

### 1. Purpose and overview:

This SOP provides instructions on activities regarding the allocation of treatment codes to villages that have agreed to participate in LAKANA trial. Participating study villages will be randomly allocated into the three intervention groups at 3:2:4 ratio (control: azithromycin quarterly: azithromycin biannually), in public allocation events where village representatives blindly pull lottery tickets out of a container.

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

Staff member	Responsibility
Study coordinator	<ul style="list-style-type: none"> <li>- Oversees supervisors</li> </ul>
District supervisor	<ul style="list-style-type: none"> <li>- Schedules the public allocation event for their own district with study coordinator</li> <li>- Reports to study coordinator</li> </ul>
Field supervisor	<ul style="list-style-type: none"> <li>- Assists District supervisor in organizing the public allocation event</li> <li>- Agrees on date of public allocation event with the village representatives</li> <li>- Instructs the village representatives on the public allocation event</li> <li>- Assists in supervision of the public allocation events</li> <li>- Reports to district supervisor and study coordinator</li> </ul>

### 3. Required materials

Item	Number	Specification
Container for the tickets	2	
Tickets with treatment codes	<i>Separate for each allocation session and dependent on the number of people participating in the group allocation event</i>	The number of tickets in an event is $n \times 9 + x$ , where $x$ denotes the number of left-over tickets from previous events, and the product $n \times 9$ is the minimal multiple of 9 that is greater than or equal to the number of villages.  (Appendix 2a-ab)

Item	Number	Specification
Tablet computer	1	
Writing Pad	1	
Pen	1	
Mobile phone	1	The study coordinator will have a mobile phone in the event.
Tissues	<i>Separate for each allocation session and dependent on the number of people participating in the group allocation event</i>	3 tissues per person in an event
Hand sanitizer	<i>Separate for each allocation session and dependent on the number of people participating in the group allocation event</i>	1 bottle for 100 participants
Disposable face masks	<i>Dependent on the number of people participating in the group allocation event</i>	To be given to each participant invited at the allocation event.
Personal Protective Equipment (PPE) individual kit	1	1 Kit/ LAKANA staff member (For details on the kit composition and utilization, refer to <i>SOP-Safety 01 Hygiene and PPE</i> )

#### 4. Definitions and general instructions

##### 4.1. Definitions

- 4.1.1.** 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.
- 4.1.2.** 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 6 supervisors for the 6

districts participating in the study (each district covers 6 CSComs: ~ 48 villages).

**4.1.3.** Field supervisor: a LAKANA staff member coordinating trial activities at the CSCom level. He or she is under the supervision of the district supervisor.

**4.1.4.** Village representative: village chief or a person appointed by him or her

## **4.2. General instructions**

**4.2.1.** During the Covid-19 epidemic, physical distancing will be enforced: a distance of at least 1 meter (3.3 feet) will be maintained between any two individuals. The LAKANA research team will remind the audience that the wearing of face masks distributed at the event will be mandatory throughout the event.

**4.2.2.** The procedure of allocation will be done in public to ensure the perception of fairness of the randomization.

**4.2.3.** In collaboration with the study coordinator, the district supervisor will invite village representatives to a public allocation event.

**4.2.4.** In the event, the village representatives will take turns to blindly pull a ticket from a container that has the treatment code for that village.

4.2.4.1. The tickets will show two different letter codes, as indicated in Appendix 1.

**4.2.5.** There will be two containers for the tickets, one to be used by representatives from smaller villages (with less than one hundred 1-11-month of infants) and another one for larger villages (with 100 or more 1-11-month-old infants). The division is based on national data.

**4.2.6.** Before the event, field supervisor will check that all written combinations are acceptable i.e. the letter pairs in containers are within the options shown in Appendix 1.

**4.2.7.** At the beginning of group allocation, there will be a sufficient number of tickets in the container so that each participating village can pull out one tickets and thereafter there are 0-8 tickets left in the container.

4.2.7.1. The exact number of tickets will be  **$n \text{ times } 9 + x$** , where  $x$  denotes the number of left-over tickets from previous events, and the product  $n \text{ times } 9$  is the minimal multiple of 9 that is greater than or equal to the number of villages.

**4.2.8.** Should there be any tickets left over from an event, the tickets that are left over will be added to a corresponding container of tickets in the next event (Appendix 2a-2b).

**4.2.9.** The study coordinator will arrange the storage of the information on the letter pair-code a village representative draws from the ballot container.

4.2.9.1. The study coordinator or a person appointed by the study coordinator will save the name of the village and the drawn letter pair-code to in a specific file in a tablet, in a way that is described in Appendix 3.

4.2.9.2. A separate person appointed by the study coordinator will write minutes from the event on paper. The person will write the same information on the minutes that have been saved to the tablet. The minutes will also include names and roles for people who represent each village, data and time of event, and names of LAKANA representatives who are present.

**4.2.10.** Field supervisors will assist the study coordinator and district supervisor in overseeing the event and answer any questions the village representatives might have.

## **5. Step-by-step procedures**

### **5.1.1. Scheduling public allocation events**

5.1.1.1. District supervisors, in collaboration with the study coordinator, will schedule a public allocation event for their respective district 2-14 weeks before the estimated start of data collection.

5.1.1.2. Field supervisor will invite village representatives to the event that will be held in the district office.

- During the Covid-19 epidemic, the LAKANA research staff will ensure that the chosen space for hosting the allocation event is adequate (allow for physical distancing), and arrangements for the audience (face masks, availability of hand-washing facilities with soap and water/liquid soap solution, or hand sanitizers) are suitable for the expected number of people.

5.1.1.3. Based on the national data, the district supervisor, in collaboration with the study coordinator, will classify the villages into two groups: those with estimated number of infants being equal to or over 100, and those with estimated number of infants being below 100.

### **5.1.2. Public allocation event**

5.1.2.1. Before the start of the event, field supervisor will check that the letter pairs in containers are acceptable as described in paragraph 4.2.5.

5.1.2.2. The study coordinator and the district supervisor will welcome the village representatives to the event and will explain the day's program.

- During the Covid-19 epidemic, the LAKANA research staff will communicate precautionary measures (physical distancing and hygiene measures) to be followed throughout the event to the audience.

5.1.2.3. The study coordinator and the district supervisor will explain that for the group allocation, the village representatives will be divided into two groups, representing larger or smaller villages as described in paragraph 5.1.1.3.

5.1.2.4. Study coordinator will ensure that two distinct containers, one per designated group, will be available and have the correct number of tickets for the event.

- The study coordinator and supervisors are involved in the randomization event activities and will have the information on the

village – letter pair combinations after the event, but no further details due to the double-masking of the drugs.

5.1.2.5. For each of the two groups of representatives, the study coordinator and district supervisor will invite each village representative to pull a ticket from the corresponding container.

- The order is determined alphabetically, with representatives from villages whose name start with “A” to start and “Z” to finish.
- To facilitate the procedure and enforce safe distance, the research staff will use safe distance floor markers to help the participants to identify a safe distance between themselves (at least 1 meter).

5.1.2.6. The study coordinator will arrange the marking and saving of the information on which village has pulled which letter pair-code, as explained earlier.

5.1.2.7. For further assurance, the CSCom, and village name will be written on the used ticket after it has been drawn from the container.

### 5.1.3. Sharing the information

5.1.3.1. The study coordinator will notify the LAKANA co-Principal Investigators on the completion of the event and provides a brief, verbal summary of the event that is based on the minutes. The summary should include information on

- the number of village representatives in the event
- the number of tickets not drawn from the container
- names and the number of villages that were agreed to participate but from which a representative didn’t arrive to the event
- any unexpected incidences during the event.

5.1.3.2. The data, the paper copy, the drawn tickets, and the minutes from the event will be kept in the district office and scanned.

## 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 presented in *SOP-Safety 01 Hygiene and PPE*.

## 7. Quality Assurance / Quality Control

### 7.1. Handwritten back up

7.1.1. As a village representative pulls a ballot from a container, the study coordinator or a person appointed by him or her will write down the CSCom, village, date and the letter pair in the ballot to a computer system as presented in Appendix 3. A person appointed by the study coordinator (who is not using the computer device) will write down the same information to the minutes.

- 7.1.2.** District supervisor will write the name of the CSCom, the village, the date on the ticket that the village representative pulled out.
- 7.1.3.** In the end, there will be multiple ways for verifying the information: the minutes from the event, the ticket that has the name of the village written on it and comparing the documented letter pairs with the actual acceptable pairs.

## 8. Appendices and other related documents

Document number	Document content
Appendix 1	Possible letter pairs.
Appendix 2	Example on the number of ballots in a container with 50 village representatives in an event.
Appendix 3	Example of the recording of the letter pair-codes.

## 9. Version history, authors and approvals

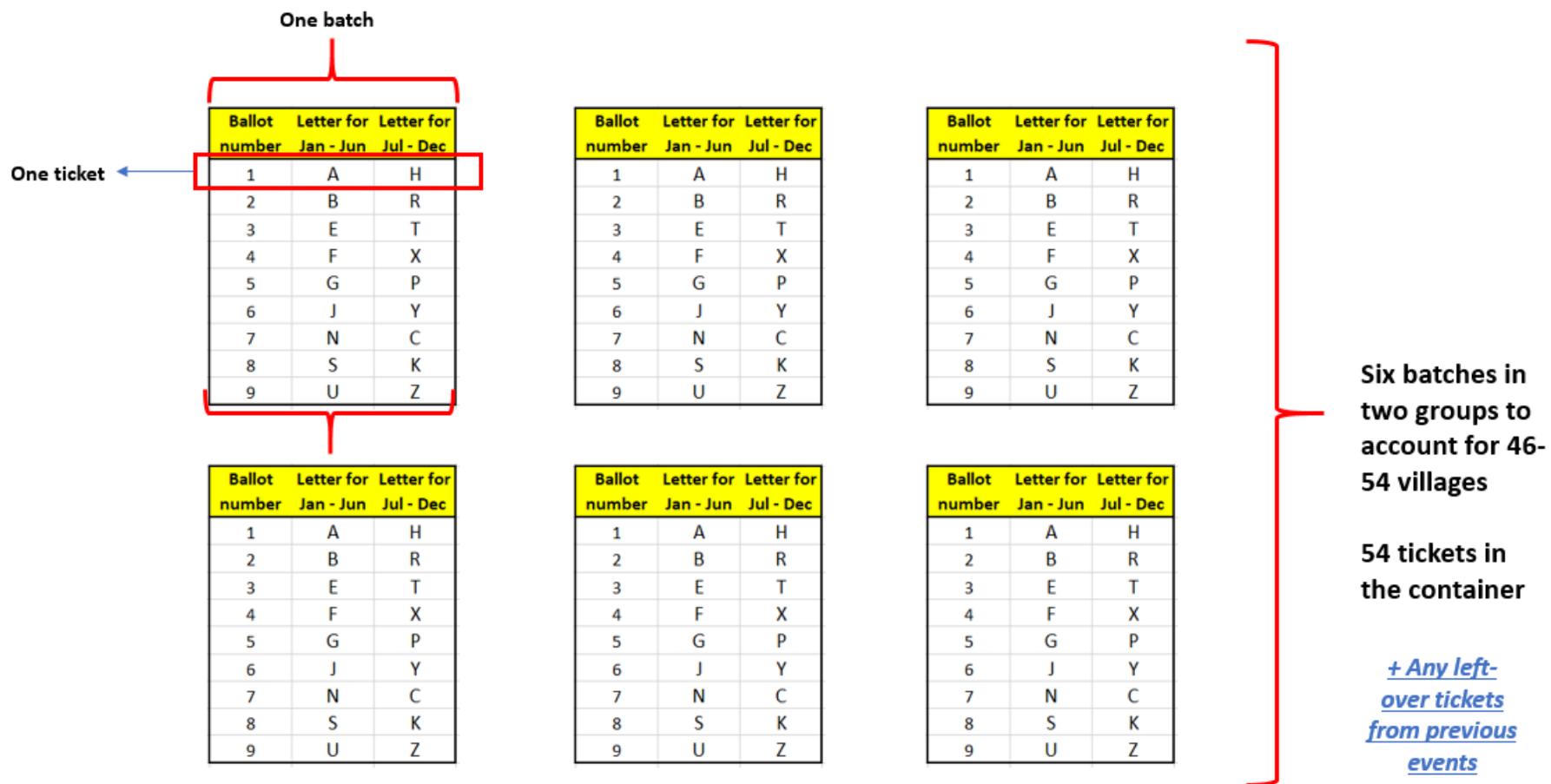
Version (date)	Edits to the SOP text (author)
Version 1.0 (2020-08-25)	Authored by Juho Luoma in consultation with LAKANA investigators.

**Appendix 1: Possible letter pairs**

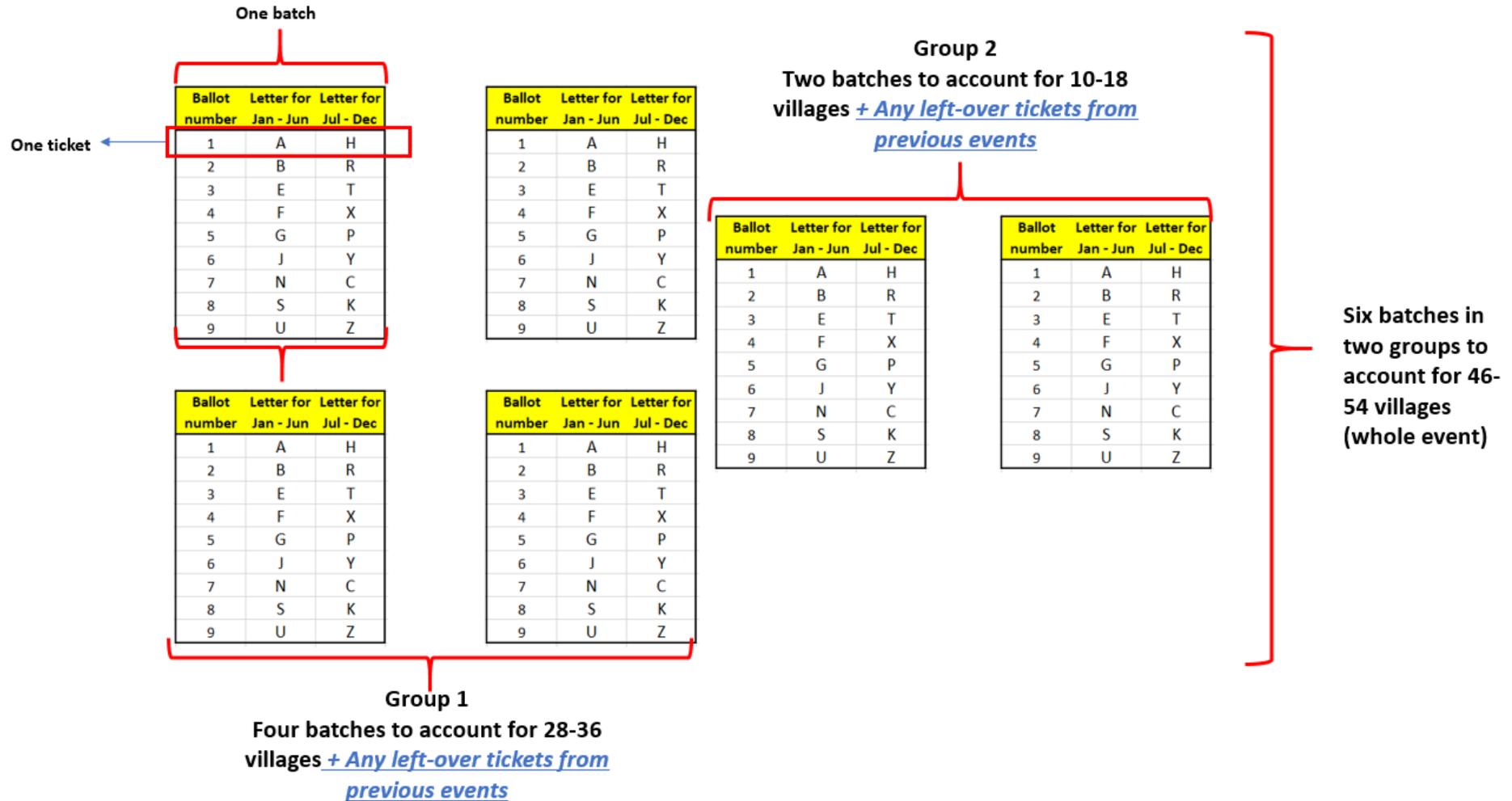
Letter code-pair ←

Letter for Jan - Jun	Letter for Jul - Dec
A	H
B	R
E	T
F	X
G	P
J	Y
N	C
S	K
U	Z

**Appendix 2a: Example on the number of ballots in a container with 50 village representatives from the same village-size category**



**Appendix 2b: Example on the number of ballots in a container with 50 village representatives from different village-size category**



**Appendix 3: Example of the recording of the letter pair-codes**

<b>Village name</b>	<b>Letter for Jan - Jun</b>	<b>Letter for Jul - Dec</b>	<b>District name</b>	<b>Date</b>
Village 1	A	H	District	YYYY/MM/DD
Village 2	B	R	District	YYYY/MM/DD
Village 3	E	T	District	YYYY/MM/DD
Village 4	F	X	District	YYYY/MM/DD
Village 5	G	P	District	YYYY/MM/DD