

1. Purpose and overview:

This SOP provides step-by-step instructions for the scheduling of mass drug administration (MDA) visits to villages for the LAKANA trial and for the assignment of data collectors to each scheduled MDA. Scheduling is performed in two steps: first, on a district by district basis, each village is scheduled and second, data collectors are assigned to each village. All 9 MDAs for all villages within a district are assigned at the same time but the scheduling of later MDA can be adjusted over time. An electronic, tablet-based scheduling tool is used to generate the initial schedule and update it over time. The scheduling tool will identify scheduling conflicts, which the study coordinator can then resolve. Once the schedule has been generated and data collector assignments have been made, district, village and data collector level schedules can be generated in PDF format.

2. Applicability to and responsibilities of various staff members

Staff member	Responsibility
Study coordinator	Oversees all scheduling activities, manages master schedule of MDAs for all districts and villages, tracks completion of MDAs according to the master schedule and remediates issues.
District supervisor	Reviews master MDA schedule and provides feedback to the schedule coordinator, adjusts schedule within agreed constraints to accommodate local scheduling issues and assigns data collector teams to each village MDA. Troubleshoots day-to-day staffing issues, seeking help from the study coordinator as needed. Tracks completion of MDAs at the village level.
Field supervisor	Works with district supervisor to ensure village MDAs are staffed and completed appropriately.
Data collector	Conducts data collection according to the schedule defined by the schedule coordinator and district supervisor. Communicates work status and MDA completion status with the field supervisor.

3. Required materials

Item	Number	Specification
Data collection tablets	One tablet per district supervisor plus one for the scheduling coordinator.	Each district supervisor needs a data collection tablet to make adjustments to the local schedule and track completion of MDAs.

4. Definitions and general instructions

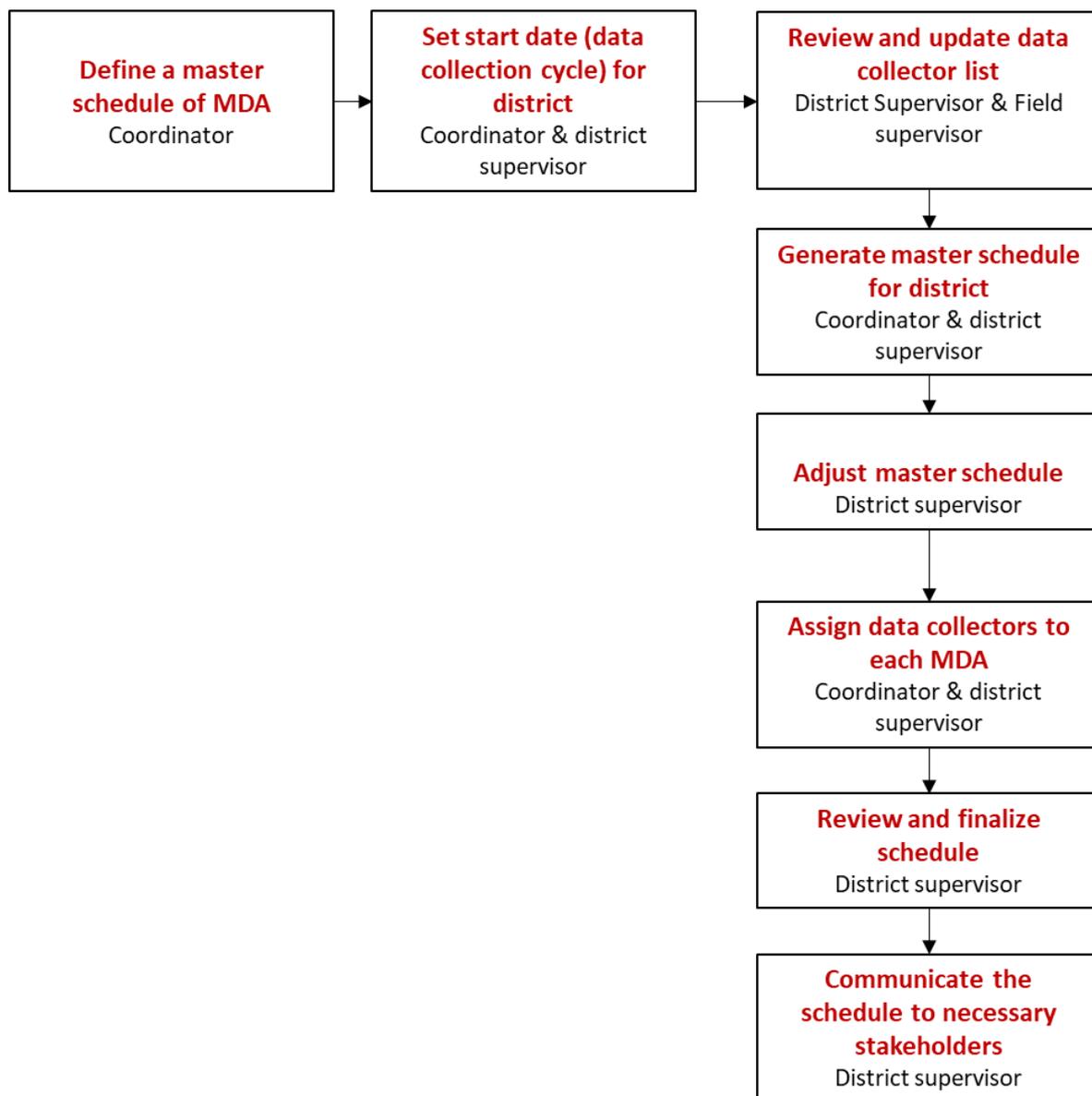
4.1. Definitions

- 4.1.1.** Village MDA: one complete round of mass drug administration in a specific village by the LAKANA team, during which all households in the village will be visited and trial activities will be conducted. Each village will be entered 9 times over the course of the trial. The first round will take longer than the others due to the novelty of the procedures, the need to establish the team's credibility in the village, and extra baseline data collection. Subsequent rounds will be shorter, and the final round will be shortest due to the absence of study drug treatment. Villages may also be entered prior to the start of data collection in order to enumerate households.
- 4.1.2.** Household enumeration exercise: if conducted, a small team of data collectors coupled with a team of census agent will visit each compound and household in the visit and collect based information to facilitate the smooth running of the subsequent village MDAs. This process will result in a complete list of households along with GPS coordinates, IDs and location descriptions.
- 4.1.3.** Initial MDA: during the initial visit (village MDA #1), each household will be visited and given the opportunity to participate in the study. Baseline data collection will be conducted and, if consented, eligible children will be given the study drug.
- 4.1.4.** Subsequent MDA: during the subsequent MDAs (village MDA #2-8) data will be updated and, if consented, eligible children will be given the study drug.
- 4.1.5.** Final MDA: during the final MDA (village MDA #9) data will be updated but no study drug will be administered.
- 4.1.6.** Master schedule: an overall study schedule that lists all villages and MDAs grouped by district, along with the scheduled dates for each MDAs. The master schedule is managed by the study coordinator.
- 4.1.7.** Scheduling cycle: a 13-week period (12 schedule weeks plus one overflow week) during which all villages within a district will complete an MDA.
- 4.1.8.** Expected schedule: an automatically generated schedule calculated based on the start date for data collection in each district.
- 4.1.9.** Scheduling window: village MDAs must be conducted within 2 weeks of the expected date; thus, the scheduling window is ± 2 weeks.

- 4.1.10.** Scheduling tool: an electronic tool that provides automatic scheduling capabilities and allows district supervisors to make adjustments and allocate data collectors.
- 4.1.11.** Scheduling constraints: rules used to generate the schedule, including: optimal duration (1 or 2 weeks), minimum number of data collectors per village, maximum number of data collectors per village, rate for initial MDA (number of households a data collector can complete in a day), rate for subsequent MDAs, rate for final MDA and district start date.
- 4.1.12.** Study coordinator: a LAKANA staff member that supports, facilitates and coordinates the daily trial activities. The LAKANA study coordinator reports primarily to the Malian co-Principal Investigator and will be mainly stationed in Kita regional office.
- 4.1.13.** District supervisor: a LAKANA staff member coordinating trial activities at the district level. The district supervisor reports primarily to the study coordinator and will be stationed in a district office. There will be 1 supervisor for each district participating in the study (each district covers 6 CSComs: ~ 48 villages).
- 4.1.14.** Field supervisor: a LAKANA staff member coordinating trial activities at the CSCom level. He or she is under the supervision of the district supervisor.
- 4.1.15.** Data collector: a LAKANA staff member who will collect data and administer study drug. He or she is under the supervision of the field supervisor. Each data collector will be paired with one or more local relais.
- 4.1.16.** Data collection team: a group of data collectors and relais assigned to work in a village.

4.2. General instructions

- 4.2.1.** There will be 8 separate phases for the scheduling of village MDAs as illustrated below. The detailed instructions for each phase are described in Section 5 Step-by-step procedures



5. Step-by-step procedures

5.1.1. Define study-level schedule, district and village characteristics: the study coordinator, in collaboration with the national district head, will discuss the general district schedule with supervisors. They will identify any large-scale events that would impact data collection and define a rough district-level schedule. In this schedule, the anticipated start dates of data collection for each village will be documented. The start will be staggered over time.

5.1.1.1. Define a high-level schedule that lists the start date for each district.

5.1.1.2. For each district, set the start dates of each 13-week cycle and ensure that all data collection can be completed within the overall study schedule. Make any needed adjustments.

5.1.1.3. For each district, set the following values in the scheduling tool:

- Optimal duration (1 week or 2 weeks);

- Minimum data collectors (minimum number of data collectors that will visit a village (this could be 1, but it may be preferable to always send at least 2 data collectors));
 - Maximum data collectors (maximum number of data collectors that will visit a village);
 - Rate for MDA #1 (expected number of households that can be visited per day for the initial visit)
 - Rate for MDA #2-8 (expected number of households that can be visited per day for the subsequent visits)
 - Rate for MDA #9 (expected number of households that can be visited per day for the final visit in which there is no drug administration)
- 5.1.2.** Set start date for next district: the study coordinator will identify the next district that will start its first data collection cycle. In collaboration with the district supervisor and field supervisor, they will verify that there are enough data collectors available between the proposed dates.
- 5.1.3.** Review and update data collector list: the district supervisor in collaboration with the field supervisor will review the list of data collectors available for data collection in the district. He will make any necessary adjustments (i.e., add new data collectors or remove data collectors who are no longer working).
- 5.1.4.** Generate master schedule for district: the district supervisor in collaboration with the study coordinator will use the scheduling tool to generate a master schedule for the district. The scheduling tool will confirm that data collection is possible within the desired duration based on the information entered and the number of available data collectors.
- 5.1.4.1. Use the scheduling tool to generate a master schedule for the district. The scheduling tool will attempt to maximize the utilization of the data collectors and balance their assignments across villages and within the 13 weeks of each cycle. It will report the following information:
- Number of data collectors needed for each week of data collection;
 - Under or over scheduling of interviewers in each week;
 - Constraint violations, such as if the data collection cannot be completed within the required duration or if there are not enough data collectors.
- 5.1.5.** Adjust master schedule: the district supervisor will adjust individual MDAs to accommodate any community events. Once dates have been agreed and meet scheduling and data collector availability constraints, lock the schedule.
- 5.1.5.1. Based on the information returned by the scheduling tool and any other available information, as needed, move the start date of data collection for each village. The scheduling tool will report the above information, which can be used to inform the final schedule.
- 5.1.5.2. Once all adjustments have been made, lock the schedule. Once the schedule is locked, it is possible to assign individual data collectors to each village.

5.1.6. Assign data collectors to each MDA: prior to the next data collection cycle, the district supervisor in collaboration with study coordinator will assign data collectors to each village, balancing necessary constraints (duration, availability of data collectors, etc.).

5.1.6.1. Use the scheduling tool to assign data collectors to each village. The tool will not allow data collectors to be double booked and will show only available data collectors for each week. (Note that smallest unit of allocation is 1 week.)

5.1.7. Review and finalize schedule: the district supervisor will review the schedule and data collector allocation. He will communicate the schedule to necessary stakeholders and make minor adjustments as needed.

5.1.7.1. Once data collector assignments have been entered and reviewed, they can be finalized and printed (pdf) schedules can be generated at the district, village, and data collector level.

5.1.8. Repeat the above steps for each district.

6. Occupational Safety Issues

There are minimal safety issues because scheduling will largely be performed electronically and in an office environment. However, general precautions should be taken by all staff to minimize the potential for Covid-19 infection. Special considerations due to COVID-19: procedures for safe and proper work will be used to reduce the risk of exposure to a hazard including: i) Providing to workers tissues, hand soap, hand sanitizer, and disinfectant to clean their work surfaces/equipment; ii) Requiring regular hand washing or using hand sanitizer. LAKANA study team will follow the recommendations of the national authorities and, if recommended, will ensure that all workers have access to and wear personal protective equipment (including face masks and gloves).

7. Quality Assurance / Quality Control

7.1. Automated Quality Control

7.1.1. The scheduling tool will use an optimization algorithm to generate an initial master schedule. The master schedule will account for the number of data collectors available and will be generated based on a set of assumptions (e.g., number of households that can be visited in a day). Manual adjustments to the schedule will be assessed automatically to ensure that the schedule is still viable. Scheduling conflicts and other issues will be highlighted to the user in real time.

7.2. Review and Approval Process

7.2.1. The schedule produced by the scheduling tool will be viable based on the information available, however there are always intangible issues that can affect on-the-ground logistics. As a result, the final schedule should be reviewed carefully by the study coordinator and other stakeholders at CVD-Mali.

8. Appendices and other related documents

None.

9. Version history, authors and approvals

Version (date)	Edits to the SOP text (author)
Version 1.0 (2020-08-18)	Original document (Author Kevin Wilson, approved by the LAKANA PSG on August 19, 2020.)