Republic of Somaliland

Ministry of Health Development

National Deployment Plan for Covax Vaccine

Standard Operating Procedures (SOPs) for COVAX vaccination

Field Guide for Regional Vaccination Teams and Administrators

(Ensuring best use of effective measures to safe life, always & at any point)

Developed by:
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1. Target Population:

Covid19 attacks all population and its vaccines is applicable to most population, despite WHO guidelines conforms the people under 21 years is not actual target. However, due to shortage of vaccine received by donation, the Somaliland will provide phase-1 vaccination to the below target categories.

Table 1 Target Vaccination population groups by category

Category	**Target #**
Frontline health care workers public sector	*As per Covid19 guideline*
Private health care workers	
National army	
Police force	
Immigration services	
Custodial corps	
Marines	
Teachers (public and private)	
Prisoners	
Health training institutions students and staff	
Customs workers	
Elders aged 65 and above years population	
People with NCDs*	
Community at large (all population)**	

NOTE:

** Pre-registration will be required for the NCDs (diabetic, hypertension, etc) which is visible now and will be panned later.*

*** Community-large target will depend of the availability of enough quantity COVAX vaccine!!!!!*

2. Vaccination Strategies (Fixed/Outreaches/Mobiles):

Since the target population of the Covid-19 vaccine are specific categories that are available in specific locations, the **mixed strategy** will be used as per below groupings and locations:

Table 2 National vaccination strategies

Category	Location	Strategy
Public hospitals staff	Hospitals	Fixed
Public Health centers staff	Health Centers	Fixed
Private hospitals staff	Hospitals	Fixed
Prisoners	Prison	Mobile
Police	Hospitals	Fixed
POEs, immigration, etc	Checkpoints	Mobile team
Military/Army	Military hosp	Mobile team

3.Dosage & Route of Administration:

- The Covid-19 vaccine used in this round is named **AstraZeneca/Oxford (COVISHEILD)**, of ready-for-use 10 dose-vial and is NOT applied to multi-dose vial policy and will be discarded after 6 hours of first puncture.
- The **DOSE** is 0.5ml IM in the deltoid muscle in either left or right upper hands.

The **2nd dose** to be administered after 2 to 3 months (**8 to 12 weeks**) after the first based on the MoHD's decision on interval taking into account WHO SAGE's latest recommendation.

- It is recommended that individuals who receive a first dose of **COVISHIELD™** complete the vaccination course with **COVISHIELD™** (Vaccine from the same manufacturer).
- In case of future COVAX vaccines, such as Johnson&Johnson, the clients will get only injection with no booster dose.

3.1. Intended use age

Persons aged 18 years and above.

3.2. Co-administration with other vaccines

There should be a minimum interval of 14 days between administration of this vaccine and any other vaccine against other conditions. This recommendation may be amended as data on co-administration with other vaccines become available.

3.3. Contraindications

A history of anaphylaxis to any component of the vaccine is a contraindication to vaccination. People who have an anaphylactic reaction following the first dose of this vaccine should not receive a second dose of the same vaccine.

3.4. Precautions

No severe allergic reactions or anaphylaxis caused by **COVISHIELD™** have been recorded in the context of clinical trials. However, as for all vaccines, **COVISHIELD™** should be given under health care

supervision, with the appropriate medical treatment available in case of allergic reactions.

As for any other vaccine, an observation period of 15 min after vaccination should be ensured. Anyone with an acute febrile illness (**body temperature over 38.5 ºC**) should postpone vaccination until they are afebrile. However, the presence of a minor infection, such as a cold, or low-grade fever should not delay vaccination.

3.5. Vaccination of specific populations

i. Persons aged 65 years and over

Taking the totality of available evidence into account and as per WHO recommendation, the MoHD considers vaccine for use in persons aged 65 years and older.

ii. Persons with comorbidities

Certain comorbidities have been identified as increasing the risk of severe COVID-19 disease and death (obesity, cardiovascular disease, respiratory disease and diabetes). Vaccination is recommended for persons with comorbidities that have been identified as increasing the risk of severe COVID-19.

iii. Pregnant women

The available data so far on AstraZeneca vaccines (**COVISHIELD**) on vaccination of pregnant women are insufficient to assess vaccine efficacy or vaccine-associated risks in pregnancy. Also, animal developmental and reproductive toxicity (DART) and pregnancy registry (safety monitoring studies on pregnancy women) are ongoing and outcomes will be closely monitored and put into consideration by MoHD when relevant. Thus, MoHD advises to exclude this population for vaccination in this initial phase based on these considerations as a precautionary measure.

Also, MoHD does not recommend pregnancy testing prior to vaccination as well as delaying pregnancy because of vaccination in line with latest WHO recommendations on the issue.

iv. Breastfeeding (Lactating Women)

Considering the substantial health benefits breastfeeding offers to lactating women and their breastfed children, the lack of current evidence on whether **COVISHIELD** vaccine is excreted in human milk as well as the vaccine's non-replicating nature, it's unlikely to pose a risk to the breastfed child and thus, **MoHD** recommends its use in these population in line with WHO SAGE recommendations.

Moreover, on the same basis, discontinuing breastfeeding after vaccination is not recommended.

v. People who have previously had SARS-CoV-2 infection

Based on many factors into consideration, MoHD recommends persons with PCR-confirmed SARS-CoV-2 infection in the preceding 6 months should delay vaccination until near the end of this period during this initial Phase 1 roll-out.

Viral or serological testing for prior infection is not recommended for the purpose of decision-making about vaccination.

vi. Persons Living with HIV

Given the fact that the vaccine is non-replicating and the possibility these groups may be at higher risk of severe COVID-19, persons living with HIV should be vaccinated. It is possible that the immune response to the vaccine may be reduced, which may lower its clinical effectiveness. It is not necessary to test for HIV infection prior to vaccine administration.

4. Selection Of Vaccination Sites:

Covid19 vaccination will be conducted in the hospitals and health centers with following selection criteria:

1. MoHD owned public hospitals
2. MoHD owned public health centers (HCs)
3. MoHD licensed private hospitals
4. MoHD licensed private center

All the sites will have the basic equipment for managing the AEFI and shock management drugs

4.1. Sites organization & layout

Generally, the site will be allocated in either hospital or health center, with well arranged place of space and ventilation if a room, or it will be an open-shared area.
In all locations, the layout in sequential of having entrance, working part and exit place.

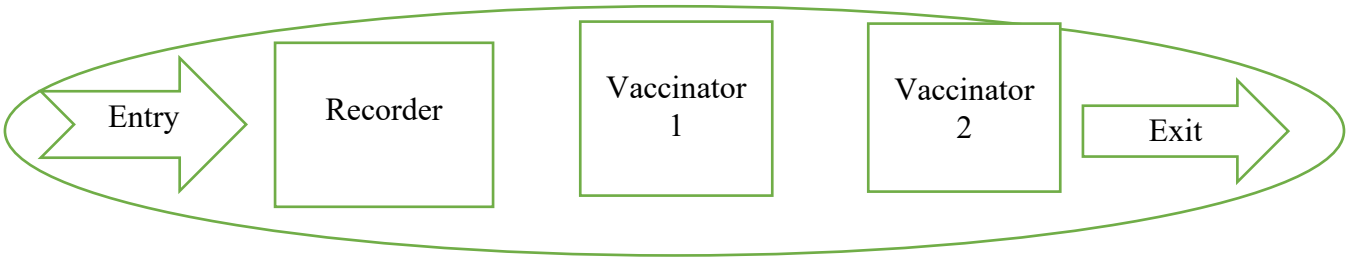

Figure 1 Site operations workflow chart

4.2. Site equipment, materials/supplies (including PPE):

In each vaccination, the following equipment, supplies and materials will be readily available and are to be in functioning state: -

1. Fridge for HCs
2. Cold box in mobile
3. Vaccine carriers 2
4. Icepacks 0.3L
5. Fridge tag
6. Soloshot (AD syringe).
7. Cotton roll
8. Safety box
9. Aprons
10. PPE (masks, gloves, sanitizer)
11. Table
12. Chairs
13. Screen (optional)
14. Data collection tools

5. Human Resources/Vaccination Teams

5.1. Selection of vaccination teams:

In much consideration the Covid-19 vaccine is new and importance of making high precaution of avoiding AEFI, the need to select well qualified + experienced health professional is very crucial.
Therefore, all vaccinators providing injection in the Covid-19 vaccine should be selected from:

1. Qualified Nurse from MoHD accredited training institution/university
2. Qualified midwife MoHD accredited training institution/university
3. Clinical officer from MoHD accredited training institution/university
4. Medical doctor from MoHD accredited university

5.2. Composition of teams:

Covid-19 vaccine in one-antigen, and provided by trained health worker in single-injection to each client. Accordingly, the team composition is based on the work-division and workload and its relation to team members could deliver.

Therefore, the following different people will be composed in each team:

1. Vaccinator-1 (also acts as team leader) for loading the AD syringe
2. Vaccinator-2 for giving injection (vaccination) to the clients.
3. Data recorder: for recording (filling register, write tallying and provide vaccination card to the clients.
4. Social mobilizer to help organize the sessions and reach out to institutions.

5.3. Workload per team day:

Depending on the workload that is matching to the actual number of people in the vaccination site, but as per immunization multi-strategies, both fixed and outreaches will be in Covid-19 vaccination, according to the following workload per day per strategy:

1. Fixed: 80 - 120 injections per day
2. Outreach: 40 injections per day

5.4. Working Hours

The standard COVID-19 immunization session working hour's duration is 8 hours per day in total. This usually should start 7:30- 8:00 a.m. in the morning until 3:30 – 4: 00 p.m. in the afternoon. However, this can be adjusted based on the situational needs as necessary and upon consultation and approval by central MoHD senior management. Thus, regional, district and site management teams are expected to comply and ensure this procedure be followed all the time.

6. Data Recording, Reporting & Management

6.1.Tools (registration, recording reporting, etc):

In each site of vaccination, the following tools will available for the recording and reporting to the people vaccinated, as well as to report any AEFI could happen in the course of the vaccination:

1. Register for the clients
2. Tally sheet
3. Vaccination card
4. AEFI case investigation from
5. AEFI reporting form

6.2. Reporting, Data Quality and Management

- The vaccination team should ensure timely accurate and complete recording of all data fields in the data collection register and tally sheets with full patient and vaccine information.
- Retrospective recording of data (filling data tools after the immunization session is not allowed) and supervisors on site are responsible for monitoring the vaccination teams to handle their responsibilities in this regard.
- Vaccine stock status should be recorded and included in the data collection and reporting tools in a timely and accurate manner.
- Ensure to give the vaccine card to each vaccinated person on site. This is very important tool serving as a proof of vaccination receipt.
- Vaccination data tools and registers are vital documents for immunization and public health national

data with sensitive individual health information and its confidentiality, correct handling and storage must be ensured by the vaccination teams.

- It's the responsibility of the RMOs and RPOs to report the aggregate daily immunization data to the MoHD assigned officials only.

7. Vaccine & Supplies Management

- The teams to take the vaccines and supplies from regional cold chain and to be stored in the fixed sites of the health facilities in the urban areas and villages those who have cold chain equipment. However, for the rural areas to be carried out using cold boxes and vaccine carriers.

- Ensure to keep the vaccine in proper temperature +2-+8 in all time at the health facilities with mounting, while for outreach and mobile teams keeping the vaccine in cold boxes and ensuring and maintaining the right temperature using conditioned ice packs and fridge tags.

- The Cold Chain Managers to document the number of issued vials to the field using delivery and issuing forms for each team. The team supervisors are accountable and responsible for keeping of the used vails (empty/ partial used vials) and should be a record for the daily vaccine usage using the Covid-19 Vaccine Accountability Form for Team Supervisor.

- Used and unused vaccine vials must be retrieved from the field and to be counted physically by the **Regional Health Management Teams**.

- Vaccine utilization report to be prepared & submitted at end of the campaign immediately.

8. Waste Management:

- Drop the used reconstitution syringes and AD syringes, needle end down, into the safety box immediately after use.
- Fill up to ¾ of a safety box or up to the "fill line", close the box and keep it in a secure place until final disposal.
- Dispose of empty vaccine vials and other waste in a separate container or a waste bag.
- Contaminated PPE (disposable gloves, gown, and masks) is infectious waste and should be disposed of in a separate container or a waste bag (labeled with the infectious substances symbol) as all other hazardous waste.
- In this phase all bio-medical waste to be returned to the regional cold chain facilities, including empty/ partial used vials.
- The regional cold chain manager is responsible for proper disposing of the waste by burning and burying as recommended by MoHD/WHO relevant disposal guidelines of medical/pharmaceutical waste.

9. Role Of Vaccines Among Other Preventive Measures

As there is not yet sufficient evidence of an effect of the vaccine on transmission, non- pharmaceutical interventions must continue, including use of face masks, physical distancing, hand-washing and other preventive measures as appropriate in particular settings. MoHD advice on public health preventive measures should continue to be followed by vaccinated individuals, as well as those who have not yet been vaccinated. This advice will be updated as information on the evidence of impact of vaccination on virus transmission and indirect protection in the community is assessed and available.

10. Monitoring, Supervision and Evaluation

10.1. Introduction and Objectives

Regular and effective implementation of CoVID-19 Vaccination is key for program success and outcomes and to ensure all activities are conducted and are in line with the operational plan during the roll-out phase.

The key objectives are to:
•Measure uptake and coverage over time, by geography and target groups.
•Monitor implementation effectiveness of national policies.
•Provide personal vaccination record/certificate.
•Ensure availability of documentation for use in coverage surveys, safety and disease surveillance, and vaccine effectiveness studies.
•Ensure all scheduled doses are administered and reduce drop out.

10.2. Strategies

The main strategies to be used for monitoring the implementation of the vaccination include:

A. Central coordination and review meetings

Attended by the National Vaccine Taskforce and senior MoHD technical managers and leadership. This should be conducted on regular daily basis to share and discuss updates, status of vaccine roll-out implementation in all districts as well as challenges faced. Moreover, this allows presentation, review, validation and cleaning of vaccination data and in-process actions and re-adjustments to be taken to address key identified gaps as a continuous (adaptive) learning process.

B. Supervision

This will entail field on-site supervision by central MoHD supervisor teams, regional health administrators as well as vaccination team supervisors to monitor implementation of the vaccination roll-out as per the plan and in line with the MoHD standards and guidelines to ensure safe, quality and effective program outcomes. All supervisors should be properly qualified with proven necessary academic and technical expertise to carry out their duties in responsible and effective manner. They should be provided with sufficient training and orientation ahead of the dispatch to the field on the use of the MoHD developed supervision checklist as field guide for their field assessment and final reporting. The central technical teams should conduct regular communications with the field supervisors and provide required technical support and advice.

10.3. Indicators

Coverage indicators to be monitored during the implementation are summarized in the table below.

Table 3 national vaccination indicators

Indicator	Definition
COV-1	Number or % of people in target group that have received the first dose of vaccine

COV-2	Number or % of people in target group that have received the 2nd dose
COV-1-COV-c drop out	Proportion of people in target group that received the first dose but did not complete the schedule; calculated as (COV-1 - COV-c)/COV-1

10.4. Evaluation

Due to their methodological complexity and susceptibility to biases, COVID-19 VE evaluations do not need to be conducted by all countries introducing COVID-19 vaccines and this should be decided by MoHD upon technical feasibility considerations. Hence, this section will be edited based on the outcome of this decision.

Objectives of VE evaluations are to evaluate real-world performance of vaccines, to address gaps in evidence from clinical trials (including effectiveness in subgroups, effectiveness against variants of concern and duration of protection), to provide input into impact models, and to provide post authorization confirmation of effectiveness of conditionally approved products.

The most feasible outcomes to evaluate in VE evaluations in most settings are symptomatic disease and severe disease. VE studies of death, infection and transmission, while of great public health importance, generally require targeted special studies with more resources.

Bibliography

1. WHO (2021). Interim recommendations for use of the AZD1222 (ChAdOx1-S [recombinant]) vaccine against COVID19 developed by Oxford University and AstraZeneca Vaccines.

2. WHO (2021). Extraordinary meeting of the Strategic Advisory Group of Experts on Immunization (SAGE) - 8 February 2021. Geneva: World Health Organization; 2021
3. WHO SAGE guidance for the development of evidence-based vaccination-related recommendations. Geneva: World Health Organization; 2017.
4. ChAdOx 1 nCoV- 19 Corona Virus Vaccine (Recombinant) –COVISHIELD- fact sheet for vaccine recipientapproved for restricted use in emergency situation of in prevention of (covid-19) disease in individuals 18 years of age and older. Serum Institute of India, Revised January, 2019.

E N D

Annex I

Vaccination Session Checklist

This checklist contains instructions intended for use by frontline health care workers who are planning a COVID-19 vaccination session to help prepare for at a fixed post or outreach sessions.

Before the session

✓	CALCULATIONS	TOTAL
	Calculate required vaccine doses = **Target number x adequate wastage factor (WF)**	
	Calculate required number of vaccine vials = **Vaccine doses ÷ number of doses per vial**	
	Ensure enough auto disable (AD) syringes = **1 per vaccine dose**	
	Ensure enough diluents (if applicable) = **1 per vaccine vial**	
	Ensure enough reconstitution syringes (if applicable) = **1 per vaccine vial**	
	Ensure enough safety boxes = **Total number of AD and reconstitution syringes ÷ 100**	
✓	**OTHER TASKS**	
	Prepare tally sheets (or other reporting forms, depending on recommendation, including tracking for 2 doses). **For outreach sessions,** prepare an up-to date microplan.	
	Develop list with contact phone numbers (e.g. supervisor, focal person for adverse events following immunization (AEFI), ambulance driver).	
	For outreach sessions, ensure enough vaccine carriers in good condition with coolant packs and foam pads.	
	Prepare an AEFI kit and COVID-19 vaccine specific AEFI reporting forms.	
	Prepare an infection prevention and control kit, including appropriate personal protective equipment (PPE).	
	Provide a waste bin (or bag) and a properly labeled bag for infectious waste.	

N.B. Ensure IPC measures are applied in all operations and at all areas of the vaccination site (physical distancing at least 2Ms, use of face masks for vaccination staff, supervisors and vaccines).