Standard Operating Procedures for the LAKANA trial
**SOP Subvisit 06–08: Conducting AMR-MDA 6, 7 and 8 visit**
Version 1.0 (2022-11-15)

## 1. Purpose and overview:

This SOP[1] gives instructions on how to conduct **AMR-MDA6, 7 and 8** visit (secondary outcome sample).

## 2. Applicability to and responsibilities of various staff members

| Staff member | Responsibility |
|---|---|
| Supervisor | - Plans date of entry to villages<br>- Makes sure data collector's rucksacks are ready<br>- Makes sure nurses and Anthropometrist receive all material needed<br>- Makes sure all required material for visits are ready before entry into villages<br>- Manages disposal of study waste with study nurse<br>- Reports issues to CVD-Mali coordinator and IWG |
| Lab technician in Bamako/another main lab | - Prepares material needed for sample collection and manages samples collected. *Refer to SOP Proc 09 for detailed sample collection material.* |
| Data collector | - Implements MDA activities (interviews, treatment of 1-5 & 9-11 mo. old infants) |
| Nurse | - Collects samples. *Refer to SOP Proc 09 for detailed activities.*<br>- Records sample-related data in study app<br>- Treats eligible 6-8 mo. infants after sample collection |
| Anthropometrist | - Takes anthropometric measurements. *Refer to SOP Proc 03 for detailed activities.*<br>- Records anthro-related data in study app |
| Relais | - Assists data collector for MDA activities<br>- Accompanies caregivers and children to pop-up facility |
| Driver/messenger | - Transports study team to villages<br>- Safely transports samples from villages to Kita/Bamako/another main lab. |

[1]Abbreviations: AMR = antimicrobial resistance, DCF = data collection form, IWG = implementation working group, SOP = standard operating procedure, LAKANA = Large-scale assessment of the key health-promoting activities of two new mass drug administration regimens with azithromycin, MDA = mass drug administration.

## 3. Required materials

| Item | Number | Specification |
|---|---|---|
| Identification Sticker for **1-11** mo. old infants | 2 identical stickers per child | **Only for children newly registered at MDA 6, 7 and 8.** *Theoretically*, a c*hild in these age groups already received a LAKANA ID at a previous visit as s/he was MDA-eligible (ID affixed on health card)* |
| Identification Sticker for **12-14** mo. old infants | | |
| LAKANA Blue card | *As required* | Card for 6-8 mo. old infants. |
| LAKANA Pink card | *As required* | Card for 12-14 mo. old children. |
| Tent | 1 | A pop-up medical tent to be set up in the village. |
| Table | 1 | Rent from village. |
| Chairs | 3 | Rent from village. |
| Tablet computer | *As required* | - A tablet per Data collector with access to main study app<br>- A tablet per Nurse with access to AMR study app<br>- A tablet per Anthropometrist with access to AMR study app |
| Material for MDA | | *Refer to SOP Visit 01* |
| Material for biological sample collection | *As required* | *Refer to SOP Proc 09 for detailed sample collection material.* |
| Instruments for anthropometric measurements | *As required* | *Refer to SOP Proc-03* |

## 4. Definitions and general instructions

### 4.1. Definitions

**4.1.1.** Supervisor: LAKANA staff member coordinating activities of the data collection team, in consultation with CVD-Mali study coordinator.

**4.1.2.** Lab technician: LAKANA staff member based in Bamako, Kita or other main lab, and responsible for preparing sample collection material and handling specimens brought from villages.

**4.1.3.** Data collector: LAKANA staff member responsible for MDA-related activities including interviews with household members and study drug administration.

**4.1.4.** Nurse: LAKANA staff member responsible for collecting biological sample and recording corresponding data in study app.

**4.1.5.** Measurer/assistant measurer: LAKANA staff member responsible for taking anthropometric measurements and recording corresponding data in study app.

**4.1.6.** Relais Communautaire: volunteer chosen by the community who serves as a bridge between professional health staff and the villagers.

**4.1.7.** Eligible infant **for MDA**: infant aged between **1 and 11 months** (age 29-364 days) and weighing at least 3.0 kilograms at the time of study drug provision, and for whom there is no record of allergy to macrolides.

**4.1.8.** Eligible child **for the growth study**: child aged **6-8 or 12-14 mo**. living in a household that consented to participate in LAKANA Growth study.

*NB: Consent to participate in LAKANA sub-studies is requested only once at the enrolment of the household. The consent given at the enrolment stage applies to all eligible children that will be found at the subsequent visits. The enrolled household representatives can decide to discontinue the study participation at any point without giving a reason.*

**4.1.9.** Caregiver: person responsible for looking after a child. The caregiver is responsible for providing permission for study drug administration to MDA-eligible infants.

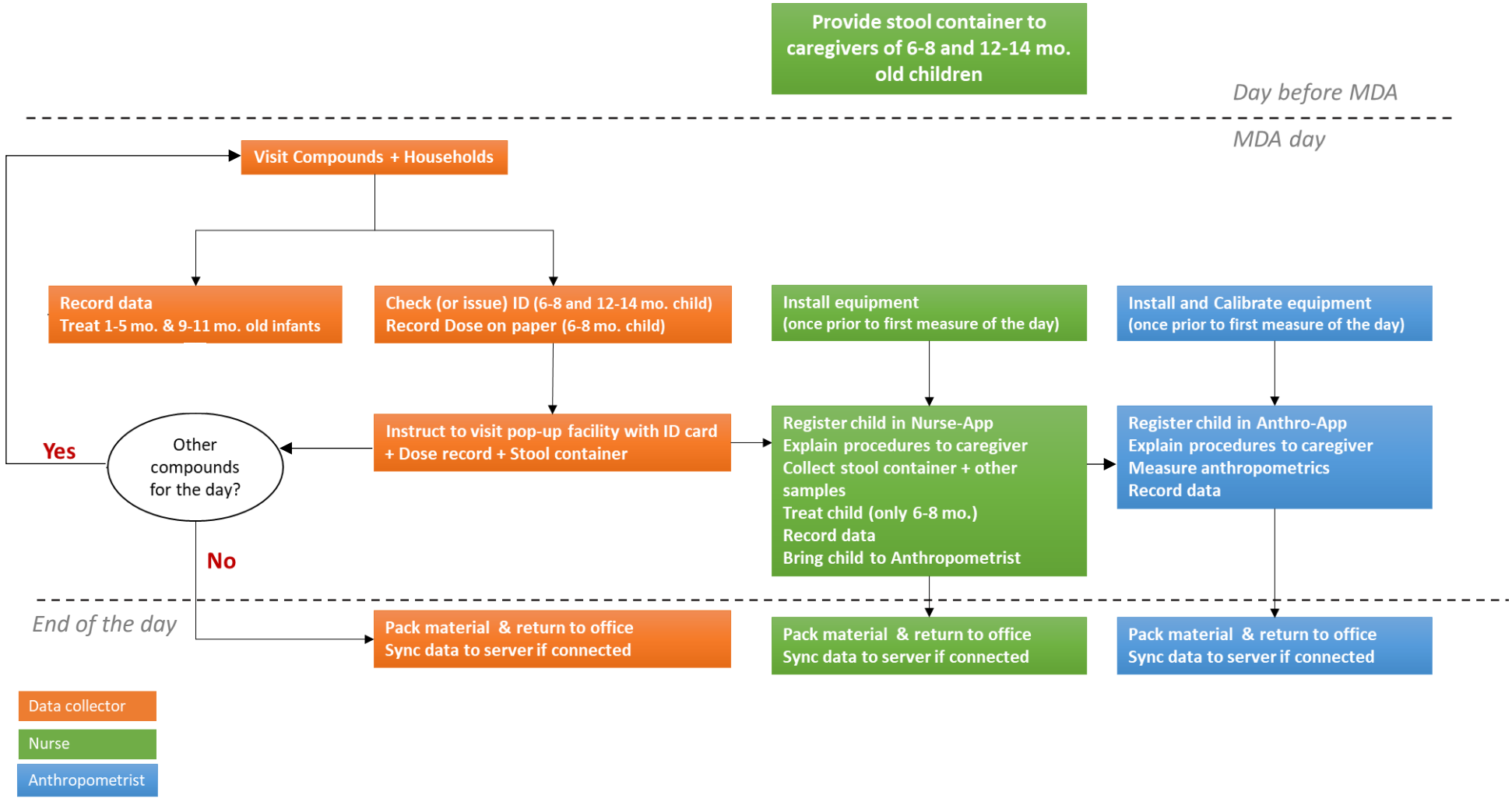
**4.1.10.** Driver: LAKANA staff member responsible for transporting sample collection materials, and samples between villages and lab.

**4.1.11.** Pop-up health facility: temporary facility, in village or nearby, to be set up for sample collection and anthropometrics measurement.

**4.1.12.** Implementation Working Group (IWG): LAKANA investigators identified by project steering group to oversee day-to-day study activities.

## 4.2. General instructions

**4.2.1.** The main processes for conducting the **AMR-MDA6-8** visits are illustrated in the figure below. Detailed instructions are provided in section 5 Step-by-step procedures.



## 5. Step-by-step procedures

### 5.1. Before MDA

**5.1.1.** ~ A week before entry in a village, the supervisor will confirm the date of visit to the village chief. At this occasion, the supervisor will

- Inform about the growth study procedures (anthropometric measurements and sample collection) to prevent rumors in the community.
- Agree on the rental of some material (table + chairs) and a place to set-up a pop-up facility for the study activities.

**5.1.2.** ~ A week before entry in a village, the study team will make sure that all the sample collection material and anthropometrics measurement tools needed are available (*refer to SOP Proc 03 & 09 for details on material*).

**5.1.2.1.** The day before the MDA, the nurses will visit the village and provide stool containers to caregivers of 6-8 and 12-14 mo. old children and explain the procedures for collecting the stools (*refer to SOP Proc 09*).

### 5.2. MDA visit – Household

**5.2.1.** The data collector will visit the compounds and households in the village.

**5.2.1.1.** When visiting a Compound, the DC will

- check from the head of compound previously registered whether there are **any new households** since the last LAKANA visit and visit them if any.

**5.2.1.2.** When visiting a Household, the DC will

- check whether the household gave consent to participate to the Growth study
  - if consent was given, see section **5.2.1.3**.
  - if consent was not given, proceed like a normal AMR-MDA i.e., update vital status of all members and register new ones, treat eligible infants, update their vaccination information, fill in the morbidity form for 4-14 mo. old children, and visit next household.
  - if it is a household newly found, proceed with enrollment procedures, ask consent for participation in sub studies, then follow steps in section 5.2.1.3 if consent is obtained.

**5.2.1.3.** When visiting a household **that consented to participate in the Growth study**, the DC will re-explain the Growth study activities to the household members and proceed as follow:

- Check and record vital status of all members
- Make sure that all 1-**14** mo. old children have a LAKANA ID in CommCare
  - If some were never given an ID i.e., do not exist in CommCare, register them.
  - If some were already registered but for some reason do not have a LAKANA ID showing in CommCare. Issue a LAKANA sticker to

the child, and open the form "*Mettre à jour l'identifiant du participant*" and record the ID.

- Check and update vaccination form (DCF03) for **1-14** mo. old children
- Fill in treatment Form (DCF02) and treat **1-5** and **9-11** mo. old infants.
- Fill in treatment Form (DCF02) of 6-8 mo. old infants and note the dose calculated by the tablet on a paper and give the note to the caregiver. **DO NOT TREAT the 6-8 mo. old infants**. They will be treated after sample collection.
- Fill in Morbidity Form (DCF08) for **4-14** mo. old children
- Ask the caregiver to go to the pop-up health facility with the **6-8 mo. and 12-14 mo.** old children and remind them to bring:
  - The child LAKANA ID
  - The note with the **treatment dose** (only for 6-8 mo. old)
  - The **stool container** (if stools were successfully collected)

## 5.3. MDA visit – Pop-up facility

**5.3.1.** The nurses, and anthropometrists assisted by community members will set up the pop-up facility at the location suggested by the village chief.

**5.3.1.1.** Every time a caregiver/Relais will arrive at the pop-up facility with a child aged 6-8 or 12-14 mo. old, the nurse will proceed as follow:

- Verify that the Child has a LAKANA ID
- Register the child in study app
- Collect stool sample and record the corresponding information
  - If the caregiver did not collect the stool sample in the container given the day before, the nurse will ask the caregiver and infant if they can wait at the pop-up facility until a stool sample is collected or come back the next day with a stool sample.
  - If they do not bring a stool sample the next day, there will be no stool collection for that infant.
- Collect urine sample and record the corresponding information (*refer to SOP Proc 09*)
- Collect blood sample and record the corresponding information (*refer to SOP Proc 09*)
- Check the treatment note and treat 6-8 mo. old infants, and record the information in study app (DCF07)
  - The nurse will advise the caregiver that in case of vomiting within approximately 15 minutes of treatment, s/he should alert the LAKANA team so that the infant can be re-treated. The nurse will also instruct the caregiver to seek the help of a health

professional/visit a health facility or alert a *Relais* if the child experiences any major symptoms in the14 days following treatment.

- Ask the caregiver to bring the child to the Anthropometrics stand

**5.3.1.2.**Every time a caregiver/Relais will arrive with a child aged 6-8 or 12-14 mo. old at the Anthropometric stand after sample collection, the Anthropometrist will proceed as follow:

- Verify that the child has a LAKANA ID
- Register the child in study app
- Measure the MUAC, weight, and length of the child (*refer to SOP Proc 03*) and record the information in study app (DCF07)

### 5.4. Sample transportation to Kita/Bamako/another main lab:

**5.1.8.1.** The nurse will coordinate with the driver the safe sample transportation to the laboratory in appropriate time. Samples should be kept at 2-8 °C for urine and stool samples. The blood sample tubes must be stored in a 18-25 °C degrees box in an upright position in the holders. Note: The collected blood sample tubes must be transported to Bamako in maximum 48 hours at 18-25 °C, so the lab can centrifuge and process it.

### 5.5. Closing of the day:

**5.5.1.** After having reached the number of households and children planned for the day, the LAKANA team will pack all the study material and return to Kita or headquarters.

**5.5.2.** All study member who has recorded data in tablets will transmit the data (sync) to the server if connectivity allows.

**5.5.3.** The supervisor and nurse will manage clinical waste and remaining drugs.

**5.5.4.** The nurse will put the remaining unused sample material in the required temperature.

**5.5.5.** The supervisor will charge the tablet computers.

**5.5.6.** The supervisor will report to the coordinator or IWG any issues that need to be addressed.

## 6. Occupational Safety Issues

- The nurse will wear disposable gloves when handling a child. S/he will wash or sanitize hands before putting on and after removing gloves. S/he will change gloves after each study participant. The study nurse will dispose of all contaminated waste into biohazard waste bags for incineration or disposal.

- All concerned study team members will handle all specimen with care and treat them as potentially infectious material. Appropriate specimen collection devices, containers, and transport media will be used to ensure optimal storage.

- Special considerations due to COVID-19 are presented in *SOP-Safety 01*.

## 7. Quality Assurance / Quality Control

The study nurse who will collect specimen, and data collectors taking anthropometric measurements will undergo practical training.

## 8. Appendices and other related documents

| Document number (Version) | Document content |
|---|---|
| SOP Proc-03 v1.0 | Performing anthropometric measurements |
| SOP Proc-9 v1.0 | Collecting blood urine and stool samples at the pop-up facility |

## 9. Version history, authors and approvals

| Version (date) | Edits to the SOP text (author) |
|---|---|
| 1.0 (2022-11-15) | Laura Adubra in consultation with Yuemei Fan, Rikhard Ihamuotila and CVD team. Approved by PSG. |