CONDUCTING TARGETED MASS DRUG ADMINISTRATION (MDA)

This SOP outlines the key processes that it is expected will be implemented during the targeted MDA at all sites, providing a template for the critical steps and an example of the level of detail required. The exact approaches will differ across sites according to the national standard of care. Therefore, it will be necessary for each site team to re-draft the sections in the template to reflect the standards of care pertaining to their national programme.

1. PURPOSE

This document describes the processes by which sites will prepare for mass drug administration (MDA) to deliver albendazole to school-age children in the study clusters randomized to receive only the targeted MDA (control clusters) in accordance with national Ministry of Health (MOH) and Ministry of Education (MOE) guidelines.

2. INTENDED USERS

The intended users of this SOP are institutions and site DeWorm3 teams involved in the delivery of targeted MDA for pre-school-age children (pre-SAC) and school-age children (SAC). Teachers and community drug distributors (CDDs) may also refer to this SOP.

3. RESPONSIBILITIES

All DeWorm3 study staff and partners involved in the targeted MDA should understand this SOP. The balance of responsibility during this activity between the site DeWorm3 staff and the MOH/MOE will differ greatly by site but the site Principal Investigator PI will ensure that this SOP is shared with the NTD programme manager, and the relevant bodies involved in coordinating the targeted MDA for their review. Finally, the PI will ensure the SOP is readily available for sharing during the targeted MDA training sessions. It is the responsibility of the site's PI to ensure that all relevant research staff comply with this SOP during all MDA campaigns.

4. DEFINITIONS

4.1. **Drug administration channel:** The mechanism through which anthelmintic drugs are provided to target population groups.

4.2. **Enrolled students:** Pupils who have registered in a public, private, or community schools for the academic year, irrespective if they attend the school of not.

4.3. **Non-enrolled students:** Pupils who have not registered in a public, private, or community school for the academic year.

4.4. **Mass Drug Administration (MDA):** Distribution of drugs to an entire targeted population of a given administrative setting. In DeWorm3 control clusters, the targeted population is pre-SAC and SAC, in accordance with existing National STH programme guidelines and the standard of care.

4.5. **Pre-school-age children (pre-SAC):** Children aged 24 months to 4.9 years who are either enrolled or non-enrolled in a preschool or nursery.

4.6. **School-age children (SAC):** Children aged 5-14 / 5-19 years who are either enrolled or non-enrolled in primary/secondary school.

4.7. **Targeted MDA:** Distribution of albendazole to all pre-SAC and SAC aged 2-14 years / 1-19 years / 5-14 years whether enrolled in school or not.

4.8. **Targeted MDA Scenario 1:** The National Deworming Programme delivers targeted MDA and accompanying activities, with consultation and technical support from DeWorm3

4.9. **Targeted MDA Scenario 2:** DeWorm3 project delivers targeted MDA and accompanying activities, with consultation and technical support from National Deworming Programme

4.10. **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, without any judgment about causality or relationship to the drug.

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. For targeted MDA Scenario 1 sites

a. Finger ink
b. Treatment summary forms
c. Tablets loaded with targeted MDA spotcheck surveys

5.2. For targeted MDA Scenario 2 sites

a. Albendazole drugs in required quantities with valid expiry dates
b. Finger ink
c. Class enrolment lists / class registers
d. MDA treatment log / report forms used in the national STH programme
e. School albendazole tracking log
f. Treatment summary forms
g. Serious adverse event case report form
h. Teacher/CDD/health worker training materials
i. Information, education, & communication (IEC) materials
j. Tablets loaded with targeted MDA spotcheck surveys

6. PROCEDURE

6.1. Defining the target population

a. Albendazole will be administered once/twice yearly to all pre-SAC and SAC (1-19 years / 2-14 years / 5-14 years) residing in the 20 control clusters randomized to receive only targeted MDA in accordance with the existing National STH Programme or similar structure.

b. Treatment exclusion criteria include: (a) children under 24 months,(b) those known to be pregnant in their first trimester, and (c) those with a known history of adverse reaction to Benzimendazole. See *SOP_ 506: Pre-MDA screening for treatment eligibility* for further details of ineligible individuals who are to be excluded from MDA.

6.2. Involvement in planning and sensitization with relevant ministries

a. In targeted MDA Scenario 1 sites: A DeWorm3 study staff representative should attend National Deworming Programme planning meetings relevant to the study site region, so that the DeWorm3 team is aware of the timeline, strategy and logistics of the targeted MDA.

b. In targeted MDA Scenario 2 sites: To encourage maximum support and engagement, planning meetings will be held at all administrative levels to clearly establish the roles and responsibilities of each cadre involved in the targeted MDA. Stakeholders should be identified from the site's stakeholder mapping worksheet.

c. The roles and responsibilities of the relevant ministries (Ministry of Health, Ministry of Education, Ministry of Health and Family Welfare) and study staff should be clearly outlined in these meetings, along with a plan for how the groups will work together to implement activities.

d. Dates for the annual/biannual targeted MDA are to be established from the MOH or agreed upon collectively with relevant ministries to avoid clashes with other ongoing programmes or activities in the region.

e. In the event that aspects such as strategy, IEC materials and remuneration have not been standardized as part of the national programme, 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 administration channel**

a. The timing of MDA across intervention and control clusters should be carefully planned to avoid double treatment of SAC and pre-SAC.

b. Albendazole will be delivered to pre-SAC and SAC through primary schools, although nursery schools and secondary schools may also be included as administration centres.

c. Albendazole will be delivered by trained teachers and/or clinical personnel or country specific authorized drug distributors in the schools, according to national practice. Ministry staff administering albendazole 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. **Recruiting and training individuals administering targeted MDA**

a. The total number of teachers/CDDs to be recruited per school are determined according to the national standard practice.

b. Training will be conducted in a cascade manner using standardized materials, checklists and pre-post-tests and will follow the national guidelines. Study staff will attend and observe the teacher/CDD trainings to identify the steps involved.

6.5. **Social mobilization and community sensitization for targeted MDA**

a. The preparations for school-age-targeted MDA involves pre-MDA social mobilization according to national mobilization strategies.

b. In targeted MDA Scenario 2, if not already available as part of a national school-based programme, sensitization materials will be developed at least 3 months prior to the MDA and sensitization activities will take place within one month prior to scheduled targeted MDA events. 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.

c. In targeted MDA Scenario 1, sensitization materials already developed as part of the ongoing national school-based programme will be collected and activities will be observed by DeWorm3 implementation science study staff to document in the routine tracker worksheets.

6.6. **Drug supply chain: calculating required albendazole doses**

a. Albendazole for the SAC-targeted MDA is procured through the standard channel – a requisition through county WHO office.

b. Once received in country, sites should follow the standard process for albendazole movement from National level to the schools. A school albendazole tracking tool will document the movement and timelines of the drugs to their destination at schools.

c. Ahead of the planned targeted MDA, a drug distribution plan will be established for each school.

d. Drug quantification calculations will be based on the number of individuals on school enrollment registers, as each individual between 1-19 years / 2-14 years / 5-14 years will receive a **single dose of 400 mg** of albendazole.

e. Provision for non-enrolled children and any loss and wastage should be included in the quantification calculation, adding a 5 % spillage and 10% buffer in storage for each school.

f. Sites should account for whether or not children in intervention clusters will be treated as part of the community-wide MDA prior to the targeted MDA in schools when calculating the required albendazole doses for the targeted MDA.

6.7. **Drug supply chain: collecting and returning albendazole tablets**

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. All batches should have at least 6 months remaining before expiry.

b. Teachers / CDDs should collect the albendazole from their supervisor at a designated centre either at the end of the training or at the time designated by their supervisor. Teachers and supervisors should confirm that the number collected aligns with the drug quantification calculation.

c. Upon collection of drugs, the number of tins of albendazole are to be logged by both the supervisors and teachers/CDDs on the school albendazole tracking log to track the quantities going out and returned.

d. On completion of the MDA, all leftover albendazole (i.e. open and unopen tins) must be returned by the teachers/CDDs to the designated centre within 24 hours of the last day of targeted MDA and must be accounted for using the school albendazole tracking log.

e. Unopened tins of albendazole can remain in storage until the following round of targeted MDA the following year. Open tins should be handled as per the National MOH guidelines.

6.8. **Delivery of albendazole via a school campaign**

a. Treatment of all eligible pre-SAC and SAC will be conducted at schools, preschools and secondary schools in the study site providing they were not treated via other platforms such as the community-wide MDA within the past six weeks.

b. Targeted MDA will be carried out during a National school deworming day.

c. The treatment logs will be pre-populated by the teachers/CDDs, where possible, at least one week prior to MDA with the names of enrolled SAC and pre-SAC based on the class registers. These logs should be filled for each individual class and for all grade levels of the school.

d. Non-enrolled SAC and pre-SAC will be encouraged to come to school for treatment on deworming days, where standard of care specifies this, and blank treatment logs will be used to register and document treatment of these individuals on the deworming day.

e. Adults that come to schools on the day of school deworming should not be treated, unless this is expressly outlined in the national programme standard of care.

f. Teachers / CDDs will be prompted to fill out the students' age, sex, school enrollment status, whether they were present and whether they swallowed the albendazole while directly observed. If the child did not swallow the albendazole, the teacher / CDD will be prompted to provide a discrete answer detailing why the individual did not take the drug as noted on the treatment log.

g. Treatment in intervention clusters (targeting individuals of all ages) will occur close in time to treatment in control clusters. Thus, pre-SAC, SAC and present caregivers will be asked if the children received deworming tablets during the community-wide MDA (at their household) or through other national programme activities within the past six weeks.

h. Once treated, the teacher / CDD should ink the child's finger or provide another method of treatment confirmation to the child.

i. For children who reside in intervention clusters:

   i. Where children are first treated by the targeted MDA: Once treated, the teacher / CDD should ink the child's finger or provide another method of treatment confirmation to the child. This will act as a marker of treatment confirmation during the house-to-house treatment in the community-based MDA. Children who report having been treated through another programme in the last six weeks should not be given treatment.

   ii. Where children are first treated by community-based MDA delivered house to house: Children who display an inked finger or some other method of treatment confirmation indicating treatment by the CDD during the community-wide MDA **should not be double treated**. Only eligible pre-SAC and SAC who do not display a marker of recent treatment should be given albendazole.

j. In cases where praziquantel is being given by the school programme, alongside albendazole, the albendazole should be given first as it is more palatable and can be chewed.

k. Appropriate administration of tablets to young children or individuals unable to swallow the tablet is important. The tablet should be broken and crushed between two spoons, and mixed with safe water to create a solution for the child to drink to help administer the drug.

l. All other children should chew the tablet and if required, consume safe water.

m. If the tablet is spat out or vomited within 30 minutes of administration the tablet should be re-administered and noted accordingly on the treatment log.

n. Teachers / CDDs and study staff must directly observe compliance and **record** when each tablet is ingested by all individuals meeting treatment criteria using the MDA treatment logs. Where the SAC-targeted programme is fully managed by the MOH, study staff will attend a selection of the schools to observe.

o. Tablets should not be given to neighbors or relatives for absent class members.

6.9. **Dealing with any occurring side effects or 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 infection intensities but these side effects disappear after some time.

b. Any immediate adverse events must be documented by the teacher / CDD.

c. AEs will be passively monitored by health workers in the region for all participants receiving treatment and recorded as per *SOP_511. Adverse event and serious adverse event reporting.* Teachers / CDDs must report all adverse events to their 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 SAE reporting form and escalated to the appropriate MOH personnel.

6.10. Monitoing and Evaluation

a. Spotchecks will be conducted by the study staff during the targeted MDA to ensure that treatment is being conducted in accordance with the national guidelines.

b. Approximately 30 study staff will be sent to a random (30%) selection of schools on deworming day to conduct these spotchecks.

c. A monitoring checklist will be used on which to document availability of necessary materials (i.e. drugs, treatment logs), timing of deworming, correct completion of treatment log books, correct implementation of finger inking (if appropriate).

d. MOH/MOE supervision of teachers/CDDs will be conducted as per the national standard of care, with additional support from DeWorm3 study staff.

6.11. Data submission and review

a. On completion of the targeted MDA campaign, MDA treatment logs will be collected / photographed/photocopied from each school by the DeWorm3 study staff for data summarization and a copy left in the schools to cascade up through the regular ministry channels.

b. Coverage will be calculated on a school-level basis.

c. DeWorm3 study staff should liaise with MOH to align reports and summarised data will be cascaded up through the MOH and MOE 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 targeted MDA coverage survey will be carried out 7 days following school deworming day.