Standard Operating Procedures for the LAKANA trial
SOP Visit-02: Conducting subsequent household visits in the main LAKANA trial
Version 2.0 (2023-11-06)

1. Purpose and overview:

Following the enrolment visit in villages participating in LAKANA trial, households that agreed to participate in the study will be visited nine more times at quarterly intervals (every 3 months). This SOP[1] provides instructions on how to conduct the first eight follow-up study visits and village MDAs.

2. Applicability to and responsibilities of various staff members

Same as MDA1, *Refer to SOP Visit-01*.

3. Required materials

Same as MDA1, *Refer to SOP Visit-01*.

4. Definitions and general instructions

4.1. Definitions

Same as MDA1, *Refer to SOP Visit-01*.

4.2. General instructions

4.2.1. Preparatory activities prior to entry in a village are similar to those for conducting MDA1, *Refer to SOP Visit-01*.

4.2.2. During follow-up visits in households, the LAKANA data collectors will:

4.2.2.1. Update household members' vital status (Form DCF06).

4.2.2.2. Register all newly arrived members including newborn babies (DCF01c-d).

4.2.2.3. Treat eligible 1-11-month-old infants for whom a caregiver consent is given and record the corresponding information (DCF02).

4.2.2.4. Update 1-11-month-old infants immunization form (DCF03).

5. Step-by-step procedures

5.1. Compound.

[1] Abbreviations: SOP = standard operating procedure, LAKANA = Large-scale Assessment of the Key health-promoting Activities of two New mass drug administration regimens with Azithromycin, DCF = Data Collection Form, DTC = Directeur Technique de Centre, CSCom = Centre de Santé Communautaire, MDA = Mass Drug Administration, CSRef = Centre de Santé de Référence, PPE = Personal Protective Equipment.

5.1.1. The first step when visiting a compound will be for the data collection team to confirm with the head of compound (or his deputy) whether the compound has previously been visited by the LAKANA staff.

NB: If this is the first time a compound is approached by the LAKANA staff, the data collection team will follow the procedure described in *SOP Visit-01*.

5.1.2. If a compound had previously been visited, the data collector will identify the compound and open the corresponding record in the tablet.

NB2: If a compound had previously been visited but did not approve basic data collection by LAKANA staff: an ID was created, and the information was recorded (DCF01b). The data collector will not ask again for permission and leave.

5.1.3. If a compound had previously been visited and had approved data collection, the data collector will proceed with follow-up visit-related data collection, see section 5.2.

5.2. Household.

5.2.1. The first step when visiting a household within a compound will be for the data collection team to confirm with the head of household (or his deputy) whether the household had previously been visited by the LAKANA staff and received an ID at this occasion.

NB: If this is the first time the household is approached by the LAKANA staff, the data collection team will follow the procedure described in *SOP Visit-01: Conducting the enrolment visit - main study*.

5.2.2. If the household had previously been visited, the data collector will ask to see the household's ID (sticker with QR code).

5.2.3. The data collector will open the household record in the tablet that has the ID matching the one on the household ID sticker.

NB: If a household had previously been visited but refused to participate in the trial, the information was recorded (DCF01f). The data collector will not ask again for consent and will leave.

NB: In case the ID sticker is not available, or the ID number is not visible, the data collector can rely on other information such as head of household name, to identify the corresponding record to open, see image below:

5.2.4. After opening the household record, the data collector will start with updating the vital status of all household members registered at the previous visit (Form DCF06).

5.2.4.1. The data collector will first ask about household wellbeing and participants with general questions (e.g., how are you, how are your children, how is everyone else in the household?)

5.2.4.2. After the general questions, the data collector will explain that s/he will next ask questions about each specific household member who has been identified earlier. S/he will explain that the purpose of this detailed data collection is to know precisely how well the study drug impacts the health of the treated infants and other household members.

5.2.4.3. The data collector will then ask about the vital status of each participant one-by-one, calling them by name, in the order they are listed in CommCare system. For each household member, s/he will record the vital status in CommCare software, before proceeding to next household member.

> **NB1:** Vital status will be recorded for each household member, even if the person is absent from the household at the time of the interview. On MDA2-9, the data collector does not necessarily have to see any other members of the household, besides the respondent and infants, who will be treated with the study drug. For unavailable household members, the data collector will record vital status as indicated by the respondent.
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> **NB2:** If the vital status of an **infant aged less than 15 months** is updated to "**Dead**", the data collector will collect information about the **date of death, if known, or an estimation of the time since death**.
>
> **NB3:** If the vital status of an adult **woman that was pregnant at the previous visit** is updated, the data collector will collect information about the **outcome of pregnancy**.

5.2.5. After having updated the vital status of all household members listed in the tablet, the data collector will register all new members in the household, if any, i.e. complete DCF01c (if new adults) and DCF01d (if new children).

5.2.5.1. For each newly arrived infant aged 1-11 mo., the data collector will issue an ID (Sticker with QR code) and proceed as described in Appendix 5 (section 4) of SOP Visit-01.

5.3. Study drug provision.

5.3.1. The data collectors will treat eligible 1-11-month-old infants for whom a caregiver consent is given and will record the corresponding information in the tablet (DCF02). *Refer to SOP Proc-01 for guidance.*

5.4. Immunization record

5.4.1. For each treated infant, the data collector will record/update the immunization history and exposure to other health interventions form (DCF03).

5.5. End of a visit

5.5.1. The data collector will thank the household head (or his deputy), inform that the next visit will take place in ~3 months, and proceed with the next household located in the compound, if any.

5.5.2. If there are no other households located in the compound, the data collector will thank the head of compound (or his deputy) and proceed with the next compound to visit.

5.6. Closing of the day

Refer to SOP Visit-01.

6. Occupational Safety Issues

In a non-epidemic situation, there are no specific occupational safety issues.

During COVID-19 epidemic, procedures for safe and proper work will be used to reduce the risk of exposure to a hazard and prevent transmission between the study team and the study participants. Special considerations due to COVID-19 are described in SOP-Safety 01.

7. Quality Assurance / Quality Control

The completeness of the data and the consistency of data collection will be monitored weekly by a responsible person.

8. Appendices and other related documents

Related documents: SOP Visit-01: Conducting the enrolment visit - main study.

9. Version history, authors and approvals

Version (date)	Edits to the SOP text (author)
Version 1.0 (2021-03-03)	Authored by Laura Adubra in consultation with Per Ashorn, Ulla Ashorn, and CVD-Mali team. Approved by LAKANA PSG.
Version 2.0 (2023-11-06)	Added more detail on data collection on vital statistics (sections 5.2.4.1 – 5.2.4.3)