ineligible for treatment.
- 4.8. **Mass drug administration (MDA):** Distribution of drugs to an entire eligible population of a given administrative setting (in the case of this SOP, the residents in the clusters randomized to receive community-wide treatment).
- 4.9. **MDA treatment log:** smartphone-based treatment forms programmed in SurveyCTO, with one form per household, pre-populated with all household members for CDDs to record on the treatment status of
- 4.10 **School-age-targeted MDA:** Distribution of drugs to all school and pre-school children aged 2-14 years / 1-19 years whether enrolled in school or not.
- 4.11 **Serious Adverse Event (SAE):** An event that is fatal, life-threatening, disabling, or incapacitating or that results in hospitalization after drug intake.

5. REQUIRED MATERIALS

- 5.1. Albendazole drugs in required quantities with valid expiry dates
- 5.2. Cluster household roster
- 5.3. smartphone-based MDA treatment log programmed in SurveyCTO
- 5.4. Serious adverse event case report form
- 5.5. Materials for DeWorm3 identification including CDD ID tags, t-shirts, bags etc.
- 5.6. CDD training materials
- 5.7. CDD job aids
- 5.8. Information Education Communication (IEC) materials
- 5.9. Albendazole tracking tool
- 5.10 Treatment summary forms

6. PROCEDURE

6.1. Defining the target population

- a. Albendazole will be administered twice yearly to **all individuals above the age of 12 months** residing in the 20 intervention clusters randomized to receive community-wide MDA.
- b. Treatment exclusion criteria include: (a) Children <12 months, (b) pregnant women in their first trimester, (c) seriously ill individuals (people unable to engage in the normal activities of daily living without assistance because of their illnesses) (d) those with a known history of adverse reaction to Benzimidazole. [any additional site-specific exclusion criteria documented in country guidelines]. See *SOP_506: Pre-MDA screening for treatment eligibility* for further details of ineligible individuals (those to be excluded from treatment).
- c. In the event that community-wide MDA is being delivered alongside or soon after school-age-targeted MDA, school children recently [within last 2 weeks] treated in school should be excluded from treatment at the household on the basis of evidence of an inked finger of/ reported treatment. These children will be recorded on the MDA treatment logs as having been treated in school.

6.2. Advanced planning with relevant ministries

- a. To encourage maximum support and engagement, planning meetings will be held at all administrative levels to clearly lay out the roles and responsibilities of each cadre involved in the community-wide MDA. Stakeholders should be identified from the site's stakeholder mapping worksheet.
- b. The roles and responsibilities of study staff and relevant ministries, and the plan for how the two groups will work together, should be established during the planning period.
- c. Dates for each round of community-wide MDA are to be agreed collectively with relevant ministries to avoid clashes with other ongoing programmes or activities in the region.
- d. Tasks such as IEC material development, remuneration decisions etc. should be planned collaboratively with the stakeholders 3 months in advance of the first round of treatment. The proposed mechanisms are to be shared with the DeWorm3 core team.

6.3. Establishing the drug distribution channel

- a. The timing of MDA across intervention and control clusters should be carefully planned to avoid double treatment of school-age children (SAC) and pre-school-age children (pre-SAC).
- b. The drug distribution channel for the delivery of albendazole to the communities is a

house-to-house administration to ensure treatment status of all individuals can be accurately recorded against the cluster household roster and MDA treatment log and to ensure individuals not residing in the cluster are not accidentally treated.

- c. Drugs should be delivered by trained clinical personnel or country specific authorized drug distributors. CDDs may be accompanied by study staff based on site preference
- d. A series of steps are documented below outlining the key processes for delivery.

6.4. CDD recruitment and training

- a. The total number of CDDs to be recruited per cluster should be identified based on the cluster household roster (i.e. number of households in the cluster). Approximately one CDD is needed per 50 households.
- b. Determine the timeline for recruitment and the period of engagement of the CDDs, as well as the remuneration and payment schedule. A bonus will be held back and paid to all CDDs in a cluster upon confirmation of cluster coverage of at least 90%.
- c. Determine recruitment criteria for CDD selection for community-wide MDA, such as individuals selected by the community or who have had previous experience in LF campaigns etc.
- d. Establish the chain of CDD management and supervision that will be provided by both MOH structures and DeWorm3 study staff. This will be highly dependent on which channel the remuneration comes from.
- e. Training will be conducted in a cascade manner using standardized materials, checklists and pre-post-tests. Study staff will attend and observe the CDD trainings to ensure cluster supervisors follow the SOP during training.

6.5. Social mobilization and community sensitization for community-wide treatment

- a. To encourage high treatment coverage in the community-wide intervention arm, community sensitization materials will be developed 3 months prior to the MDA and sensitization activities will take place within one month prior to scheduled MDA events.
- b. Sensitization activities will be designed in close consultation and collaboration with the National NTD programme and in accordance with site norms and past MDA experiences. Refer to *SOP_503. Sensitisation and IEC for community-wide deworming* for details of recommended sensitization channels. Due to the nature of the trial, public address systems and radio are not advised.
- c. Where possible, MDA activities will be scheduled to accommodate seasonal and cultural activities that might influence MDA participation, such as holidays, migratory events, or crop harvesting.

6.6. Drug supply chain: calculating albendazole doses

- a. Albendazole for the community-wide MDA is procured through the standard channel – a requisition through county WHO office.
- b. Once received in county, an “albendazole tracking tool” will document the movement and timelines of the drugs to their destination.
- c. Ahead of the planned community-wide MDA date, a drug distribution plan should be drawn up for each of the 20 clusters, to ensure that the correct number of albendazole doses are delivered to the distribution centre for each of the intervention clusters.

- d. Drug distribution plan calculations will be based on the number of individuals on the cluster household rosters, as each individual over 12 months will receive a **single dose of 400 mg** of albendazole.
- e. Provision for loss and wastage should be included, adding a 5 % spillage and 10% buffer in storage for each cluster. Sites should account for whether or not children in intervention clusters are treated in communities or in schools. For the latter, treatments should be ordered by the MOH or other managing entity.

6.7. Drug supply chain: collection and return of albendazole

- a. The expiry date of batches of albendazole should be confirmed prior to distribution, to ensure that drugs have not already expired. If drugs have expired, they should be discarded according to manufacturer directions.
- b. CDDs should collect the albendazole from their supervisor at a designated centre. They should collect a sufficient number of drugs to last them 5 days. After 5 days CDDs should check in with the supervision and collect any additional drugs required
- c. On collection of drugs by the CDDs, the numbers of tins of albendazole are to be logged by both the supervisors and CDDs to track the numbers going out and returned. A cluster-level albendazole tracking tool should be used to document this.
- d. On completion of the MDA all leftover albendazole (i.e. open and unopen tins remaining after MDA) must be returned by the CDDs to the designated centre within 24 hours of the final treatment distribution day and must be accounted for using the cluster-level albendazole tracking tool.
- e. Unopened tins of albendazole can remain in storage until the following MDA round.

6.8. Delivery of albendazole via a house-to-house campaign

- a. House to house MDA will be conducted and treatment will be delivered to all adults and children above the age of 12 months, who are determined to be eligible providing they were not treated via other platforms within the past two weeks.
- b. CDDs should use the cluster household roster to plan their route around the village and locate and check off the houses they are to visit.
- c. CDDs will carry smartphone-based MDA treatment logs programmed in SurveyCTO as they provide treatment house-to-house. A separate MDA treatment log will be filled out for each household in the area that the CDD will be visiting.
- d. The treatment logs will be pre-populated with the names of individuals in each household. On locating each household the CDD will confirm that they have reached the correct household, this can be done by reading out the household members listed. The household member list can be updated based on the residence criteria outlined in *SOP_202: Administering the household census*. For example, if there is a new household member (i.e. by marriage) the name of this individual should be written in the blank rows of the MDA treatment log.
- e. CDDs will be prompted to fill out the household members' age, sex, school enrollment status, whether they were present and whether they took the drug in front of the CDD (i.e. directly observed therapy). If the member did not take the drug, the CDD will be prompted to provide a discrete answer for why the individual did not take the drug.
- f. The CDDs should also carry empty treatment logs in the event that a pre-populated household treatment log is missing, or a new household is present in the targeted area that has not been previously identified and is not on the cluster household roster.
- g. Caregivers, pre-SAC and SAC will be asked if children in the household received

deworming tablets in school or through other national programme activities within the past 2 weeks.

- i. In clusters where children are first targeted by National Programmes: All children not treated through any other National Programme as indicated by lack of finger inking or some other method of treatment confirmation will be treated in the household. Children who do not remember if they have been treated (and in the absence of caregiver confirmation) through another programme should be given treatment.
 - ii. In clusters where children are first targeted by community-based MDA delivered house to house: CHVs ink the finger of any pre-school or school-age child treated in the household to avoid double treatment during the subsequent school-age-targeted MDA that follows in the area.
- f. Appropriate administration of tablets to young children or individuals unable to swallow the tablet is important. The tablet should be broken and crushed between 2 spoons, then safe water added to help administer the drug.
 - g. Others should chew the tablet and if required consume safe water.
 - h. If the tablet is spat out or vomited within 30 minutes of administration the tablet should be re-administered.
 - i. CDDs and field officers will directly observe compliance and **record** when each tablet is ingested by all individuals meeting treatment criteria using the MDA treatment logs.
 - 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 3 times to try to reach individuals who were absent at the time of MDA.

6.9. 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, all likely due to the worms being passed through the body. Side effects are usually experienced by children with high infections but these side effects disappear after some time.
- b. Any immediate side effects are to be documented by the CDD on the drug distribution case report forms.
- c. Adverse events will be passively monitored by health workers in the region for all participants receiving treatment and recorded as per *SOP_511. Surveillance and reporting of AEs/SAEs*. CDDs shall report all adverse events to the cluster supervisor who will escalate the report through the MOH and study 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.

6.10 Monitoring and Evaluation

- a. Spotchecks will be conducted by the study staff during the community-wide MDA to ensure that treatment is being conducted in line with the SOP and to ensure high coverage.
- b. Midway through the campaign CDDs should meet with their supervisor to top up any drugs required and have their MDA treatment logs reviewed for completeness. Cluster household rosters will be reviewed by the supervisor at this midpoint.
- c. MOH supervision of CDDs will be conducted alongside study staff supervision.

6.11 Data submission and review

- a. On completion of the community-wide MDA campaign, remaining MDA treatment logs will be collected from each CDD by the DeWorm3 cluster supervisor. They will summarise the data, submitting this to the DeWorm3 site office.
- b. Coverage will be calculated on a cluster-level basis. If the coverage is 90% or above at the end of the MDA campaign, payment plus the bonus will be made to CDDs working in the cluster.
- c. DeWorm3 study team should liaise with MOH to align reports and summarised data will be cascaded up through the MOH channels using summary forms at each administrative level, for the data to be captured by Health Management Information Systems / Demographic Health Information System II.
- d. The post MDA coverage survey will be carried out within 7 days following last day of treatment.

6.12 Mop up

- a. Any clusters not reaching 90% population coverage according to the post-MDA coverage survey will be required to conduct a mop-up campaign. The CDD and cluster supervisor bonus will only be paid once this has been conducted.
- b. During the mop-up campaign, the CDDs will use the MDA treatment log to identify the individuals not treated during the main campaign. Following the 3 days of mop up, the data will be resubmitted and a decision on the bonus made.