

Standard Operating Procedures for the LAKANA trial
SOP Safety 01: Hand hygiene, surface and environmental cleaning and disinfection, and use of PPE in the context of Covid-19.

Version 2.0. (2020-10-20)

1. Purpose and overview:

In the context of the Covid-19 epidemic, in order to keep workers and communities safe, appropriate infection prevention measures will be incorporated into LAKANA trial-related activities. This SOP¹ provides guidance for all LAKANA research staff on hand hygiene, surface and environmental cleaning and disinfection, and use of Personal Protective Equipment (PPE) when conducting tasks that require close and frequent interaction with people whose infectious status is unknown.

The recommendations in this document do not override local health authorities' advice or guidelines which should be taken in account.

2. Applicability to and responsibilities of various staff members

Staff member	Responsibility
Study coordinator	<ul style="list-style-type: none">- Makes sure all protective equipment are available at every level (District, CSCoM, Data collection hubs).- Makes sure all LAKANA research personnel are trained on using PPE.- Enforces protection measures as described in this SOP.- Oversees PPE maintenance.
LAKANA personnel (Supervisor, Pharmacist/Drug manager, Data collector, Relais, Driver, Nurse, Anthropometrist)	<ul style="list-style-type: none">- Enforces protection measures as described in this SOP.- Reports any issues to the study coordinator.

3. Required materials

Item	Specification
Mask	
Glove	Single-use glove.

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, PPE = Personal Protective Equipment, WHO = World Health Organization, CSCoM = Centre de Santé Communautaire, MDA = Mass Drug Administration.

Item	Specification
Hand sanitizer	Sanitizer with 60–80% alcohol
Hand soap	
Bin	Foot-operated waste bin.
Waste bag	To be placed in the bin designated to collect used PPE.
Disinfectant/antiviral wipes	For disinfection of equipment: 70-90% ethanol (ethyl alcohol) (or antiviral wipes). For disinfection of surfaces: sodium hypochlorite (bleach / chlorine) at 0.1% (equivalent to 1000 ppm).
Hand washing station	Installed for the LAKANA staff collecting biological samples (sub-studies) at the pop-up health facility and CSCom (if CSCom not already equipped).

4. Definitions and general instructions

4.1. Definitions

- 4.1.1. Personal Protective Equipment (PPE) is safety equipment issued to help employees in protecting themselves, and the study participants, from the hazards of their work environments. For LAKANA, PPE includes gloves, and face masks.
- 4.1.2. Hand hygiene includes cleansing hands either with an alcohol-based hand rub (if a source of water is not available) or with soap and water and drying them with a single-use clean towel.
- 4.1.3. Surface and environmental cleaning and disinfection includes all procedures implemented to protect employees, and study participants, from the hazards of their work environments. Cleaning with soap and water reduces number of germs, dirt and impurities on the surface. Disinfecting kills germs on surfaces.

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.
- 4.2.2. The LAKANA research staff will perform hand hygiene often, even in the absence of any physical contact with persons or surfaces. The staff will always clean hands (wash hands with soap and water or use hand sanitizer) before and

after direct participant contact, after the risk of exposure to body fluids and after interactions with the environment.

- 4.2.2.1. For the biological sample collection in the sub-studies, portable hand washing stations will be installed, for the LAKANA research staff collecting samples, at the pop-up facility in the village and at the CSCoM (if CSCoM not already equipped).
- 4.2.3. Unless otherwise specified, the LAKANA research staff will clean at least twice a day equipment and surfaces with water and soap and or a disinfectant.
- 4.2.4. Protective equipment for MDA in village: the LAKANA data collectors and Relais will wear masks at all time. The Relais will always disinfect hands with hand sanitizer before and after weighing an infant. The data collector will always disinfect hands with hand sanitizer before and after weighing and dosing an infant. In cases where the data collector or Relais sees it necessary, the Relais may also use gloves. If the child's condition or the covid epidemic situation demands it, the study coordinator or supervisor may also request all Relais to wear gloves during weighing.
- 4.2.5. Protective equipment for sample collection and anthropometric measurement: the LAKANA research staff taking biological samples or performing anthropometric measurement will wear mask, and gloves at pop-up health facility and CSCoM.
- 4.2.6. Instructions on using protective equipment:
 - 4.2.6.1. The LAKANA staff will follow a standardized procedure to put on and remove mask (See Appendix 1 for medical mask, see Appendix 2 for cloth mask).
 - If cloth mask is used, see Appendix 3 for WHO guidance and practical considerations on the composition, construction and management of non-medical mask.

5. Step-by-step procedures

- 5.1. **The LAKANA workers will follow the instructions described in Table 1 depending on setting and activity they are involved in:**

Table 1: Hand hygiene, environmental cleaning measures and PPE for use by setting and activity:

LAKANA Personnel	Setting	Activity	Equipment in PPE kit	Hand Hygiene	Environmental cleaning measures
Study coordinator	District office	No routine activities in village.	Mask. Soap. Hand sanitizer. Disinfectant.	Clean hands often: Use soap and water or hand sanitizer, dry hands with a single-use paper towel.	Discard waste in intended bin. Practice routine cleaning/disinfection of frequently touched surfaces (tables, doorknobs, light switches, desks, phones, keyboards, etc.).
Supervisor (district & field)	District office/data collection hub	Preparing and prepositioning data collection material. Managing waste (used drug bottles, syringes, other).	Mask. Soap. Hand sanitizer. Gloves. Disinfectant.	Clean hands often: Use soap and water or hand sanitizer, dry hands with a single-use paper towel. Put on gloves when handling study waste.	Discard waste in intended bin. Practice routine cleaning/disinfection of frequently touched surfaces (tablet computers, tables, doorknobs, light switches, desks, phones, keyboards, etc.).

LAKANA Personnel	Setting	Activity	Equipment in PPE kit	Hand Hygiene	Environmental cleaning measures
Pharmacist/Drug manager	District office/data collection hub	Overseeing drug reception, storage, transportation, and disposal.	Mask. Hand sanitizer. Disinfectant.	Clean hands often: Use soap and water or hand sanitizer, dry hands with a single-use paper towel.	Discard waste in intended bin. Practice routine disinfection of frequently touched surfaces (thermometers, doorknobs, light switches, desks, phones, keyboards, etc.).
Data collector	Village	Conducting interviews and recording data into tablet computer. Preparing and administering study drug to 1-11 mo. old infants.	Mask. Hand sanitizer. Disinfectant.	Use hand sanitizer often. Always disinfect hands with hand sanitizer before and after visiting a household. Always disinfect hands with hand sanitizer before and after handling drugs and infants.	Practice routine disinfection of frequently touched surfaces (tablet computers, hook of hanging scale, pen, phones, etc.). Discard waste in intended waste bag.

LAKANA Personnel	Setting	Activity	Equipment in PPE kit	Hand Hygiene	Environmental cleaning measures
Relais	Village	Assisting the data collector in weighing infants.	Mask. Hand sanitizer. (Gloves)	Use hand sanitizer often. Always disinfect hands with hand sanitizer before and after visiting a household. Always disinfect hands with hand sanitizer before and after weighing an infant.	
Anthropometrist	CSCom	Sub-study: Taking anthropometric measurements (weight, height, MUAC)	Mask. Soap. Hand sanitizer. Gloves. Disinfectant.	Clean hand often: Use soap and water or hand sanitizer, dry hands with a single-use paper towel. Always wash or disinfect hands before donning gloves and after removing gloves. Change gloves between participants. Always wash or disinfect hands between participants.	Practice routine cleaning/disinfection of frequently touched surfaces (tablet computer, pen, phone). Always disinfect anthropometric equipment (scale, length board, MUAC tape) between participants. Discard waste in intended bin.

LAKANA Personnel	Setting	Activity	Equipment in PPE kit	Hand Hygiene	Environmental cleaning measures
Nurse	CSCom	Sub-study: Collecting biological samples	Mask. Soap. Hand sanitizer. Gloves. Disinfectant.	Clean hands often: Use soap and water or hand sanitizer, dry hands with a single-use paper towel. Always wash or disinfect hands before donning gloves and after removing gloves. Change gloves between participants. Always wash or disinfect hands between participants.	Practice routine cleaning/disinfection of frequently touched surfaces (table, chairs, tablet computer, etc.). Discard waste in intended bin.
Driver	District office/data collection hub/Village	Ensuring transportation of staff, equipment and samples collected.	Mask. Soap. Hand sanitizer. Disinfectant.	Use hand sanitizer often.	Practice routine cleaning and disinfection of the vehicle.

6. Occupational Safety Issues

The LAKANA Malian co-PI will ensure that suitable personal protective equipment is provided to all LAKANA staff who may be exposed to a risk to their health or safety while at work.

7. Quality Assurance / Quality Control

The LAKANA study coordinator (or his designee) will routinely inspect and replace PPE when needed.

8. Appendices and other related documents

Document number	Document content
Appendix 1	How-to put-on and remove a medical mask.
Appendix 2	How-to put-on and remove a cloth mask.
Appendix 3	WHO Summary guidance and practical considerations for non-medical mask (cloth mask) production and management.

9. Version history, authors and approvals

Version (date)	Edits to the SOP text (author)
Version 1.0 (2020-09-24)	Authored by Laura Adubra and Rikhard Ihamuotila in consultation with Per Ashorn and CVD_TroDa team. Approved by the LAKANA PSG.
Version 2.0 (2020-10-20)	Edits: Removed drug provision from the responsibilities of the Relais. The text in section 4.2.4 and Table 1 has been modified accordingly. Authored by Laura Adubra and Rikhard Ihamuotila in consultation with Per Ashorn and CVD_TroDa team. Approved by the LAKANA PSG.

Appendix 1: How-to put-on and remove a medical mask.

- Wash or sanitize your hands before touching the mask.
- Pick up your mask by its ear loops (or ties).
- Without touching the mask, itself, inspect the masks for tears or hole. If the mask looks damaged, pick another mask.
- Find the top side where the metal piece or stiff edge is. Ensure the color side faces outwards.
- Bring the loops up to your ears, securing them as tightly as possible. If the mask is equipped with ties instead of loops, tie the upper pair around the rear crown of your head, then the second pair around the base of your neck.
- Be sure that it covers your nose and your mouth.
- Adjust the fit of the mask to ensure your chin is covered. Adjust the mask to your face without leaving gaps on the sides.
- Secure the mask around the bridge of your nose (if the mask comes equipped with a metal tab just where the bridge should be). Be sure to pinch it into place so that the top of the mask feels snug to your face. Even if there is no metal tab, try your best to ensure it won't slip down your nose later.
- Avoid touching the mask while wearing it.
- To remove the mask: Wash or sanitize your hands before touching the mask.
- Remove the mask by the straps from behind the ears or head.
- Keep the mask away from you and surfaces while removing it.
- Discard the mask immediately after using it in the designated bin.
- Wash or sanitize your hands after discarding the mask.

NB: *Never re-use single-use masks.*

Appendix 2: How-to put-on and remove a cloth mask.

- Wash or sanitize your hands before touching the mask.
- Pick up your mask by its ear loops.
- Without touching the mask itself, inspect the masks for damage or dirt. If the mask looks damaged or is dirty, pick another mask.
- Bring the loops up to your ears, securing them as tightly as possible.
- Be sure that it covers your nose and your mouth.
- Adjust the fit of the mask to ensure your chin is covered.
- Avoid touching the mask while wearing it.
- All masks should be changed if wet or visibly soiled; a wet mask should not be worn for an extended period of time.
- To remove a mask: Wash or sanitize your hands before touching the mask.
- Remove the mask by the straps behind the ears.
- Pull the mask away from you face.
- Place the mask in a sealable bag where it will be kept until you can wash it.
- Wash or sanitize your hands immediately afterwards.

NB: Under no circumstances you will share your masks with others

Appendix 3: WHO Summary guidance and practical considerations for non-medical mask (cloth mask) production and management.

Guidance and practical considerations
Fabric selection:
Choose materials that capture particles and droplets but remain easy to breathe through.
Avoid stretchy material for making masks as they provide lower filtration efficiency during use and are sensitive to washing at high temperatures.
Fabrics that can support high temperatures (60° or more) are preferable.
Construction:
A minimum of three layers is required, depending on the fabric used: an inner layer touching the mouth and an outer layer that is exposed to the environment.
Choose water-absorbing (hydrophilic) materials or fabrics for the internal layers, to readily absorb droplets, combined with an external synthetic material that does not easily absorb liquid (hydrophobic).
Mask management:
Masks should only be used by one person.
All masks should be changed if soiled or wet; a soiled or wet mask should not be worn for an extended period of time.
Non-medical masks should be washed frequently and handled carefully, so as not to contaminate other items.
Clothing fabrics used to make masks should be checked for the highest permitted washing temperature, which is indicated on the clothing label.
Non-woven polypropylene (PP) spunbond may be washed at high temperature, up to 140°C.
The combination of non-woven PP spunbond and cotton can tolerate high temperatures; masks made of these combinations may be steamed or boiled.
Where hot water is not available, wash mask with soap/detergent at room temperature water, followed by either i) boiling mask for one minute OR ii) soak mask in 0.1% chlorine for one minute then thoroughly rinse mask with room temperature water, to avoid any toxic residual of chlorine.

Source: World Health Organization. Advice on the use of masks in the context of COVID-19. Interim guidance (5 June 2020)