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MINISTRY OF HEALTH-ETHIOPIA
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Federal Democratic Republic of Ethiopia

Ministry of Health

Covid-19 Vaccination Training

Participant Manual

October, 2022

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Acknowledgement

The Federal Ministry of Health would like to sincerely thank all individuals and organizations who have contributed to the revision of the COVID-19 vaccine training participant manual and facilitator guide. This is the result of teamwork between FMOH, EPHI, EFDA, EPSS, WHO, UNICEF, USAID, CHAI, JSI-UI-FHS, GHSC-PSM, BMGF, TBI, PATH, CDC and AMREF who are committed to improving immunization services in Ethiopia.

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LIST OF ABBREVIATIONS

ACT	Access to COVID-19 Tools
AEFI	Adverse events following immunization
AESI	Adverse Events of Special Interest
CDC	Centers for Disease Control
CCE	Cold Chain Equipment
CEPI	Coalition for Epidemic Preparedness Innovations
CHAI	Clinton Health Access Initiative
CIOMS	Council for International Organizations of Medical Sciences
COVAX	the vaccine pillar of the ACT Accelerator
COVID-19	Coronavirus disease 2019
CTC	Controlled Temperature Chain
DNA	Deoxyribonucleic Acid
EBS	Event Based Surveillance
EIR	Electronic Immunization registry
EPHI	Ethiopian Public Health institute
EUL	Emergency Use Listing
EPSA	Ethiopian Pharmaceutical and supply agency
FMOH	Federal Ministry of Health
FPL	Focal Point for Logistics
FPV	focal point for vaccination
GACVS	Global Advisory Committee on Vaccine Safety
Gavi	Global Alliance for Vaccine and Immunization

HMIS	Health Management Information System
HEW	Health extension worker
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immune deficiency virus
IA2030	Immunization Agenda 2030 (WHO)
IBS	Indicator-Based Surveillance
ICC	Inter-Agency Coordinating Committee
ICU	Intensive care Unit
IFRC	International Federation of Red Cross and Red Crescent Societies
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IHR	International Health Regulation
IM	Incident Manager
IPC	Infection Prevention and Control
KAP	Knowledge, Attitudes and Practices
LMICs	Low- and Middle-Income Countries
mRNA	Messenger ribonucleic acid
MERS	Middle East Respiratory Syndrome
MMGH	MM Global Health
MoF	Ministry of Finance
MoH	Ministry of Health
MoU	Memorandum of understanding
NCC	National Coordinating Committee
NCL	National Control Laboratory

NDVP	National Deployment and Vaccination Plan
NGO	Non-Governmental Organization
NIP	National Immunization Program
NITAG	National Immunization Technical Advisory Group
NRA	National Regulatory Authority
PLWV	People living with HIV
PCR	Polymerase Chain Reaction
PHEIC	Public Health Emergency of International Concern
PHEM	Public Health Emergency Management
POE	Point of Entry
PPE	Personal Protective Equipment
RRT	Rapid Response Team
SARI	Severe Acute Respiratory Infection
SARS-COV-2	Severe Acute Respiratory Syndrome Coronavirus 2
TTS	Thrombosis with thrombocytopenia syndrome
THDF	Travelers Health Declaration Form
UCC	Ultra-Cold Chain
UNICEF	United Nations Children Fund
VAR	Vaccine Arrival Report
VOC	Variants of concern
VOI	Variants of interest
VPD	Vaccine Preventable Disease
WHO	World Health Organization

FOREWARD

The most recently discovered coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), causes coronavirus disease 2019 (COVID-19). COVID-19 was unknown prior to the outbreak in Wuhan, China, in December 2019, but is now a pandemic affecting most countries globally.

The Government, in collaboration with partners, has maximized its efforts in response to the COVID-19 pandemic: including intensified case search; investigation and lab testing; establishing quarantine centres; establishing and expansion of COVID-19 treatment centres and diagnostic facilities; enforcement of COVID-19 prevention, and infection prevention and control (IPC) measures.

As a continued effort, the Ministry of Health has planned to introduce COVID-19 vaccine with the objective to reduce morbidity and mortality from the COVID-19 disease and minimize the overall negative impacts of the pandemic on health, social and economic wellbeing of the people of Ethiopia. Synchronized COVID-19 vaccination was launched on 13th of March 2021 nationwide in the presence of national and sub-national political leaders, religious leaders, other influential public figures and partner organization representatives.

Due to concern of limited supply of vaccine for the entire population, Ethiopia has followed SAGE's roadmap and country SARS CoV-2 epidemiology for prioritization of target populations to identify most at risk and prioritize them for the COVID-19 vaccination. As the vaccine supply increased significantly the need for target shifting was made and all people age 12 years and above are the target populations for COVID-19 vaccination.

Therefore, the MOH, in collaboration with partners, has revised this training manual accommodating and including latest WHO emergency use list vaccines (EUL) and those which will be available in the global market that will be used as a guide to train and enable health professionals who will be involved during the COVID 19 vaccination to acquire and stay updated with the necessary knowledge, attitudes, and skills for the successful delivery of the COVID-19 vaccines.

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About the manual

- This manual is intended to guide and update health professionals, EPI experts, and partners on each WHO approved COVID-19 vaccine
- The manual is built upon existing documents and the core principles of the WHO Strategic Advisory Group of Experts (SAGE) values framework for the allocation and prioritization of COVID-19 vaccination, SAGE interim vaccine specific recommendations, and COVID-19 vaccine explainer
- Due to the constantly changing environment for COVID-19 vaccine development, the guidance is based upon the best available and updated information at the time of publication. These assumptions will require updating over time due to the evolving situation
- This manual included all WHO Emergency Use listing vaccines, procured, and distributed through COVAX facility and vaccines on bilateral donation
- In this manual the upcoming lists of vaccine under review are highlighted

The manual consists of 8 sections covering key thematic areas and it can be updated whenever there is a new development.

Introduction

Coronaviruses are a large family of viruses that may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections with symptoms ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and severe acute respiratory syndrome (SARS). The most recently discovered coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2), causes coronavirus disease 2019 (COVID-19). COVID-19 was unknown prior to the outbreak in Wuhan, China, in December 2019, but is now a pandemic affecting most countries globally. The epidemiology of COVID-19 is changing rapidly. As of October 28, 2022, globally, the total confirmed cases of COVID-19 reached over 625 million and above 6.5 million deaths.

The first COVID-19 case in Ethiopia was reported on 13th March 2020. Subsequently, the government declared a five-month state of emergency in April 2020. As of October 28, 2022, Ethiopia reported 493,905 confirmed cases of COVID-19 and 7,572 deaths (CFR 1.53%).

The impact of the Covid-19 pandemic in Ethiopia has been multi-faceted challenges including social, economic, and psychological aspects as a result jeopardizing the overall well-being of its people. The pandemic's negative impact on health for instance has not been limited to COVID-19 mortality and morbidity. Essential public health services have been disrupted in many parts of the country, including routine immunization services. The impact on essential health services was marked during the initial three to four months of the pandemic (March–June 2020). Immunization coverage has declined and drop-outs have been increased during the COVID-19 pandemic period; planned polio and measles vaccine campaigns were delayed and VPD surveillance has been interrupted.

In response to the challenges, the Government, in collaboration with partners, implementing different interventions including intensified case search, investigation and lab testing, establishing quarantine centers, establishing and expansion of COVID-19 treatment centers and diagnostic facilities, enforcement of COVID-19 prevention and infection prevention and control (IPC) measures, promotion of disease prevention and control, ensuring the continuity of Essential Health Services, and distributing vital medical supplies for COVID and non-COVID health services. Furthermore, as one part of the COVID-19 pandemic prevention and response strategy, Ethiopia has introduced COVID-19 vaccine with the objective to reduce morbidity and mortality from COVID-19 disease and minimize the overall negative impacts of the pandemic on health, social and economic wellbeing of the people.

After receiving AstraZeneca vaccine from COVAX facility, Ethiopia launched its roll out on March 13, 2021. Subsequently the country received about 73 million doses and as of October 2022, more than 43.1 million people received at least one dose of COVID-19 vaccine.

This training manual has been revised to accommodate and include latest WHO emergency use list vaccines (EUL) and those which will be available in the global market in the near future to train and update health workers. The objective of the training is to enable health professionals and related experts to acquire and stay updated with the necessary knowledge, attitudes, and skills for the successful delivery of the COVID-19 vaccines. The primary target audience of this training manual will be health professionals and public health officials who will be participating on COVID-19 vaccination at managerial and service provision levels. All or portions of the manual can be used as a reference to train health professionals and programmers as appropriate to the contents incorporated in each topic to refer. The monitoring tools are also annexed at the end of the document.

The training manual incorporates concepts of COVID-19 disease, global and national COVID-19 disease epidemiology, COVID-19 vaccines landscape, each WHO EUL vaccine management and administration, vaccine safety and AEFI, guides on prioritizing and targeting population for COVID-19 vaccination, surveillance, advocacy and risk communication for COVID-19 vaccination, the role of stakeholders, and coordination, planning, implementation, monitoring and evaluation of the COVID-19 vaccine introduction process.

Strategic Advisory Group of Experts (SAGE) and Emergency Use Listing (EUL)

SAGE is the principal Global advisory group to WHO for vaccines and immunization, charged with advising WHO on overall global policies and strategies, ranging from vaccines and technology, research, and development, to delivery of immunization and its linkages with other health interventions.

The WHO Emergency Use Listing (EUL) is a procedure for assessing unlicensed vaccines, therapeutics, and in vitro diagnostics during public health emergencies. The EUL procedure assesses the suitability of novel health products during public health emergencies. The objective is to make medicines, vaccines, and diagnostics available as rapidly as possible to be able to address the emergency. The EUL pathway involves a rigorous assessment of late phase II and phase III clinical trial data as well as substantial additional data on safety, efficacy, quality, and a risk management plan. WHO's EUL is a prerequisite for COVAX Facility vaccine supply, it allows countries to expedite their own regulatory approval to import and administer COVID-19 vaccines.

The COVAX facility

Access to Covid-19 Toll (ACT) Accelerator is a ground-breaking global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. COVAX is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi and the World Health Organization (WHO), alongside key delivery partner UNICEF. Its aim is to accelerate the development and manufacture of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world.

Course syllabus

Course Description	This 2 days training is designed to equip trainees with appropriate knowledge, skill and attitude to EPI mangers and service providing health workers regarding COVID-19 vaccines.
Course Goal	To transfer knowledge, skills and attitude to EPI managers and health workers on COVID-19 vaccines and enable them to provide better immunization services to the community.
Participant Learning Objectives	After completing this course participants will be able to: ■ Describe covid-19 mode of transmission, clinical features, epidemiological background, and prevention and control of the disease pandemic. ■ Describe facts on the rationale and objectives of the COVID 19 vaccine introduction in Ethiopia. ■ Describe the effective communication methods, demand promotion strategies and activities, and the communication process for successful COVID-19 vaccine introduction and implementation. ■ Explain basic concepts on targeting and prioritization of risk groups for COVID 19 vaccination and explain service delivery strategies as well as organization of vaccination sessions. ■ Describes concepts on Adverse Events Following Immunization (AEFIs) monitoring to enable the participants to acquire the necessary knowledge and skills to monitor and manage AEFIs. ■ Describes the current global development on COVID-19 vaccine, WHO EUL vaccines, forecasting and procurement, vaccine storage, handling and cold chain management and stock management. ■ Describes the necessary coordination mechanisms and planning process for COVID-19 vaccine introduction ■ Describes the importance of monitoring and evaluation during the COVID 19 vaccine introduction ■ Describes the role of health workers in COVID-19 surveillance and acquires necessary knowledge, skill and attitude of basic surveillance strategies and methods to support active case search, contact tracing, alert investigation, and screening effectively. ■ Describes the roles and responsibilities of the major stakeholders involved during the COVID 19 vaccine at all levels.

Training Methods	■ Interactive PowerPoint presentation
	  ■ Group based learning: Group work, Exercises, Brainstorming, Plenary discussion
	  ■ Case study, case scenario

	▪ Demonstration (session organization, vaccine administration, recording and documentation) ▪ Reading
Training Materials	▪ Printed materials: participant manual, facilitator guide, Power point ▪ Non- projected materials: Flip chart, writing board, marker ▪ Projected materials: LCD, Laptop computer ▪ Stationary materials: Notebooks, pens, papers, Flipcharts, and markers ▪ M&E tools: - (print-out) ▪ Infrared thermometer ▪ PPEs supplies (face mask, sanitizer, etc.)
Participant selection criteria	The target audiences for this training includes EPI managers/ focal persons, nurses, health officers, midwives, and medical practitioners (it includes all health care providers involved in the provision of immunization services and facilitation of this course)
Trainer selection criteria	Health care providers, program managers involved in the development of this training package or trained health workers with basic COVID-19 vaccine and those who have experience in facilitating trainings
Method of course evaluation	Participant ▪ Pre/ post course evaluation ▪ Daily course evaluation (discussions, recaps, reflections) ▪ Reflection from the trainers and trainees ▪ Participant attendance
Certification Criteria	The participants need to score minimum 70% in post course assessment and 100% attendance
Course Duration	2 days
Suggested Class size	Approximately 25-30 participants, with trainer to trainee ratio of 1: 5-8
Training Venue	Convenient enough to accommodate participants and to conduct group exercises, role play/demonstrations, presentations, well ventilated and lighted, allow physical distancing, and PPE supplies available ▪ This training will be delivered in accredited IST centers

Table 1: Course schedule

Topic/Activity	Time	Duration
Day One		
Registration, welcome address, and introduction of participants	8:30- 8:45 AM	15 mins
Pretest	8:45- 9:05 AM	20 mins
Background: basic facts about and epidemiology of COVID-19 disease	9:05- 9:25AM	20 mins
Rationale to introduce the vaccine	9:25-9:35AM	10 min
Supply Chain and waste management	9:35-10:00 AM	25 min
Tea Break	10:00-10:20 AM	20 min
Supply Chain and waste management cont…	10:20-12:30 PM	130 min
Lunch	12:30-1:30 PM	60 min
Surveillance of Adverse Event Following Immunization	1:30-3:00 PM	90 min
Demand promotion	3:00-3:30 PM	30 min
Tea Break	3:30-3:50 PM	20 min
Demand promotion	3:50 -5:50 PM	120 min
Day Two		
Recap Day one	8:30 -8:45 AM	15 min
Coordination and Planning	8:45 - 10:00 AM	75 mins
Tea Break	10:00-10:20 AM	20 min
Planning and Coordination cont…	10:20-10:35 AM	15 min
Service Delivery	10:35-12:35 PM	120 mins
Lunch	12:35-1:35 PM	60 min
Monitoring and evaluation	1:35-3:30 PM	115 mins
Tea Break	3:30 -3:50 PM	20 min
Monitoring and evaluation conti…	3:50-4:55 PM	65 min
General Discussions	4:55-5:30 PM	35 min

SESSION I

BASIC FACTS ON COVID-19 PANDEMIC

Section duration: 20 minutes

Section description: The section discusses the natural features of COVID-19 diseases and describes its mode of transmission, clinical features, epidemiological background, and prevention and control of the disease pandemic.

Learning objectives

By the end of the session, participants will be able to:

- Understand the basic facts about the SARS-CoV-2 disease
- Describe the COVID-19 global and national Epidemiology
- Understand the new nomenclature for different variants
- Explain the comprehensive prevention and control of the COVID-19 pandemic

1.1. COVID-19 Disease

Etiology: -Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus, the severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2). Coronaviruses are a large family of viruses that may cause illness in animals and humans. In humans, several coronaviruses are known to cause respiratory infections with symptoms ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and severe acute respiratory syndrome (SARS).

The most recently discovered coronavirus, severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) causes coronavirus disease 2019 (COVID-19). COVID-19 was unknown prior to the outbreak in Wuhan, China, in December 2019, but is now a global pandemic affecting all countries. Most people infected with the COVID-19 virus will experience mild to moderate respiratory illness and recover without requiring special treatment. Older people, and those with underlying medical problems like cardiovascular disease, hypertension, diabetes, chronic respiratory disease, and cancer are more likely to develop serious illness.

The viral characteristics are changing over time, while most changes have little to no impact on the virus' properties. However, some changes may affect the virus's properties, such as how easily it spreads, disease severity, effectiveness of vaccines or therapeutic medicines, diagnostic tools, or other public health and social measures. The dynamicity of the viral character and mutation resulted in discovery of new variants, as result of potential risk to global public health these variants are categorized as variants of concern (VOC) and variants of interest (VOI) to prioritize for monitoring, research, and ongoing response. VOC has been demonstrated to be associated with one or more of the following changes at a degreeof lobal public health significance:

increase in transmissibility or detrimental change in COVID-19 epidemiology; increase in virulence or change in clinical disease presentation; decrease in effectiveness of public health and social measures or available diagnostics, vaccines, and therapeutics. SARS-CoV-2 isolate is VOI if, compared to a reference isolate, its genome has mutations with established or suspected phenotypic implications, and either: has been identified to cause community transmission/ multiple COVID-19 cases/clusters, or has been detected in multiple countries; OR is otherwise assessed to be a VOI by WHO in consultation with the WHO SARS-CoV-2 Virus Evolution Working Group.

WHO recommended non-stigmatizing labeling of VOI and VOC by Greek alphabet and advocate the use of this alphabet. The current SARS-CoV-2 variant landscape is characterized by the emergence of an Omicron descendent lineage, the increase in the prevalence followed by the spread to many countries globally and replacement of the former dominant descendent lineage(s). The surge of cases linked to a specific descendent lineage is either due to its higher intrinsic transmissibility or higher immune evasion characteristics. The extent to which the emergence of a variant causes a rise in the number of cases, hospitalizations, and deaths in a country depends on several factors, including the levels of population immunity following either SARS-CoV-2 infection, vaccination, or a combination of the two, and the stringency of public health and social measures in place.

Includes BA.1, BA.2, BA.3, BA.4, BA.5 and descendent lineages. It also includes BA.1/ BA.2 circulating recombinant forms such as XE. WHO emphasizes that these descendant lineages should be monitored as distinct lineages by public health authorities and comparative assessments of their virus characteristics should be undertaken.

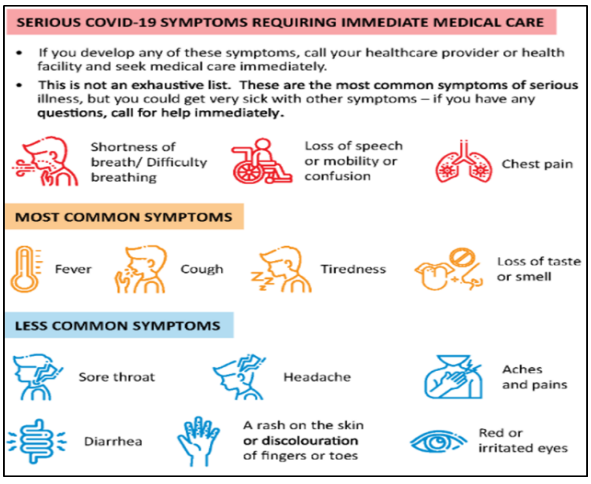
WHO label	Pango lineage•	GISAID clade	Nextstrain clade	Additional amino acid changes monitored°	Earliest documented samples	Date of designation
Omicron*	B.1.1.529	GR/484A	21K, 21L, 21M, 22A, 22B, 22C, 22D	+S:R346K +S:L452X +S:F486V	Multiple countries, Nov-2021	VUM: 24-Nov-2021 VOC: 26-Nov-2021

WHO label	Pango lineage	GISAID clade	Nextstrain clade	Earliest documented samples	Date of designation
Variants of Concern (VOCs):					
Alpha	B.1.1.7	GRY (formerly GR/501Y.V1)	20I (V1)	United Kingdom, Sep-2020	18-Dec-2020
Beta	B.1.351	GH/501Y.V2	20H (V2)	South Africa, May-2020	18-Dec-2020
Gamma	P.1	GR/501Y.V3	20J (V3)	Brazil, Nov-2020	11-Jan-2021
Delta	B.1.617.2	G/478K.V1	21A	India, Oct-2020	VOI: 4-Apr-2021 VOC: 11-May-2021
Variants of Interest (VOIs):					
Epsilon	B.1.427/ B.1.429	GH/452R.V1	21C	United States of America, Mar-2020	5-Mar-2021
Zeta	P.2	GR/484K.V2	20B	Brazil, Apr-2020	17-Mar-2021
Eta	B.1.525	G/484K.V3	21D	Multiple countries, Dec-2020	17-Mar-2021
Theta	P.3	GR/1092K.V1	21E	Philippines, Jan-2021	24-Mar-2021
Iota	B.1.526	GH/253G.V1	21F	United States of America, Nov-2020	24-Mar-2021
Kappa	B.1.617.1	G/452R.V3	21B	India, Oct-2020	4-Apr-2021
Lambda	C.37	GR/452Q.V1	20D	Peru, Aug-2020	14-Jun-2021

[1] Includes BA.1, BA.2, BA.3, BA.4, BA.5 and descendent lineages. It also includes BA.1/BA.2 circulating recombinant forms such as XE. WHO emphasizes that these descendant lineages should be monitored as distinct lineages by public health authorities and comparative assessments of their virus characteristics should be undertaken.

1.2. Mode of transmission of COVID-19

COVID-19 is primarily transmitted from person to person through respiratory droplets, from sneezing, coughing, and talking. Transmission through aerosols has also been implicated, as well as indirect transmission through contaminated fomites. Recent data suggest transmission of COVID- 19 from those with mild to severe symptoms, and from those who are pre-symptomatic (prior to symptom onset) or asymptomatic (a person infected with SARS CoV-2 that does not develop any symptoms). The onset and duration of viral shedding and the period of infectiousness for COVID-19 are not yet known with certainty. The estimated incubation period is between 2 and 14 days with a median of 5 days.



[1] *https://www.who.int/activities/tracking-SARS-CoV-2-variants https://www.nature.com/articles/s41564-021-00932-w*

1.3. COVID-19 illness clinical presentation

A wide range of symptoms for COVID-19 have been reported. These include fever or chills, cough, shortness of breath or difficulty in breathing, fatigue, headache, nasal congestion or runny nose, muscle or body aches, sore throat, new loss of smell or taste, rash on skin or discoloration of fingers or toes and diarrhea. Most of COVID-19 illnesses are mild, and most patients (approximately 80%) will recover without hospitalization. Data from several countries suggest that 14%- 19% of cases are hospitalized and 3%-5% will develop severe disease that require Intensive Care Unit (ICU) admission for complications such as respiratory failure, acute respiratory distress syndrome, sepsis and septic shock, thromboembolism, and/ or multiorgan failure, including acute kidney injury and cardiac injury.

The full range of COVID-19 disease, including long-term sequelae, is still to be fully understood and requires further research. Older age, smoking and underlying medical conditions such as cardiovascular disease, chronic respiratory or kidney disease, obesity, type 2 diabetes, solid organ transplantation and cancer, have been reported as risk factors for severe disease and death. As more data become available, additional risk factors for severe COVID-19 may be identified.

Gender differences:- Initial data demonstrate that men are more likely to suffer from severe COVID-19 than women. Men have a higher frequency of underlying conditions, including cardiovascular disease, and are more likely than women to smoke. However, data from rapid gender assessment surveys suggest that women are particularly vulnerable to COVID-19.

Women are more likely to be the caregivers and less likely to have access to health care and testing. In addition, health care workers are particularly at risk of contracting COVID-19, and women make up 70% of health care workers globally, and 80% of nurses in most regions. It is critical that efforts to address the pandemic should not jeopardize the fragile gains made for women in the workforce.

Special populations Children:- Clinical manifestations of COVID-19 are generally milder in children compared with adults. Relatively few cases of infants and young children confirmed with COVID-19 have been reported; of the few young children with COVID-19, most have had mild illness or remain asymptomatic. However, an acute presentation with a hyperinflammatory syndrome leading to multiorgan failure and shock has been described as multisystem inflammatory syndrome in children and adolescents temporally associated with COVID-19. Robust evidence associating underlying medical conditions with severe illness in children is still lacking. There is some indication that the Delta variant may affect more children than adults.

Pregnant women:- Pregnant women are at increased risk for severe COVID-19 illness, including increased rates of hospitalizations, ICU care and mechanical ventilation, but not death. Additionally, pregnant women with COVID-19 are more likely to experience preterm birth, and their neonates are more likely to be admitted to a neonatal ICU. During the postpartum period, mother and

infant should have contact at birth regardless of COVID-19 status. A mother should not be separated from her infant unless too sick to care for her baby. From the available evidence, the benefits of breastfeeding substantially outweigh the risks of illness associated with COVID-19.

Older people:- Older people and people with underlying medical conditions appear to develop serious illness more often than others with higher rates of morbidity, and mortality.

People with underlying medical conditions (comorbidities):- Certain comorbidities have been identified as increasing the risk of severe COVID-19 disease and death. Persons with comorbidities such as hypertension, chronic lung disease, significant cardiac disease, obesity, diabetes, and human immunodeficiency virus (HIV) infection have higher rates of morbidity and mortality.

1.4. COVID-19 Epidemiology: Global

COVID-19 was first identified in December 2019 in Wuhan, Hubei, China, and has resulted in an ongoing global pandemic. On 30th January 2020, WHO declared the COVID-19 outbreak as a public health emergency of international concern, and on 11th March 2020, WHO characterized the outbreak as a global pandemic. As of October 28, 2022, globally, the total confirmed cases of COVID-19 reached over 625 million and more than 6.5 million deaths, and as of October 28, 2022, over 12.8 billion vaccine doses have been administered.

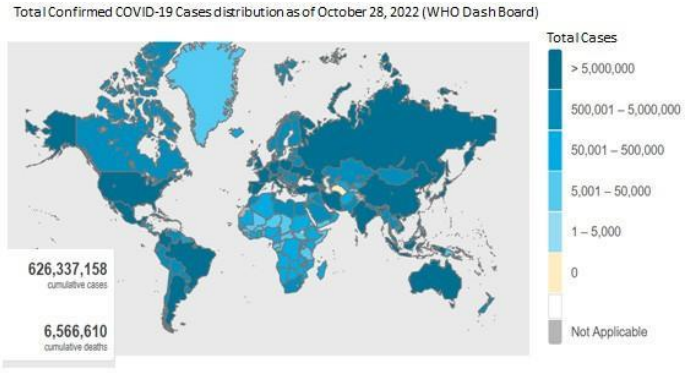


Figure 1: flow diagram for rapid convenience sampling

The Epidemiology in Africa

Africa is also highly affected by the COVID-19 pandemic; as of October 28, 2022, more than 12.4 million cases and 256,000 deaths (CFR =2.06%) were reported. When Africa experienced its first wave, attributed to the spread of the wild SARS-CoV-2 virus, the average case fatality ratio (CFR)—or the proportion of infected people who die from COVID-19—was high (2.5%). That figure rose to 2.7% during the Beta-driven second wave, before going back down to 2.4% during the Delta-powered third wave.

The Epidemiology in Ethiopia

The first COVID-19 case in Ethiopia was reported on March 13, 2020. As of October 28, 2022, Ethiopia reported 493,905 confirmed cases of COVID-19 and 7,572 deaths (CFR 1.53%) since the start of the outbreak in mid-March. Majority of the cases have been reported by Addis Ababa and Oromia regions. Ethiopia is the 6th COVID-19 highest affected countries in Africa following South Africa, Morocco, Tunisia, Libiya and Egypt.

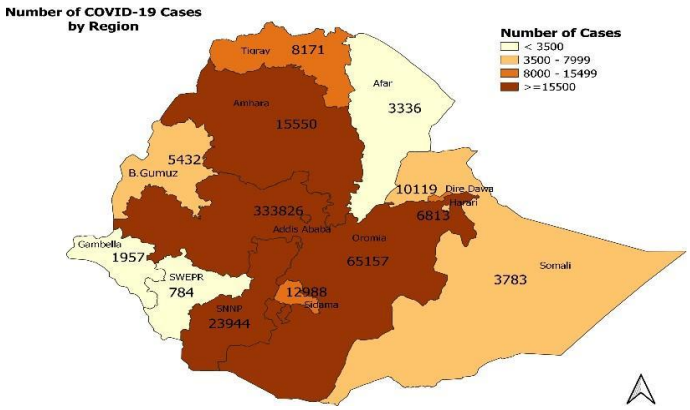


Figure 2:- COVID-19 Cases by Region as of July 29, 2022

The impact of the Covid-19 pandemic in Ethiopia has been multi-faceted involving social, economic, and psychological aspects as a result jeopardizing the overall well- being of its people. Essential public health services have been disrupted in many parts of the country, including routine immunization services increasing the risk of vaccine-preventable disease outbreaks like measles and polio; prevention and treatment of services for acute and chronic, communicable and non-communicable diseases and their complications, maternal and child health services; and mental health and rehabilitation are among others.

1.5. Comprehensive prevention and control of COVID-19 disease

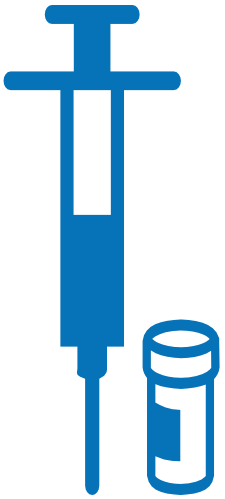
The best way to prevent and slow down transmission of COVID-19 is to be well informed about the COVID-19 virus, the disease it causes and how it spreads, through protecting infection by washing your hands or using an alcohol-based rub frequently, not touching your face, and keeping physical distancing and covering the nose and mouth. Vaccines are one critical tool in preventing COVID-19-related illness. Generally, to prevent and to slow transmission of COVID-19, the following practices are necessary:

- Vaccination against COVID 19 virus
- Wash your hands regularly with soap and water or clean them with alcohol-based hand rub.
- Maintain at least 1-meter distance between you and people coughing or sneezing.
- Cover your mouth and nose when coughing or sneezing.
- Stay home if you feel unwell.
- Practice physical distancing by avoiding unnecessary travel and staying away from large groups of people.

Ethiopia will continue the strong comprehensive approach to prevention and control of COVID-19. Risk mitigation procedures (wearing masks, washing hands, maintaining proper distance from those not in your immediate household, minimizing office presence and contact with others, etc.) will continue to be observed by everyone even after vaccination to protect ourselves and others.

SESSION II

RATIONALE AND OBJECTIVES FOR COVID-19 VACCINE INTRODUCTION



Section duration: 10 minutes

Section description: This section aims to provide facts on the rationale and objectives of the COVID 19 vaccine introduction in Ethiopia.

Learning objectives

By the end of the session, participants will be able to:

- Understand the rationale for COVID-19 vaccine introduction in Ethiopia
- Explain objectives for COVID-19 vaccine introduction in Ethiopia

2.1. Rationale

COVID-19 vaccines offer the most effective means to protect populations from novel coronavirus. Recognizing that the high transmission of COVID 19 and its health, negative impacts on socio-economic and social being of the people and believing that vaccines can halt the transmission of the disease, Ethiopia introduced COVID-19 vaccine as the best opportunity to protect the people from COVID-19 morbidity and mortality and to reduce the overall negative impacts on the wellbeing of the people. As of October 28, 2022, Ethiopia, introduced Four COVID-19 vaccines as the best opportunity to protect the people from COVID-19 morbidity and mortality and to reduce the overall negative impacts on the wellbeing of the people.

2.2. Objectives of vaccine introduction in Ethiopia

The objective of COVID-19 vaccine introduction in Ethiopia is to avert COVID-19 morbidity and mortality by minimizing the spread of COVID-19 infection and societal and economic disruption due to the pandemic.

The specific objectives are:

- To protect the integrity of the health care system
- To reduce morbidity and mortality by vaccinating older persons and adults with comorbidities.
- To restore social and economic functionality, by maintaining essential services.
- To ultimately reach population immunity and reduce transmission of COVID-19.

SESSION III

COVID-19 VACCINE SUPPLY CHAIN AND WASTE MANAGEMENT

Section duration: 155 minutes

Section description:

This section describes the current global development on the COVID-19 vaccines, and WHO EUL vaccines, it also describes forecasting, vaccine storage and handling, cold chain, and stock management, as well as waste management.

Learning objectives:

The primary objective of this section is to describe the current global development status of COVID-19 vaccines and their logistics and supply chain management. By the end of this section, participants will be able to:

- Describe the COVID-19 vaccine landscape
- Describe WHO EUL COVID-19 vaccines and their characteristics
- Explain how to forecast the COVID-19 vaccine and associated supplies
- Describe COVID-19 vaccine stock management and distribution
- Describe the storage and handling of COVID-19 vaccines
- Describe Management of waste associated with COVID-19 vaccination

Section Topics

- COVID-19 Vaccine landscape
- WHO emergency use list vaccines
- COVID-19 vaccine currently in use in Ethiopia
- Perquisites and recommendations for all EUL vaccine types
- COVID-19 vaccines storage and handling
- Demand Forecasting of COVID-19 Vaccine & Supplies
- COVID-19 vaccines stock management
- Distribution and delivery of COVID-19 vaccines
- Management of waste associated with COVID-19 vaccination

3.1. COVID-19 Vaccine Landscape

Efforts have been taken to develop safe and effective vaccines to combat COVID-19. According to the latest updates from WHO`s novel coronavirus candidate vaccine development tracker, as of October 18, 2022, there are about 371 total candidate vaccines of which 172 are in the clinical phase, while 199 were in the pre-clinical phase and 9 WHO EUL approved. The time required by these vaccine candidates to become available in the market depends on the success of all the phases of clinical trials.

Table 2:-Summary of COVID-19 Vaccines by their types

Type of vaccine	Description	Pros	Cons	EUL COVID-19 vaccines
Inactivated virus vaccines (whole cell)	An inactivated version of the target pathogen. The virus is detected by immune cells but is unable to cause disease.	Induces strong immune response	Requires lots of viruses	▪ Sinopharm SARS-CoV-2 Vaccine (Vero Cell) ▪ Sinovac ▪ Bharat Biotech
Viral-vector vaccines	A virus is genetically engineered or modified to contain antigens from the target pathogen. When the nucleic acid is inserted into human cells, they produce copies of the virus' protein, which stimulates a protective response from the host immune system.	Rapid development	Prior exposure to viral vectors may reduce immunogenicity	▪ Gamaleya ▪ Janssen ▪ AstraZeneca
Nucleic-acid vaccines	RNA or DNA vaccines include a target pathogen protein that prompts an immune response. When nucleic acid is inserted into human cells, RNA or DNA is then converted to antigens.	Strong cellular immunity, rapid development	Low antibody response	▪ Pfizer ▪ Moderna
Protein sub-unit vaccines	These vaccines use fragments of the target pathogen that is important for immunity.	May have fewer side effects than the whole virus	May be poorly immunogenic, complex process	▪ Novavax ▪ Sanofi ▪ Pasteur/GSK ▪ Shenzhen

3.2. WHO Emergency use Listing

Brainstorming

How many EUL COVID-19 vaccines do you know globally and in Ethiopia context?

As of October 2022, at least nine different vaccines across multiple platforms have been rolled out in multiple countries and seven vaccines have received WHO EUL, with multiple others currently in the process. Sputnik V vaccines are being used by some countries but have not yet received WHO EUL approval, the vaccine is likely to be included in this guideline soon once EUL is approved.

COVID-19 Vaccines with WHO Emergency Use Listing as of October 2022

1. AstraZeneca ChAdOx1-S/nCoV-19 [recombinant]
2. Sinopharm vaccine (Vero Cell)
3. Janssen Ad26.COV2. S (COVID-19) vaccine
4. Pfizer–BioNTech (BNT162b2) (COMIRNATY ®)
5. Sinovac- CoronaVac vaccine
6. Moderna mRNA-1273 vaccine (Moderna Covid-19 vaccine)
7. NVX-CoV2373 vaccine (Novavax)
8. Bharat Biotech's Covaxin
9. CanSinoBIO Ad5-nCoV-S [recombinant] vaccine (Convidecia™)

Astra Zeneca ChAdOx1-S/nCoV-19 [recombinant]

The ChAdOx1-S/nCoV-19 [recombinant] vaccine is a replication-deficient adenoviral vector vaccine against coronavirus disease 2019 (COVID-19). The vaccine efficacy against symptomatic SARS-CoV-2 infection was 74%. For participants aged 65 years and above the efficacy was found to be 83. %

Table 4: AstraZeneca product characteristics

Presentation	Liquid, preservative-free, multi-dose suspension
Number of doses	SK Bioscience: 10 or 8 doses per vial (each dose of 0.5 mL)
	COVISHIELD™: ■ Two doses per vial (each dose of 0.5 mL), or ■ Ten doses per vial (each dose of 0.5 mL)
Vaccine syringe	■ Auto-disable (AD) syringe: 0.5 mL
Type of needle	■ Needle for intramuscular injection 23G x 1" (0.60 × 25 mm)

Vaccine administration

The recommended schedule is two doses (0.5 ml) given intramuscularly into the deltoid muscle. WHO recommends an interval of 8 to 12 weeks between the two doses. Vaccine efficacy tended to be higher when the interval between doses was longer. If the administration of the second dose is inadvertently delayed beyond 12 weeks, it should be given at the earliest possible opportunity.

Table 5: Schedule and administration summary of AstraZeneca vaccine

Recommended age	■ 18 years of age and above
Recommended schedule	■ First dose at the start date ■ Second dose 8-12 weeks after 1st dose ■ Booster does 6 months after completion of the primary series
Route and site of administration	■ Intramuscular ■ Preferably deltoid muscle
Dosage	■ 0.5ml per dose
Diluent	■ Not needed

Storage and handling

Unopened vaccine vials should be stored in a refrigerator (+2 °C to +8 °C) and should not be frozen. Once a vial has been opened (first needle puncture), it should be handled according to the WHO policy on opened multi-dose vial vaccines and be discarded at the end of the immunization session

or within six hours of opening, whichever comes first. The open vaccine vials should also be kept at cooled temperatures between +2 ˚C to +8 ˚C during the in-use period.
Table 14: AstraZeneca storage and stability summary

Storage temperature	• Store in the original packaging in a refrigerator at +2 to + 8 ˚C • Have a temperature monitoring device in place
Shelf life	• Unopened vials in a refrigerator between +2 and +8˚C until the expiry date stated on the cover
	• Opened vials after the first needle puncture should be kept cool at temperatures between +2 ˚C and +8˚C during the immunization session
Freeze sensitive	• Do not freeze
Light sensitive	• Avoid exposure to direct sunlight and ultraviolet light
Condition before use	• It is ready to use, no reconstitution is required • It may be used if kept cooled at +2 ˚C to +8 ˚C within 6 hours after opening
VVM	• The vaccine has no VVM

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. People who have had TTS (a very rare syndrome of blood clotting combined with low platelet counts) following the first dose of this vaccine should not receive a second dose of the same vaccine.

Sinopharm vaccine (Vero Cell)

The Sinopharm SARS-CoV-2 vaccine (Vero Cell) is an inactivated vaccine against COVID-19. This vaccine is adjuvanted (with aluminum hydroxide), to boost the response of the immune system. A large multi-country phase 3 trial has shown that two doses administered at an interval of 3-4 weeks had an efficacy of 79% against symptomatic SARS-CoV-2 infection 14 days or more after the second dose.

Table 6: Sinopharm product characteristics

Presentation	■ Fully liquid, inactivated, adjuvanted ■ Preservative-free suspension in vials
Dosage	■ 0.5 mL per dose; 2 dose per vial and one dose per vial
Vaccine syringe type of needle	■ AD syringes or
	Vials, for which the following is needed: ■ Auto-disable (AD) syringes: 0.5 mL ■ Needles for intramuscular injection 23G × 1” (0.60 × 25 mm)

Administration

The recommended schedule for the primary vaccine series is two doses (0.5 ml each dose) given intramuscularly into the deltoid muscle. WHO recommends 3–4 weeks. If the administration of the second dose is delayed beyond 4 weeks, it should be given at the earliest possible opportunity. It is recommended that all vaccinated individuals receive two doses. The vaccine is ready to use, during inspection of the vial or mono dose prefilled syringe make sure that the liquid is opalescent suspension, milky-white in colour, if the stratified precipitate is formed, disperse it by shaking. When using vaccine vials, draw up the vaccine from the vial at the time of administration. Use it immediately as this vaccine contains no preservatives.

Table 7: Summary of The Schedule and Dose of Sinopharm Vaccine

Recommended age	■ 18 years and above
Schedule	■ First dose at the start date ■ Second dose 3 to 4 weeks after the first dose ■ Booster does 6 months after completion of the primary series
Route of administration	■ Intramuscular ■ The preferred site is the deltoid muscle
Dosage	■ 0.5ml dose
Diluent	■ Not needed

Table 8: Stability And Storage Summary For Inactivated Sinopharm Vaccine.

Storage temperature	• Store the original packaging in a refrigerator at +2 to+ 8 °C • Have a temperature monitoring device in place
Shelf life	• Unopened vials in a refrigerator between 20C and 8 °C: 24 months or until the expiry date stated on the label
Freeze sensitivity	• Do not freeze
Light sensitivity	• Store in the original packaging to protect from light • Avoid exposure to direct sunlight and ultraviolet light
Condition before use	• The vaccine is ready to use
VVM	• It has VVM and may also come without VVM

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.

Janssen Ad26.COV2. S (COVID-19) vaccine

Janssen Ad26.COV2. S vaccine against COVID-19 is a recombinant, replication-incompetent adenovirus serotype 26 (Ad26) vector encoding a full-length and stabilized SARS-CoV-2 spike protein. This vaccine does not contain adjuvants, preservatives, materials of animal origin, or fetal tissue. Efficacy shown in clinical trials in participants who received a single dose of the COVID-19 Vaccine Janssen was 67% against symptomatic SARS-CoV-2 infection, 77% against severe COVID-19 after 14 days, and 85.4% after 28 days, and 93.1% against hospitalizations.

Table 9: Janssen product characteristics

Presentation	▪ Preservative-free, multi-dose suspension for injection
Number of doses	▪ One vial (2.5 ml) contains 5 doses of vaccine
Vaccine syringe	▪ Auto-disable (AD) syringe: 0.5 ml
Type of needle	▪ Needle for intramuscular injection 23G x 1” (0.60 × 25 mm)

Administration

The vaccine received Emergency Use Listing for a single dose at 0.5ml given intramuscularly into the deltoid muscle based on a Phase 3 trial using a single dose. WHO recommends two doses, 2-6 months apart. If the administration of the second dose is delayed beyond 6 months, it should be given at the earliest opportunity.

Inspect the vial visually to make sure that the liquid is colorless to slightly yellow and clear to very opalescent suspension. If any particulate matter and discoloration are present, do not use it, discard the vial. Swirl the vial gently in an upright position for 10 seconds, do not shake.

Remember to record the date and time of the first use (first puncture and withdrawal of the dose) on the vial label. Draw up the vaccine dose (0.5 mL) when ready to vaccinate, pre-loading of syringes is not recommended. Preferably, use the vaccine immediately after the first puncture or within 6 hours afterwards. Discard if the vaccine is not used within this time or at the end of the session, whichever comes first, the multi-dose vial policy applies for the Janssen vaccine. A maximum of 5 doses can be withdrawn from one vial. Do not combine residual vaccines from multiple vials. Discard any remaining vaccine in the vial after 5 doses have been withdrawn.

A longer inter-dose interval between the two doses with Ad26.COV2. S (6 months rather than 2 months) has been shown to result in a larger increase in humoral immune responses (ELISA titres). The two-month interval increased responses by 4–6-fold and the six-month interval by 12-fold. Countries could therefore consider an inter-dose interval of up to 6 months.

Table 10: schedule and administration of the Janssen vaccine

Recommended age	18 years and above
Schedule	▪ First dose at the start date
	▪ Booster does 6 months after completion of the primary series
Route and site of administration	▪ Intramuscular
	▪ The preferred site is the deltoid muscle
Dosage	▪ 0.5ml single dose
Diluent	▪ None needed

Storage and handling

The Janssen vaccine can be stored at 2°C to 8 °C and -25 °C to -15 °C however the shelf-life changes depending on the temperature range stored. If the vaccine comes with a temperature range of -25 °C to -15 °C, it will have a shelf life of being labelled in the vial by the manufacturer. If the vaccine is transported and stored at 2°C to 8 °C it will have an 11-month shelf starting from the manufacturing date. The shelf life of the Janssen vaccine can be extended depending on the stability study result by the manufacturer and dynamic shelf-life labelling will be used. The shelf life of the vaccine can be obtained in two ways. The first is by scanning the bar or QR code in the vial, these vaccines are donated from the US. The other type of vaccine donated from the COVAX facility will have an expiry date in the vial of the vaccine.

TABLE 11: STABILITY AND STORAGE OF THE JANSSEN VACCINE

Vaccine storage temperature	• If the vaccine is received frozen, store it in the original carton at -25 to -15 °C • Do not store on ice packs If the vaccine is received thawed at +2 to +8 °C, store it refrigerated at +2 to +8 °C in the original carton
Shelf life*	• Frozen unopened vaccine vial in the freezer at -25 and -15 °C: 24 months, or from receipt until the expiry date printed on the vial and outer carton • Thawed unopened vaccine vial in the refrigerator at +2 to +8 °C: once removed from the freezer, for a single period of up to 11 months • Keep at +2 to +8 °C: up to 6 hours after the first dose has been withdrawn
Freeze sensitivity	• Never refreeze thawed vials • Do not store in an insulated passive container with frozen icepacks
Light sensitivity	• Store in the original outer carton to protect from light • Avoid exposure to direct sunlight and ultraviolet light
Condition before use	• After thawing, visual inspection, and gentle swirling of the vial, the vaccine is ready for use
VVM	• No VVM

Shelf life*- Thawed unopened vaccine vial in the refrigerator at +2 to +8 °C: once removed from the freezer, for a single period of up to 11 months. It is advised to assess the following: -

The expiry date must be updated when the vaccine is removed from the freezer and before it is stored in the refrigerator

If the 11-month period is within the original expiry date printed on the outer carton, cross out the original expiry date on the outer carton to mark it as not valid. Write down the new expiry date which would be eleven months from the date you removed the vaccine from the freezer

If the 11-month period is longer than the original expiry date printed on the outer carton, respect the original expiry date.

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 Ad26.COV2. S should not receive any further doses of the same vaccine. People who have had thrombotic thrombocytopenia following the first dose of this vaccine should not receive a second dose of the same vaccine. Known history of anaphylaxis to any component of the vaccine Individuals with a known history of Capillary leak syndrome should not be vaccinated with this vaccine.

Precautions:

Based on post-marketing safety surveillance, the following safety concerns were identified: thrombosis with thrombocytopenia syndrome and Guillain-Barre Syndrome.

Anyone with an acute febrile illness (body temperature over 38.5 ºC) should postpone vaccination until they are afebrile.

Pfizer-BioNTech (BNT162b2) (COMIRNATY ®)

> **Brainstorming**
>
> What are the storage requirements for Pfizer vaccine?
>
> What types of Pfizer vaccine formulations do you know?
>
> What is shelf-life dynamic labeling?

BNT162b2 is an mRNA vaccine-based vaccine encoding the viral spike glycoprotein (S), unique to SARS-CoV-2. BNT162b2, an mRNA vaccine against COVID-19 developed by BioNTech and Pfizer, has been shown to have an efficacy of approximately 95%, based on a median follow-up of two months. The vaccine is recommended for ages 6 months and above.

Table 12: BNT162b2 (Pfizer BioNTech) Product Characteristics

Presentation	Frozen, sterile, and preservative-free multi-dose concentrates for dilution before administration
Number of doses	One vial (0.45 mL) contains six doses of vaccine after dilution
Vaccine syringe type of needle	Vaccine syringe and needle: auto-disable (AD) syringe: 0.3 mL, needle for intramuscular injection 23G × 1” (0.60 × 25 mm) Mixing syringe and needle: 2 mL or 5 mL low dead reuse prevention (RUP) syringe, needle 21G or narrower

Administration

The recommended schedule is two doses (30 µg, 0.3 ml each for all persons aged> 12 years) given intramuscularly into the deltoid muscle. WHO recommends that the second dose should be provided 3-4 weeks after the first dose.

Table 13: Summary of the schedule and dose of the BNT162b2 (Pfizer BioNTech) vaccine

Recommended age	• 12 years of age and older persons without an upper age limit
Schedule	• First dose at the start date
	• The second dose is 3-4 weeks after the 1st
	• Booster does 6 months after completion of the primary series
Route of	• Intramuscular

administration	• the preferred site is the deltoid muscle
Dosage	• 0.3 mL (single dose after dilution), Use only 0.3ml low dead volume syringe for administration. Use of other types of syringes is not allowed which can cause over or under-dose administration.
Diluent for Purple Cap	• 0.9% sodium chloride solution for injection
	• No dilution is needed for TRIS formulation (Grey cap)
Preparation*	• the vaccine is stored at Central Level in a ULT freezer at -80°C to -60°C at the sub-national level stored and at +2 to +8 °C in a refrigerator for 31 days for purple cap and 10 weeks for grey cap.
	• Discard the vaccine if exposed over 30°C for more than 2 hours
	• Diluent for Pfizer vaccine is 10ml plastic vials. Use a 2ml syringe to take 1.8ml from the 10ml volume of the diluent vial and discard the rest of the diluent. Use One diluent vial for one Pfizer vaccine vial. Both Over dilution of the Pfizer vaccine vial and the use of one plastic 10ml vial for more than one vial of Pfizer vaccine increases potential AEFI risk.
Multi-dose vial policy	• Discard any unused vaccine 6 hours after dilution, or
	• At the end of the immunization session, whichever comes first

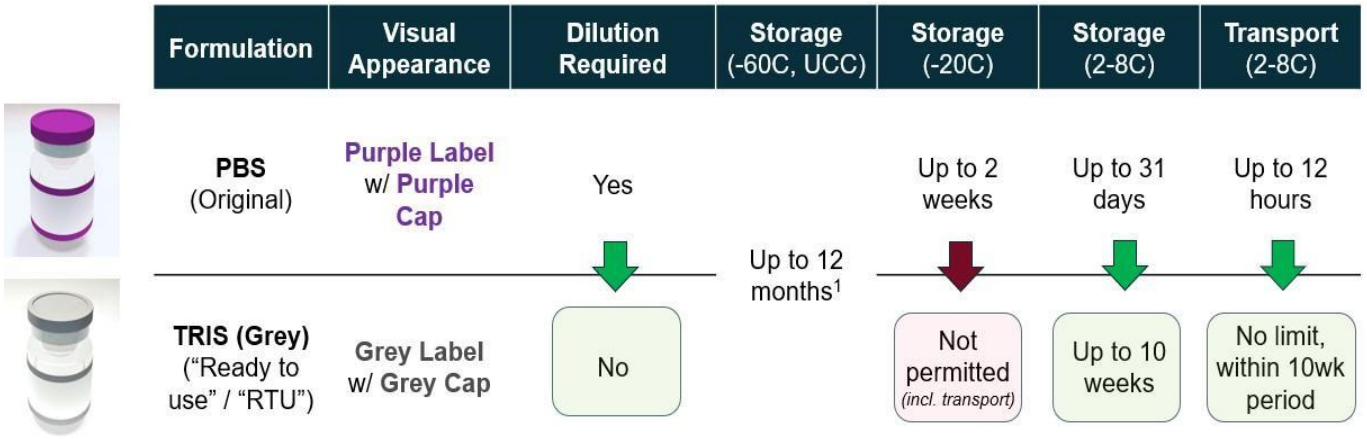
Preparation for Purple cap*- Dilute before use:

Before dilution, invert the vaccine vial gently 10 times, do not shake. Draw into the mixing syringe 1.8 mL of diluent. Add 1.8 mL of diluent into the vaccine vial; level/equalize the pressure in the vial before removing the needle by withdrawing 1.8 mL of air into the empty diluent syringe. Discard the diluent syringe in the safety box (do not reuse it) and discard the diluent vial. Gently invert the vial with diluted vaccine 10 times to mix; do not shake. Inspect to make sure that the vaccine is an off-white uniform suspension; do not use it if discolored or if containing particles. Record the date and time of dilution on the vaccine vial label. Draw up the vaccine dose at the time of administration, pre-loading the vaccine into syringes is not recommended. Use all vaccines within 6 hours after dilution. Use one diluent vial for one vial of Pfizer vaccine irrespective of the volume of the diluent. Do not use one diluent vial for more than one vial of the Pfizer vaccine which may cause AEFI.

Pfizer TRIS (Gray) Formulation

TRIS (Grey) – also known as the "ready to use" or "RTU" formulation – is the newer formulation of the Pfizer BioNTech vaccine for ages 12+. It is identical to the original (PBS) formulation in terms of vaccine efficacy. It has been reformulated to be simpler to deliver. Specifically, it does not need to be diluted at the point of care, and (ii) has more permissive storage at 2-8C. This formulation has a shelf of 15 months from the manufacturer's printed dates.

Overview of key differences between PBS and TRIS formulations



Storage and Handling of Pfizer Vaccines

The BNT162b2 vaccine currently requires ultra-cold-chain distribution and storage conditions that will be challenging in many country settings. When assessing the feasibility of deploying BNT162b2, the immunization program should consider the cold-chain requirements, the current minimum number of doses per shipment, the need to administer a whole batch of vaccine within a brief period after removal from cold storage, and the need to ensure bundling with an adequate independent supply of the correct diluent. Conditions must be met to avoid exposure of vials to sunlight and ultraviolet light.

TABLE 14: STABILITY AND STORAGE SUMMARY FOR PFIZER BIONTECH COVID-19 VACCINE

Storage temperature (Purple cap)	• Ultra-low temperatures: • -86 °C to -40 °C in freezer • At Health facility 2°C to 8°C for 31 days • After 31 days discard the vaccine
Storage temperature (Gray cap)	• Ultra-low temperatures: • -86 °C to -40 °C in freezer • At facility 2°C to 8°C for 10 weeks • After 10 weeks discard the vaccine
Diluent storage temperature	• Room temperature (up to 30 °C) at the national level and 2°C to 8°C in health facilities

Shelf life	• Before mixing, the vaccine may be stored in an ultra-cold freezer between -80°C and -60°C for 15 months after the time of manufacturing • Before mixing, the vaccine may be stored in the freezer between -25°C and -15°C for up to 2 weeks (For purple cap) • Vaccines stored in the freezer can be transferred to refrigerator storage where they can be stored for up to 1 month (31 days) for purple cap and 10 weeks for Tris (Gray cap). • Discard the vaccine if it is exposed to 30°C for more than 2 hours. • Diluted vaccine shall be discarded after 6 hours or at the end of the immunization session whichever comes first
Freeze sensitivity	• Do not refreeze thawed vials • Do not freeze diluted vaccine
Light sensitivity	• Minimize exposure to room light • Avoid exposure to direct sunlight and ultraviolet light
Condition before use	• For the purple cap, use one diluent vial for one vial and discard the extra diluent in the. Do not use one diluent for more than one vial of Pfizer vaccines
VVM	• No VVM

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.

3.3. Precautions and Recommendations for All EUL Vaccine Types

Vaccination settings and observation:

All persons should be vaccinated in healthcare settings where appropriate medical treatment is available in case of allergic reactions. An observation period of 15 to 30 minutes after vaccination should be ensured.

Reactogenicity:

When scheduling vaccination for occupational groups (e.g., health workers) consideration should be given to the reactogenicity profile of the vaccine observed in clinical trials, occasionally leading to time off work in the 24-48 hours following vaccination.

Co-administration with other vaccines

For adults, based on several co-administration studies of COVID-19 vaccines and inferred from co-administration studies of other adult vaccines, COVID-19 vaccines may be given concomitantly, or at any time before or after, other adult vaccines including live-attenuated, inactivated, adjuvanted, or non-adjuvanted vaccines. When administered concomitantly the vaccines should be injected in separate sites, preferably in different extremities. For children and adolescents, evidence from co-administration studies is currently insufficient to make a recommendation for concomitant administration with COVID-19 vaccines.

Vaccination of specific population

Persons aged 65 years and over

The risk of severe COVID-19 and death increases steeply with age. WHO recommends the vaccine for use in persons aged 65 years and older. Per the WHO Prioritization Roadmap, a booster dose is recommended for the highest and high priority-use groups such as older adults, administered 4–6 months after completion of the primary series.

Persons with comorbidities

Certain comorbidities and health states such as diabetes mellitus, cardiovascular and respiratory disease, neurodegenerative disease, and obesity have been identified as increasing the risk of severe COVID-19 disease and death. Data for vaccine effectiveness after 2 doses suggests a similar safety and effectiveness profile for persons with comorbidities. WHO recommends vaccination of persons with comorbidities. Per the WHO Prioritization Roadmap, a booster dose is recommended for the highest and high priority-use groups such as persons with comorbidities, administered 4–6 months after completion of the primary series.

Children and adolescents below 18 years of age

Children aged 6 months to 17 years with comorbidities that put them at higher risk of serious COVID-19 disease should be offered vaccination.

For healthy children and adolescents, COVID-19 is rarely lethal. Children can

experience significant morbidity but most infections are self-limiting, with only a small proportion requiring hospitalization. Currently WHO approved Pfizer and Moderna for children aged 6 months and above.

Pregnant women

Pregnant women with COVID-19 are at higher risk of developing severe disease, with increased risk of intensive care unit admission and invasive ventilation, compared to non-pregnant women of reproductive age. COVID-19 in pregnancy is also associated with an increased risk of preterm birth, and neonates requiring neonatal intensive care. It may also be associated with an increased risk of maternal mortality. Pregnant women who are older (aged ≥35 years), have a high body mass index or have existing comorbidity such as diabetes or hypertension are at particular risk of serious outcomes from COVID-19.

WHO has identified pregnant women as a priority-use group for COVID-19 vaccination, given their increased risk of severe outcomes. WHO recommends use of the COVID-19 vaccine in pregnant women when the benefits of vaccination to the pregnant woman outweigh the potential risks. To help pregnant women make this assessment, they should be provided with information about the risks of COVID-19 in pregnancy, the benefits of vaccination in the local epidemiologic context, and the current limitations of the safety data in pregnant women. WHO does not recommend pregnancy testing prior to vaccination. WHO does not recommend delaying pregnancy or terminating pregnancy because of vaccination.

Breast feeding women

WHO recommends the same use of the COVID-19 vaccine in breastfeeding and non- breastfeeding women. This is based on the following considerations: breastfeeding offers substantial health benefits to breastfeeding women and their breastfed children; vaccine effectiveness is expected to be similar in breastfeeding women as in non-breastfeeding individuals. Data are not available on the potential benefits or risks of the vaccine to breastfed children. WHO does not recommend discontinuing breastfeeding because of vaccination.

Moderately and severely immunocompromised persons, including persons living with HIV with CD4 cell count of <200 cells/µl.

Available data for WHO EUL COVID-19 vaccine products suggest that vaccine effectiveness and immunogenicity are lower in ICPs compared to persons without immunocompromising conditions. Emerging evidence suggests that an additional dose included in an extended primary series enhances immune responses in some ICPs.

Reactogenicity data of an additional (third) dose given to ICPs, where reported, have been like those observed for the standard primary series. Given the significant risk of severe COVID-19 for ICPs, if infected, WHO recommends an extended primary series including an additional (third) dose for ICPs and considers that the benefits of an additional (third) dose outweigh the risks based on available data, although additional safety monitoring is required.

Persons living with HIV who are stable on antiretroviral therapy

Persons living with HIV (PLWH) may be at higher risk of severe COVID-19. Available data on the administration of the vaccine is currently insufficient to allow assessment of vaccine efficacy or safety for PLWH who are not well controlled on therapy. In the interim, given that the vaccine is not a live virus, PLWH who are part of a group recommended for vaccination may be vaccinated. Information and, where possible, counselling about vaccine safety and efficacy profiles in ICPs

should be provided to inform the individual benefit-risk assessment. It is not necessary to test for HIV infection before vaccine administration.

Persons who have previously had SARS-CoV-2 infection

Vaccination should be offered regardless of a person's history of symptomatic or asymptomatic SARS-CoV-2 infection. Viral or serological testing for prior infection is not recommended for decision-making about vaccination. Data from the pooled analyses indicate that the vaccine is safe in people with evidence of prior SARS-CoV-2 infection. With the emergence of Omicron, reinfections after prior infection appear to be more common. Hybrid immunity is superior to immunity induced by a vaccine or infection alone. The optimal time interval between infection and vaccination is not yet known. Persons with laboratory-confirmed SARS-CoV-2 infection before primary series vaccination may choose to delay vaccination for 3 months. Persons with breakthrough infections following any dose could also consider delaying the next dose by 3 months. When more data on the duration of immunity after natural infection become available, the length of this time may be revised as well as the number of doses needed.

Persons with current acute COVID-19

Persons with acute PCR-confirmed COVID-19, including persons who are in-between doses, should not be vaccinated until after they have recovered from acute illness and the criteria for discontinuation of isolation have been met as per government advice. The optimal minimum interval between natural infection and vaccination is not yet known. An interval of 3 months could be considered.

Persons who previously received passive antibody therapy for COVID-19

In people who have previously received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, vaccination does not need to be delayed. Although some reduction in vaccine-induced antibody titers was observed in people who previously received antibody products, the clinical significance of this reduction is unknown, and the balance of benefits versus risks favours proceeding with vaccination even considering the possibility of diminished vaccine effectiveness in this situation.

Other considerations SARS-CoV-2 tests

Prior receipt of the vaccine will not affect the results of SARS-CoV-2 nucleic acid amplification or antigen tests for diagnosis of acute/current SARS-CoV-2 infection. However, it is important to note that currently available antibody tests for SARS-CoV-2 assess levels of IgM and/or IgG to the spike or the nucleocapsid protein. A positive nucleocapsid protein-based assay indicates prior infection, while a negative nucleocapsid protein-based assay is expected after vaccination (unless a natural infection has occurred). Antibody testing at an individual level is currently not recommended to assess immunity to COVID-19 following ChAdOx1-S [recombinant] vaccination.

Table 15: Summary of COVID-19 Vaccine Currently Used in Ethiopia

COVID-19 Vaccine Type	Target age group	Characteristics	Route	Formulation, Presentation	Dosage	Number of doses	Schedule	Handling procedures	Storage temperature	Shelf life
AstraZeneca	18 years and above	Recombinant	IM	Liquid, preservative free.	0.5ml	Two doses	First dose at the start	Freeze and light sensitive.	+2˚C to +8˚C	Unopened vials are kept at +2˚C to +8˚C until the expiry date.
				Multi-dose suspension.			Second dose after 8-12 weeks Booster does 6 months after completion of the primary series	The vaccine has no VVM.		Opened vials at +2˚C to +8˚C for six hours.
Sinopharm	18 years and above	Inactivated	IM	Liquid, adjuvanted.	0.5ml	Two doses	First dose at the start date	Freeze and light sensitive.	+2˚C to +8˚C	Unopened vials kept at +2 to +8 ˚C: 24 months or until the expiry date. Opened vials at +2˚C to +8˚C for six hours.
				Preservative- free suspension.			Second dose 3 to 4 weeks after the first dose Booster does 6 months after completion of the primary series	Mostly the vaccine has no VVM. Some batches may have VVM		
Janssen (J&J)	18 years and above	Recombinant	IM	Preservative- free	0.5ml	Single	Single Booster does 6 months after completion of the primary series	Light sensitive.	Frozen vaccine - in the original carton at -25 to -15 ˚	Frozen at -15 to -25 for 24 months
				Multi-dose suspension.				Never refreeze thawed vials.	If thawed store at +2 to +8 ˚C in the original carton	Thawed unopened at +2 to +8 ˚C for 11 months
								The vaccine has no VVM.		Opened at +2 to +8 ˚C for 6 hours

COVID-19 Vaccine Type	Target age group	Characteristics	Route	Formulation, Presentation	Dosage	Number of doses	Schedule	Handling procedures	Storage temperature	Shelf life
Pfizer	12 years and above	mRNA vaccine	IM	Frozen, sterile, Preservative- free, and multi-dose concentrate	0.3ml	Two doses	First dose at the start date Booster does 6 months after completion of the primary series	The vaccine has no VVM. Transport (2-8C) -Up to 12 hours (Purple Cap) and For Gray Cap no limit within 10 weeks	At -80 to -60 ˚C in freezer or 2˚C to 8˚C	Undiluted (Purple Cap) vaccine and Gray Cap (No Need of Dilution) at storage temperature -80 to -60 ˚C: 15 months
							The second dose is 3-4 weeks after the first dose			THAWED vaccine 31 days -For Purple Cap and 10 weeks for gray cap Opened at +2 to +8 ˚C, Purple cap for 6 hours and Gray Cap for 12 Hours

Table 16:Cold chain surge capacity options to manage COVID-19 vaccine

Storage temperature	Standard Procedure	Storage capacity is insufficient, consider:
+2 to +8 °C	■ Map all cold-chain storage points at this temperature range. ■ Conduct a gap analysis to determine cold-chain storage needs.	■ Procurement of solar direct drive (SDD), ice- lined refrigerators (ILRs) and/or cold boxes and vaccine carriers. ■ Leasing of a private facility. ■ Splitting shipments and increasing distribution frequency, and ■ Staggering campaigns.
- 25 to -15 °C	■ Map all cold-chain storage points at this temperature range leveraging all polio vaccine infrastructure. ■ Conduct a gap analysis to determine cold-chain storage needs.	■ Procurement of freezers, cold boxes, and vaccine carriers. ■ Leasing of a private facility. ■ Splitting shipments and increasing distribution frequency, and ■ Staggering campaigns.
-86 °C to -40°C	■ Most health workers are not familiar with managing vaccines at this temperature range. ■ Follow the recommended strategy for managing ultra-cold-chain equipment, including recommended coolant packs and the use of personal protective equipment (cryogenic gloves).	

Table 17: How to manage COVID-19 vaccine stored at +2 to +8 ºC?

General Principles for COVID-19 vaccine	What To do and not to do
Storage condition +2 to +8 ºC: 	**What TO do:** ■ Ensure all vaccines and diluents are kept in their original secondary packaging and are clearly labelled. ■ Whenever possible, keep both vaccine and diluent in the same refrigeration unit. ■ Monitor and record temperature more frequently (>2x/day). ■ Investigate any fluctuation in temperature and correct the root cause as soon as possible. ■ Use a labelled container or tray for loose unopened vaccine vials to facilitate inventory. ■ Follow the “first manufacture/expiry, first out” principle: ■ Use first the vaccine with an earlier manufacturing/expiry date and/or darker VVM (if available) to minimize wastage. ■ Record and discard all wastage of vaccines immediately according to national guidelines. ■ Review and update contingency plans in case of power failure, equipment breakdown, or cold chain breach.

General Principles for COVID-19 vaccine	What To do and not to do
Storage condition +2 to +8 °C: 	**What NOT to do:** ■ Do not return opened vaccine vials to the cold chain. Discard them according to existing standard operating procedures (SOPs). ■ Never put vaccines in contact with or close to the evaporator plate in the refrigerator. ■ Since heat/freeze sensitivity information is not fully known, keep vaccine vials in the middle section, especially if the refrigeration unit has a freezer compartment, to avoid freezing the vaccine. ■ Do not keep reconstituted vaccines for more than 6 hours after opening or after the end of an immunization session, whichever comes first – this may change once vaccine stability information is available.

Table 18: How to manage COVID-19 vaccine stored at -80 ºC?

General Principles for COVID-19 vaccine	What To do and not to do
Storage condition for UCC 	**What TO do:** In addition to general cold-chain management principles for +2 to +8ºC, when handling vaccines stored at UCC, it is also essential to: ■ Follow existing guidance specific to UCC management. ■ Use appropriate personal protective equipment (e.g., cryogenic gloves) for personnel in charge of managing UCC; and ■ Follow the guidance and apply best practices for managing and disposing of used phase-change material (PCM). All responsible personnel (supply chain/ cold-chain personnel, vaccination team and supervisors) should be trained and demonstrate the ability to manage UCC according to SOPs.
Storage condition for UCC 	**What NOT to do:** ■ Do not return opened vaccine vials to the cold chain. Discard them according to existing guidance. ■ Do not store laboratory specimens, drinks, food products, or expired health products with vaccines. ■ Do not keep vaccines with VVM that have reached the discard point. ■ Do not keep expired vaccines in the refrigerator.

Cold chain equipment requirement for COVID-19 Vaccines

The cold chain system is a means for storing and transporting vaccines in a potent state from the manufacturer of the vaccine to the person being immunized. Most COVID-19 vaccines do not have Vaccine Vial Monitor (VVM), hence; it is recommended that a temperature monitoring device must be in place to follow the viability of the vaccine. The cold chain and management system comprises three major elements:

- Personnel who use and maintain the equipment and provide the health service.
- Equipment for safe storage and transportation of vaccines.
- Procedures and information to manage the programs and control the distribution and use of vaccines.

The cold chain consists of a series of links that are designed to keep vaccines within WHO-recommended temperature ranges, from the point of manufacture to the point of administration. Ultra-cold chain (UCC) equipment is used for vaccines that are expected to be managed at the temperature of -80 ºC. The following types of Equipment/Supplies are needed for UCC.

Ultra-low Temperature Freezer (Gold Controller)[1]

✔Ultra-low temperature (ULT) Freezers are widely used in scientific research for long-term storage of samples. As ULT freezers are often operated at -80°C continuously for years, reliability is of paramount importance to the researchers.

✔Constructed from high-quality proven components with energy-efficient refrigeration design, Esco Lexicon® II ULT freezers provide top- notch protection that can withstand the test of time to guarantee the integrity of your samples. Superior performance, lower energy costs, and better protection.

1 http://www.escoglobal.com/product/cold-storage/lexicon-ii-ultra-low-temperature-freezer-gold- controller/uus-b/

UCC equipment is costly and not recommended to be installed in every facility.

- Establishing a UCC hub at the national and strategic sub-national level is a cost-effective approach.
- Utilizing available cold-chain or UCC facilities from private sectors with appropriate training and monitoring systems is a practical approach.

The use of long-term passive containers and thermal shippers to store vaccines and to conduct immunization sessions is favorable at the facility level.

UCC supplies/equipment recommended at the facility level:

- Cryogenic gloves
- Arktek + PCM
- Thermo shippers + dry ice
- Dry icebox + dry ice.

There are 2 types of Arktek passive vaccine storage device

1. Arktek passive vaccine storage device: a super-insulated container optimized to safely store vaccines between 0 to +10 ºC for 35 days or more, using only coolant packs in hot zone conditions.

2. Arktek + PCM: a modified version of the Arktek device that uses phase-change material rather than coolant packs to maintain a cold environment for up to 6 days.

Phase-change materials require special considerations: Phase-change materials (PCMs) are substances that improve thermal performance when applied to a cold-chain product by transitioning from solid to liquid or vice versa.

3.4. Demand Forecasting of COVID-19 Vaccine & Supplies

Calculating COVID-19 vaccine requirements

The current vaccine portfolio data shows, most of the vaccines in the pipeline are two doses per target within 4-12 weeks intervals. In vaccine forecasting, the vaccine wastage rate of 10% will be used to calculate the total amount of vaccines per target.

Vaccine wastage factor=100/ [100-vaccine wastage rate]

Example: For the COVID vaccine with a wastage rate of 10% the wastage factor will be,

Wastage factor=100/ [100-10] =1.11

This means that 1.11 times more vaccines should be ordered to cover the estimated 10% vaccine wastage

Example: 1 Calculating COVID-19 vaccine requirements

The current vaccine portfolio data shows, most of the vaccines on pipeline are two doses per target within 4-12 weeks interval. In vaccine forecasting, the vaccine wastage rate of 10% will be used to calculate the total amount of vaccine per target.

Vaccine wastage factor=100/ [100-vaccine wastage rate]

Example: For COVID vaccine with wastage rate of 10% the wastage factor will be,

Wastage factor=100/ [100-10] =1.11

Example: 1

To vaccinate the first 20% of the total population (112,078,730) in the initial phase, the total quantity of COVID 19 vaccines required with 10 dose vial presentation will be:

Target population: 20% X Total population (112,078,730) = 22,415,746

Vaccine requirement = 22,415,746 X 2doses X 1.11 = 49,762,956 doses

If a COVID vaccine supplied as 10 dose per vial, to get the number of vials of COVID 19 Vaccines required we divide the number of doses required by 10 using the formula:

Number of vials = Number of doses required/10 = 4,976,296 vials.

Calculating injection and safety devices

Most of the COVID-19 vaccines on the Pipeline are injectable and hence injection and safety devices must be quantified properly.

Auto-disable syringe & Mixing syringe requirements

Auto-disable syringes/needles and Mixing syringes needed shall be calculated considering an indicative wastage rate of 5% (WF: 1.05) and two syringes per target for AD syringes and one dilution syringe per vial.

Example: 2

AD syringe requirement: 22,415,746 X 2 AD syringes X 1.05 (5% WR) = 47,073,067

Mixing syringe requirement: # of COVID 19vaccine vials (4,976,296) X 1 mixing syringe X 1.05 (WR 5%) =5,225,110

Total number of Mixing syringe needed = 5,225,110 each

EXAMPLE: 3

Quantity of AD syringes = 47,073,067

Quantity of Mixing syringes = 5,225,110

Safety boxes required = [(47,073,067+ 5,225,110)/100] X 1.05 (5% WR) = 549,131

Safety boxes

- Safety boxes = 1 box for 100 Syringes
  = (AD+ mixing Syringes)/ 100 X 5% wastage rate.

Calculating PPEs

Using personal protective equipment (PPEs) is very important to protect against the spreading of the virus during the implementation of the COVID-19 vaccination. One or two surgical mask/s per day and one- litre alcohol-based hand rub for the entire SIA days will be provided for each vaccinator and supporting staff.

Adrenaline injection

It is imperative to expect adverse events following immunization (AEFIs) during COVID-19 vaccinations. Therefore, an adequate quantity of adrenaline shall be reserved at all vaccination sites. Each vaccination team must secure 5 ampoules of adrenaline injection during the implementation of the SIA.

Exercise

Adama City has a population of 3 million and plans to vaccinate 70 % of the population in the coming year. The current vaccine portfolio data shows, most of the vaccines in the pipeline are two doses per target within 4-12 weeks intervals and the estimated vaccine wastage rate is 10% and 5% for syringe and safety boxes.
Based on the given data: Calculate:
A. The total doses of COVID-19 Vaccine
B. Syringes
C. and safety boxes required to address the targets.

3.5. COVID-19 Vaccine Stock Management

One of the major aspects of the process of COVID vaccine deployment and vaccination plan is to manage vaccine stock and inventory with the release of the COVID-19 vaccine. It is critical and complex to manage vaccine stock properly. If the conditions are not up to the mark, vaccines can result to be ineffective jeopardizing public health measures and increasing health care costs. As healthcare organizations procure enough safe vaccines that are available for use, it is important to monitor their condition constantly.

A stock control system comprises three steps, each of which must be performed regularly, accurately, and completely. The three steps are:

- Checking and recording details of vaccine consignments when they arrive at a storage point.
- Checking details and conditions of vaccine stocks during the time they are kept in storage.
- Checking and recording details of vaccine consignments when they leave the storage point for distribution to regions, woredas, health facilities and eventually, the user.

- In addition, good warehousing practices should be adopted and physical stock counts.

Standardized recording and reporting of all stock transactions are carried out, during:

Arrival/Receiving:

- Accurately record incoming vaccines, diluents, and other consumables
- Submit VAR within 72 hours of receiving
- Put away vaccines to the designated storage condition, maintaining the required temperature condition

Dispatch:

- Establish a pre-delivery or pre-collection notification system as per the logistics micro plan developed.
- Issue vaccines, diluents, and other date- limited products in earliest-expiry first- out (EEFO) orders.
- If vaccine vial monitor (VVM) status indicates that some vaccine vials should be used ahead of their correct EEFO order, this may be done, but the reason for doing so should be recorded.
- When vaccines and consumables leave the store, verify the information in the stock record system for all items that are issued. Record any change in VVM status in the stock record system and transfer this information accurately to the vaccine delivery/arrival form.

Arrival at the next supply chain level: When vaccines and consumables arrive at the next supply chain level, check the delivery/arrival form, report any discrepancies, and report all indicator changes.

Good warehousing practices are in place.

- **Stock security:** keep all vaccines and consumables under secure conditions.
- **Data security:** keep all records secure.

Storage: store all vaccines, diluents and droppers and other consumables in an orderly fashion

- **Cleanliness:** Keep the vaccine store clean and free of pests.
- **Supervision:** ensure that all staff are effectively supervised.

COVID-19 vaccine wastage monitoring

The WHO reports over 50% of vaccine wastage around the world. Despite the availability of many tools to reduce vaccine wastage, countries still score high wastage rates. Vaccine wastage is expected in all programs; the question is whether any of the wastage is preventable and how to prevent it. Wastage in unopened vials is usually due to cold chain and stock management problems and can be minimized.

There are two types2 of vaccine wastage in immunization programmes:

•The remaining doses of vials opened thrown away after the immunization session, in line of multidose vial policy (MDVP),

•Unopened/closed vials discarded during storage, handling, and transportation of the vaccines due to temperature damage or expiry.

Table 19: Types Of Vaccine Wastage

Vaccine wastage in unopened vials	Vaccine wastage in opened vials
■ Expiry ■ VVM indication ■ Heat exposure ■ Freezing ■ Breakage ■ Missing inventory ■ Theft ■ Discarding unused vials returned from an outreach session	■ In addition to the types listed in the previous column: ■ Discarding remaining doses at end of the session ■ Not being able to draw the number of doses indicated on the label of a vial ■ Poor reconstitution practices ■ Submergence of opened vials in water ■ Suspected contamination ■ Patient reactions requiring more than one dose

Vaccine wastage calculations in storage facilities:

Vaccine wastage rate in vaccine stores always corresponds to a proportional, vaccine wastage rate in unopened vials is calculated as follows

$$\text{Wastage rate} = \frac{\text{Number of doses discarded} \times 100}{\text{Start balance} + \text{doses received}}$$

Opened vial vaccine wastage – Formula at Service delivery Point

$$\text{Wastage} = \frac{(\Sigma n \text{ Doses opened} - \Sigma n \text{ Doses administered})}{(\Sigma n \text{ Doses Opened})}$$

Doses administered----------Cumulative doses administered to the target population.

Doses opened----------Cumulative number of doses of the vaccine vials opened for vaccination

Wastage Factor

Knowing the wastage rate helps to determine the wastage factor, which is one of the parameters used to estimate vaccine needs.

The formula to calculate the wastage factor on the basis of wastage rates, is as follows

$$\text{Wastage factor} = \frac{100}{(100\text{-Wastage})}$$

Where: "100" is the total No (100%) of vaccine doses supplied

"Wasted rate" is the No of doses (in %) wasted

Example 4.

Wastage rate Calculation Exercise

Bole Health Centre received 3000 doses of the AstraZeneca vaccine in 10-dose vials and about 2,670 individuals were immunized 1st dose and about 1,950 individuals were immunized 2nd dose and 650 were immunized to a booster dose. There was a start balance of 2500 doses leftover from previous Covid 19 Campaigns. Currently, the AstraZeneca Physical count is 1100 doses.

A. Calculate the AZ Wastage rate

B. Calculate the Wastage Factor.

CAVEAT!

Given the COVID-19 pandemic context, some vaccines may not be prequalified at the time of the initial vaccine in-country delivery. They will be used under WHO's Emergency Use Listing (EUL) procedures. It is possible that some vaccine profile characteristics, such as the VVM type and expiration date, may not be established by the time they are labelled for use. Most vaccines may come with date of manufacture in lieu of the expiry date. Therefore, strict compliance with the standard protocols for storage, handling, supply distribution, transportation and logistics procedures and practices is critical throughout the deployment period.

3.6. Distribution and delivery of COVID-19 vaccines

Vaccine supply chain management is the backbone of a successful immunization program. Cold chain and logistics management ensure regular and smooth flow of vaccines and other cold storage requiring health commodities to all health facilities. Effective supply chain management is crucial to the successful deployment of COVID-19 vaccines. Based on the current information shared by the manufacturers, it is assumed that most vaccines will be stored at +2 °C to +8 °C, with the exceptions of a few vaccines which require ultra-cold chain (UCC) equipment (-70 °C), frozen Phase Change Material (PCM) or dry ice, instead of traditional cold packs during transport.

General considerations when transporting vaccines

- Plan the route of vaccine delivery and time to each destination to include time for checking temperature based on existing guidance.
- Assess potential risks to the delivery personnel and delay delivery for foreseeable reasons (e.g. weather conditions) and include risk mitigation strategy in the plan.
- Ensure availability of reliable transport and sufficient funds for fuel. A refrigerated vehicle equipped with a data logger is preferred; consider renting, if needed.
- Bundle supplies when delivering to ensure all logistics are available for vaccination.
- Ensure required documentation is duly prepared and available before departure.
- Never transport multi-dose vials that are opened. Discard open multi-dose vials.

Vaccine carriers (VC).

Table 20: Managing cold chain at the vaccination post

	Vaccine stored at +2 to +8 °C: vaccine carriers	Vaccine stored at -86 to -40 °C: thermal shippers
	Standard VC without a barrier separating the vaccine storage compartment from the conditioned ice packs.	■ Specific vaccine carriers requiring device ■ Temperature range: -86 to -40 °C ■ Capacity: 3.4 to 6.2 litres ■ With a vial rack system ■ Built-in temperature data logger
	Freeze-preventive VC with a barrier separating the vaccine storage compartment from the frozen icepacks.	 

Handling COVID-19 vaccine vials after opening:

- Always check for the latest information about the suitability of the vaccine to the multi-dose vial policy (MDVP).
- As a precaution to maintain vaccine safety and quality, the following are recommended until more information becomes available:
  - For opened vials, if possible, use a separate vaccine carrier with a temperature monitoring device to allow monitoring of temperature during use.
  - Reconstituted vaccines should be discarded 6 hours after opening or at the end of the immunization session, whichever comes first.
  - Do not use opened vials if the temperature in the vaccine carrier is found to exceed recommended range; discard vials and replace the coolant packs as needed.
  - Never expose opened vials to direct heat, light or sunlight.
  - Never transport or return opened multi-dose vials used in vaccination to the cold chain discard them.

NB: While delivering vaccines and their related consumable supplies, it is important to bundle the necessary printing materials for conducting COVID-19 immunization.

Distribution of COVID-19 Vaccines in Ethiopia

Currently, woreda health offices and health facilities throughout all regions, as well as the two city administrations, were getting routine immunization vaccines directly from EPSS. According to a distribution schedule shared by the ministry of health, the EPSS is delivering COVID-19 vaccines to woreda health offices along with the necessary dry supplies.

Reverse Logistics

Reverse logistics is the process of retrieving unused vaccines either to dispose of or re- use.

> Brainstorming
>
> What is reverse logistics? When would you use reverse logistics?

Reverse logistics is the process of retrieving unused vaccines either to dispose of or re- use.

Reasons to conduct reverse logistics:

- Need to relocate vaccines to higher- risk areas based on the latest epidemiological information.
- Return of unused vaccine to higher-level store at the end of the vaccination campaign
- During a temporary pause of the vaccination campaign for any reason

3.7. Management of waste associated with COVID-19 vaccination

Waste management is a very important activity during vaccinations that involves injectable vaccines and other supplies. The waste management plan for COVID-19 vaccination should be included in the micro plan. In each Woreda, there are Health Centers with disposal incinerators. These health centres will form the focus for waste disposal during the COVID-19 vaccination. Each COVID-19 vaccination post as part of the micro-plan should be linked to a health centre with an incinerator and at the end of each day of the vaccination, filled safety boxes will be sealed, collected, and transported for disposal in the incinerators.

Table 21: summary of healthcare waste management during COVID-19 vaccination.

Waste	Recommendation
Disposal of syringes 	■ Use auto-disable (AD) syringes and dispose of them as sharps waste. ■ Without recapping the needle, discard the used syringe into the safety box or safe syringe container. ■ Do not fill the safety box more than 3/4 of its capacity or up to the red line marked on the container. ■ Ensure the box is properly labelled with the infectious substances symbol. ■ Seal the safety box before transporting it to the treatment site

	
Disposal of vials  	■ Put used vaccine vials and unopened vaccine vials which have expired or suffered heat exposure into a red or yellow bag for infectious waste, or into a biohazard container. ■ Open vials posing a risk of cuts may be classified as sharps waste. ■ Ensure that bags/containers are properly labelled with the infectious substances symbol. ■ Seal the containers before transporting them to the treatment site
Disposal of PPE 	■ PPE includes single-use gloves, aprons and gowns, surgical masks, and face protectors in the form of glasses, goggles or face shields. Use a room/place away from the vaccination area to remove all used PPEs. Consult the national guidelines to follow special procedures for removing PPEs use and disposal. ■ After safely removing used PPEs, put them into a special waste container or bag for infectious waste (yellow or red). ■ Ensure that the bag/container is properly labelled with the infectious substances symbol. Seal the containers before transporting them to the treatment site.

Key considerations for used Phase change materials (PCM)

- PCM is held in plastic or metal containers and if the containers are intact, the PCM should not enter the environment.
- But plastic and metal will degrade over time and the ambient conditions of much cold-chain equipment (CCE) disposal locations (e.g., open-air landfills or other outdoor areas) will speed the degradation or facilitate puncturing of the container.

Therefore, PCM should ideally be drained for proper disposal at the end of their useful life.

SESSION IV

SURVEILLANCE OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

Session duration: 90 min

Section description: This section describes concepts on Adverse Events Following Immunization (AEFIs) monitoring for COVID-19 to enable the participants to acquire the necessary knowledge and skills to monitor and manage AEFIs.

Learning objectives

By the end of this session, the participants will be able to

- Define an Adverse Events Following Immunization
- Differentiate serious and minor AEFI
- Describe the five categories of AEFIs
- Explain how to prevent AEFI
- Detect, manage and report COVID 19 vaccines related AEFIs
- Explain the importance of COVID 19 vaccine safety monitoring and response

Training method and materials

- Interactive lecture
- Case study

Materials

- Computer
- LCD projector
- Flip chart
- Plaster
- Marker

Session evaluation

- Self-assessment
- Quiz

Session outline

- Definition and category of AEFI
- COVID-19 vaccine related AEFI
- Prevention and Management of AEFI
- AEFI surveillance, reporting, investigation, and communication.

Definition and categories of AEFI

Brainstroming

What is AEFI?

Do you think that AEFI is preventable?

Adverse event following immunization (AEFI); is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.

The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.

Reported adverse events can either be true Vaccine related AEFI i.e. resulting from the vaccine or immunization process or coincidental events that are not due to the vaccine or immunization process but are temporally associated with immunization.

AEFI can be categorized by its cause, seriousness, and frequency

1.Cause-specific vaccine reactions:	2.Vaccine reactions by seriousness	3.Frequency:
a) Vaccine product-related reaction b) Vaccine quality defect-related reaction c) Immunization error related d) Immunization anxiety related e) Coincidental event	a) Minor reactions; b) Serious reaction	a) Very common b) Common c) Uncommon d) Rare e) very rare

1. Cause-specific vaccine reactions:

Vaccine product-related reaction: This is an individual's reaction to the inherent properties of the vaccine, even when the vaccine has been prepared, handled, and administered correctly. The reaction may be due to an idiosyncratic immune mediated reaction (e.g., anaphylaxis, fever, or local reactions)

Vaccine quality defect-related reaction: This is due to a defect in a vaccine (or its administration device) that occurred during the manufacturing process. Immunization error-related reactions: Error of all processes that occur after a vaccine product has left the manufacturing/packaging site – i.e., handling, prescribing and administration of the vaccine Immunization error-related reactions are usually preventable, and they divert attention from the benefit of the immunization program. Some of them are described in Table 27.

Table 22: Immunization Error-related Reactions

Immunization error		Related reaction
Error in vaccine handling	Exposure to excess heat or cold because of inappropriate transport, storage or handling of the vaccine (and its diluents where applicable)	Systemic or local reactions due to changes in the physical nature of the vaccine, such as agglutination of aluminum-based excipients in freeze sensitive vaccines.
	Use of a product after the expiry date	Failure to protect because of loss of potency or no viability of an attenuated product.
Error in vaccine prescribing or non-adherence to recommendations for use	Failure to adhere to a contraindication	Anaphylaxis, wrong age, does etc. disseminated Tuberculosis in immune compromised person
	Failure to adhere to vaccine indications or prescription (dose or schedule)	Systemic and/or local reactions, neurological, muscular, vascular or bony injury due to incorrect injection site, equipment or technique.
Error in administration	Use of an incorrect diluent or injection of a product other than the intended vaccine	Failure to vaccinate due to incorrect diluent, reaction due to inherent properties of whatever was administered other than the intended vaccine or diluent.
	Incorrect sterile technique or inappropriate procedure with a multi-dose vial	wrong site (subcutaneous rather than intradermal injection infection due to contamination of the needle, vaccine etc.

Cluster of events associated with immunization. These clusters are usually linked to a particular provider or health facility, or even to single or multiple vials of vaccine that have been contaminated or inappropriately prepared. For instance, freezing vaccines during transport may lead to an increase in local reactions.

Immunization anxiety-related reactions:- Individuals and groups can become stressed and may react in anticipation to, and because of, any kind of injection.

- Fainting (vasovagal syncope or syncope) and syncopal hypoxic convulsion.
- Hyperventilation because of anxiety about the immunization leads to specific symptoms such as light-headedness, dizziness, tingling around the mouth and in the hands.
- Breath-holding and vomiting as a common symptom of anxiety.
- Children scream or run away to avoid the injection.
- Needle-phobia and Mass hysteria

Coincidental events:- An event may occur coincidentally with immunization and sometimes be falsely attributed to the vaccine i.e., a chance temporal association is falsely attributed to immunization. Such temporal associations are inevitable especially in a mass immunization campaign.

Table 23: summary on cause-specific categorization of aefi (who)

Cause-specific type of AEFI	Definition
Vaccine product-related reaction	An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product. **e.g. fever, anaphylaxis, TTS (thrombotic thrombocytopenic syndrome following adenovirus - vector based COVID 19 vaccines. etc.**
Vaccine quality defect-related reaction	An AEFI that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration device as provided by the manufacturer. **e.g., wild polio virus (**Insufficient inactivation of wild-type vaccine agent**), e.g., AE due to contamination of the vaccine during production**
Immunization error-related reaction	An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable. **e.g. infection during injection, TSS, cold abscess**
Immunization anxiety-related reaction	An AEFI arising from anxiety about immunization. **e.g., Fainting (vasovagal syncope or syncope), hyperventilation**
Coincidental event	An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety, but a temporal association with immunization exists. **e.g., sudden infant death syndrome, the appearance of severe COVID immediately after vaccination**

Self-assessment (matching)

AEFIs following COVID-19 vaccination (hypothetical)	LIKELY Causality CATEGORY
1. Sweating and palpitations in a HCW following Covid-19 vaccination	**A.** Vaccine product-related reaction (As per published literature)
2. Febrile seizure one day post AZ vaccination in a patient diagnosed with severe malaria.	**B.** Immunization anxiety-related reaction
3. Sudden onset of generalized purpura, petechiae and ecchymosis in a 45-year-old, Female accompanied by severe abdominal pain, elevated D-dimer levels. Death one week after vaccination.	**C.** Underlying or emerging condition(s), or condition(s) caused by exposure to something other than vaccines.

4.1. Vaccine reactions by seriousness and frequency

Most vaccine reactions are minor and subside on their own. Severe reactions are very rare and in general do not result in death or long-term disability.

Table 24: Frequency of Occurrence of Reported Adverse Reactions

Frequency category	Frequency in rate	Frequency in %
Very common	≥ 1/10	≥ 10%
Common (frequent)	≥ 1/100 and < 1/10	≥ 1% and < 10%
Uncommon (infrequent)	≥ 1/1000 and < 1/100	≥ 0.1% and < 1%
Rare	≥1/10,000 and <1/1000	≥ 0.01% and < 0.1%
Very rare	< 1/10,000	< 0.01%

Common, minor vaccine reactions: They are caused when the recipient's immune system reacts to antigens or the vaccine's components (e.g., aluminum adjuvant, stabilizers, or preservatives) contained in the vaccine. Most AEFI are minor and settle on their own. Minor AEFIs could be local or systemic.

Local reactions include pain, swelling and redness at the injection site. Systemic reactions include fever, irritability, and malaise. A successful vaccine reduces these reactions to a minimum while producing the best possible immunity.

Rare, more severe (and serious) vaccine reactions: They are caused by the body's reaction to a particular component in a vaccine. The term "severe" is used to describe the intensity of a specific event (as in mild, moderate, or severe); the event itself, however, may be of relatively minor medical significance.

Severe AEFI can be disabling but is rarely life threatening. Some examples are seizures, thrombocytopenia, Hypotonic Hypo Responsive Episodes (HHE), prolonged crying etc.

Severe AEFIs is a term including serious reactions but also including other severe reactions. Severe AEFI is considered **Serious** if they:

- Result in death
- Are life-threatening
- Require in-patient hospitalization or prolongation of existing hospitalization
- Result in persistent or significant disability/incapacity
- Result in a congenital anomaly/birth defect

4.2. COVID-19 vaccine related AEFI

Known minor AEFIs from COVID-19 vaccines of different platforms are like other injectable vaccines and include injection site pain, headache, fatigue, and muscle pain.

Other minor AEFIs include fever, chills, nausea, arthralgia (pain in a joint).

There are reports of differences in severity of reactions related to the vaccine. Some vaccines have more reaction after the first dose but less during the second dose (AstraZeneca more after the first dose and Pfizer more during after the second dose).

There are only a few serious safety concerns that have been reported to date, further in-depth analysis is ongoing to see the casual relationship with COVID-19 vaccines.

General precaution/contraindication for any vaccine is possible allergic reaction, including anaphylaxis to a vaccine component

Be advised to look at and familiarize yourself with specific AEFIs for each vaccine types

Table 25: Common AEFIs of each COVID 19 vaccine identified during clinical and after vaccine rollout

Moderna	Pfizer	AstraZeneca	Janssen
Injection site pain (92%) Fatigue (70%) Headache (65%) Myalgia (62%) Arthralgia (46%) Chills (46%) Injection site pain (92%) Fatigue (70%) Headache (65%) Myalgia (62%) Nausea/vomiting (23%), Axillary swelling/tenderness (19.8%) Fever (15.5%) Injection site swelling (14.7%) Redness (10%)	Tiredness (>60%) Headache (> 50%) Muscle aches (> 30%) Chills (> 30%) Tiredness (>60%) Headache (> 50%) Muscle aches (> 30%) Chills (> 30%) Joint pain (> 20%) Raised temperature (> 10%)	Headache and tiredness (>50%) Muscle aches and malaise (>40%) Raised temperature and chills (>30%) Joint pain and nausea (>20%) Headache and tiredness (>50%)	**Clinical trial** Injection site pain 48.6% Headache 38.9% fatigue 38.2% Myalgia 33.2% Nausea 14.2% **Post authorization use** ■ Anaphylaxis ■ Thrombosis with thrombocytopenia syndrome (TTS) ■ Guillain barre syndrome(GBS) ■ Capillary leak syndrome.

All mild, moderate, severe, and serious adverse events must be reported, follow the required steps to report immediately to higher level

It is absolutely contraindicated to give a vaccine for a person with history of anaphylaxis to any component of the vaccine or following the first dose of the same vaccine.

Note: ALL COVID-19 Vaccine related AEFI should be reported and all serious AEFI should be investigated, and causality should be assessed.

4.3. PREVENTION and management of AEFI

Brainstorming

How to prevent and manage AEFI?

General principles of prevention and management of AEFIs

Do not store and/or pack other diluents or medications together with the COVID-19 vaccine.

Always check the labels of vaccines and diluents before reconstitution – vaccines and diluents should be from the same manufacturer.

Follow manufacturer's recommendations on storage, vaccine preparation, route and technique of administration, and contraindications and precautions.

Draw the auto-disable (AD) syringe just before vaccination.

Do not touch the needle.

Do not touch the rubber cap of the vaccine vial.

If reconstituted, never carry vaccines from one place to another.

Do not cover the vaccine carrier with the lid while the reconstituted vaccine vial is in the foam pad.

Discard the vaccine if it was reconstituted before the maximum recommended time

or atthe end of the session, whichever comes first.

When in doubt, contact your supervisor for clarification. Do not hesitate to report issues or concerns when identified.

Prevention and management of immunization error-related reactions

Immunization error-related reactions are preventable and identification and correction of these errors in a timely manner are important.

For instance, children immunized with contaminated vaccine (usually the bacterium Staphylococcus aureus) become sick within a few hours with an injection site reaction (local tenderness, redness and swelling) and then develop systemic symptoms (vomiting, diarrhea, high temperature, rigors, and circulatory collapse).

To avoid/minimize immunization error, the following should be observed.

- It is both important and necessary to maintain the cold chain at all levels.
- Vaccines must be reconstituted only with the diluents supplied by the manufacturer.
- Reconstituted vaccines should be maintained in the recommended cold chain and used within six hours after reconstitution; it must be discarded at the end of each immunization session and should never be retained.
- Other than vaccines, no other drugs or substances should be stored in the refrigerator of the immunization center.
- Immunization workers must be adequately trained and closely supervised to ensure that proper procedures are followed.
- Careful epidemiological investigation of an AEFI is needed to pinpoint the cause and to correct immunization practices.
- Prior to immunization, adequate attention must be given to contraindications.

Fainting (syncope)

Patients are at risk for falls due to syncope during and after vaccine administration, which can result in serious injury. Know that the signs someone has before fainting pale complexion, weak, dizzy, and/or sweating.

To decrease this risk, have a place for patients to sit down while they are vaccinated and be ready to lower them to a lying position, if needed. Vaccinators are encouraged to observe the vaccinated person (sitting or lying down) for:

- 30 minutes in people with a history of a severe allergic reaction (anaphylaxis) due to any cause.
- 15 minutes for all other people to monitor for any immediate adverse reactions.

Allergic reaction (anaphylaxis)

Table 26: DISTINGUISHING ACUTE STRESS RESPONSE AND ANAPHYLAXIS

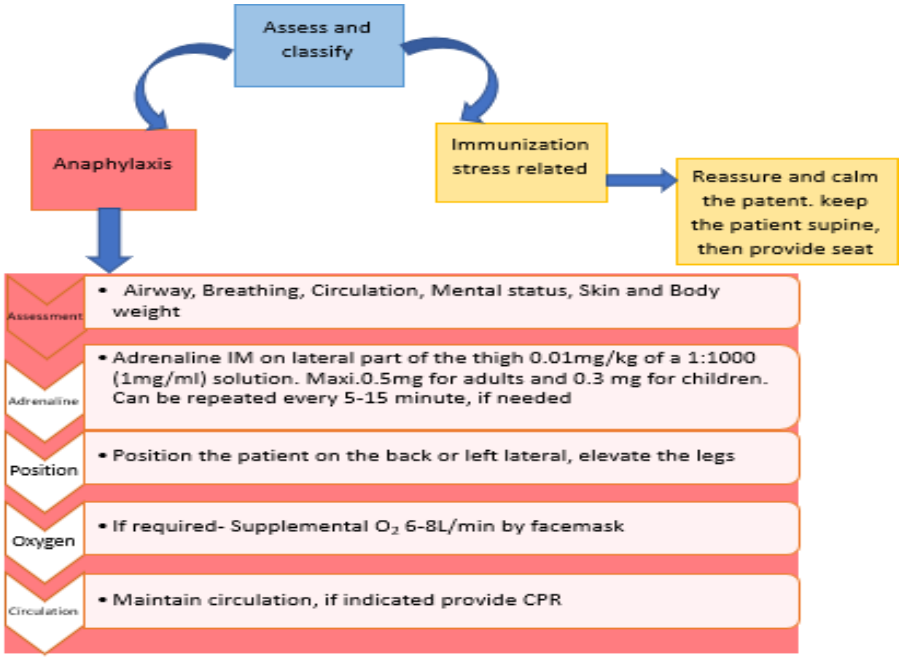
	Acute stress response (vasovagal syncope - VVS)	Anaphylaxis
At onset	VVS and General: Occurs suddenly, before, at time of or soon after injection	Seconds to minutes after exposure, almost all cases within 1 hour
Skin	VVS and General: Pale, cold, sweaty/clammy	Red, raised itchy rash, swollen eyes and face, generalized rash
Respiratory	VVS: normal to deep breaths General: rapid deep breathing	Noisy breathing, wheeze or stridor, persistent cough
Heart	VVS: slow pulse, transient hypotension General: normal or fast pulse or hypertension	Fast pulse, hypotension
Gastrointestinal	VVS: nausea, vomiting General: nausea	Abdominal cramps, vomiting, nausea
Neurologic	VVS: transient loss of consciousness reversed by supine position General: fearfulness, dizziness, numbness, weakness, tingling around lips, spasms in hands and feet.	May develop loss of consciousness not relieved by supine position

Table 27: Treatment of Anaphylaxis (who recommended)

Drug, site and route of administration	Frequency of administration	Dose
Adrenaline (epinephrine) 1:1000, immediate intramuscular injection to the midpoint of anterolateral aspect of the middle third of the thigh	Repeat every 5-15 minutes as needed until there is resolution of the anaphylaxis. Note: Persisting or worsening cough associated with pulmonary edema is an important sign of adrenaline overdose and toxicity.	According to age Children: 0.01mg/kg Adults: 0.2 mL to maximum of 0.5 mL

Steps of anaphylaxis management

- Quick assessment of the patient's Airway, Breathing, Circulation, Mental status, Skin and Body weight/kg (if possible)
- Call for help: resuscitation team hospital or emergency service team or even colleagues
- Epinephrine (Adrenaline)
- Position the patient
- Maintain oxygenation
- Maintain circulation
- CPR
- Monitor the patient blood pressure, heart rate, respiratory rate, level of consciousness
- The patient should be referred to hospital immediately after possible resuscitation
- Algorithm to manage AEFIs anaphylaxis and immunization stress related syncope



4.4. AEFI surveillance, reporting, investigation and communication

AEFI surveillance

Surveillance for adverse events following immunization (AEFI) is an integral part of the National Pharmacovigilance Activities and reinforces the safe use of all vaccines in the country while also helping to maintain public confidence in its immunization program.

It is the systematic data collection, reporting, analysis, and interpretation of AEFI data for action. AEFI surveillance can be active and passive surveillance types.

Passive surveillance is unsolicited reports of adverse events that are sent to the woreda, Zone, Region and national EFDA database that will then be shared to the global database.

Whereas active surveillance is primarily used for characterization of the AEFI profile, rates, and risk factors, but logistical and resource constraints limit its wide application.

Countries may carry out active AEFI surveillance only for selected AEFI at selected institutions (sentinel sites). Active surveillance can also be carried out in the community setting (e.g., cohort event monitoring). Additional approaches like the cohort event monitoring (CEM) and AESI sentinel surveillance will be continuing.

Objectives of AEFI surveillance

- Identify problems with vaccine lots or brands leading to vaccine reactions caused by the inherent properties of a vaccine
- Detect, correct, and prevent immunization errors caused by errors in vaccine preparation, handling, storage, or administration
- Prevent incorrect impression of association arising from coincidental adverse events following immunization, which may have a known or unknown cause but unrelated to the immunization
- Reduce the incidence of Injection Reactions caused by anxiety or pain associated with immunization, by educating and reassuring individual vaccines, parents/guardians, and the public about vaccine safety
- Estimate rates of occurrence of AEFIs in the local population compared with trial and international data, particularly for new vaccines that are being introduced.

AEFI surveillance cycle The AEFI surveillance cycle outlines the different steps in identification (detection), notification, reporting, investigation, data analysis, causality assessment and feedback following all AEFI including AEFIS, following COVID-19 immunization.

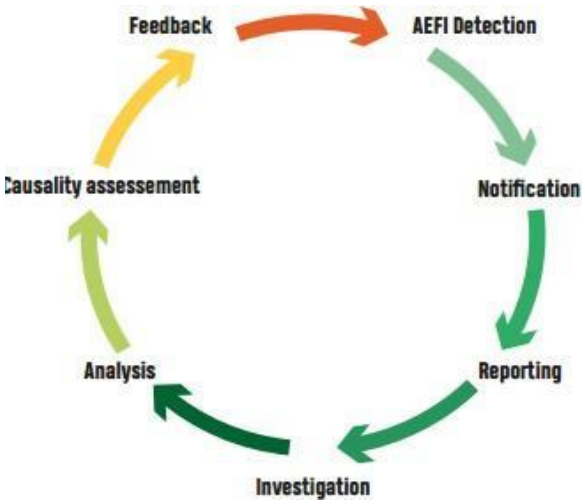


Figure 7: AEFI Surveillance cycle

AEFI detection, Notification, and reporting

The vaccine recipients, parents of immunized infants and children or vaccine administrators, may detect EFIs.

At the time of immunization, it is important for health workers to sensitize the parents and vaccine receipts about expected events such as fever and pain at injection sites and should be informed about what to report and when to seek health care service.

All vaccine AEFIs cases including AEFI following COVID-19 immunization and brought to the notice of the health care worker or detected by the worker should be reported to the Woreda Immunization Officer using the standard COVID 19 AEFI reporting form (Annex xxx).

Healthcare professionals should report all AEFIs that are brought to their notice regardless of its seriousness since COVID 19 vaccines are new and there is no rigorous safety information. In case of serious AEFI, inform your supervisor and/or Woreda immunization officer immediately (over telephone) and complete the reporting form **within 24 hours.**

The woreda immunization officer should review the report sent to the Zonal or regional immunization officer through e-mail or fax immediately and the Zonal or regional immunization officer should send the reports to EFDA.

Note: All serious AEFIs should be investigated and a completed AEFI investigation form (Annex 4.14) routed to the national level. The details of each case should be included in the woreda and regional AEFI line list (Annex 4.13).

Reporting Tools

1. Paper Based reporting format
2. Electronics -reporting system (Go to EFDA website www.efmhaca.gov.et)

The following AEFIs should be reported immediately to EFDA

- Serious AEFIs in vaccinated patients
- The occurrence of events with an unexpected high rate or unusual severity.
- Signals generated because of individual or clustered cases.
- Significant events of unexplained cause,
- Events causing significant parental, family, or community concerns.
- Adverse Events of Special Interest (AESIs) which are listed in (Annex 1)

Weekly reporting: this includes reporting of non-serious AEFI cases of all vaccines this information is collected and compiled by AEFI focal persons using the line list reporting formats; the non-serious cases include Pain, Pruritus/Itching. , Fever, Redness, Headache
,Myalgia etc

The woreda will prepare and compile the AEFIs reported during one week from the health facilities and will share to the zone and the zone similarly compile the woreda report and share to the region using the AEFI Surveillance line listing form (Annex-)

If there are not any side effects observed in the week, the report shall be submitted as zero.

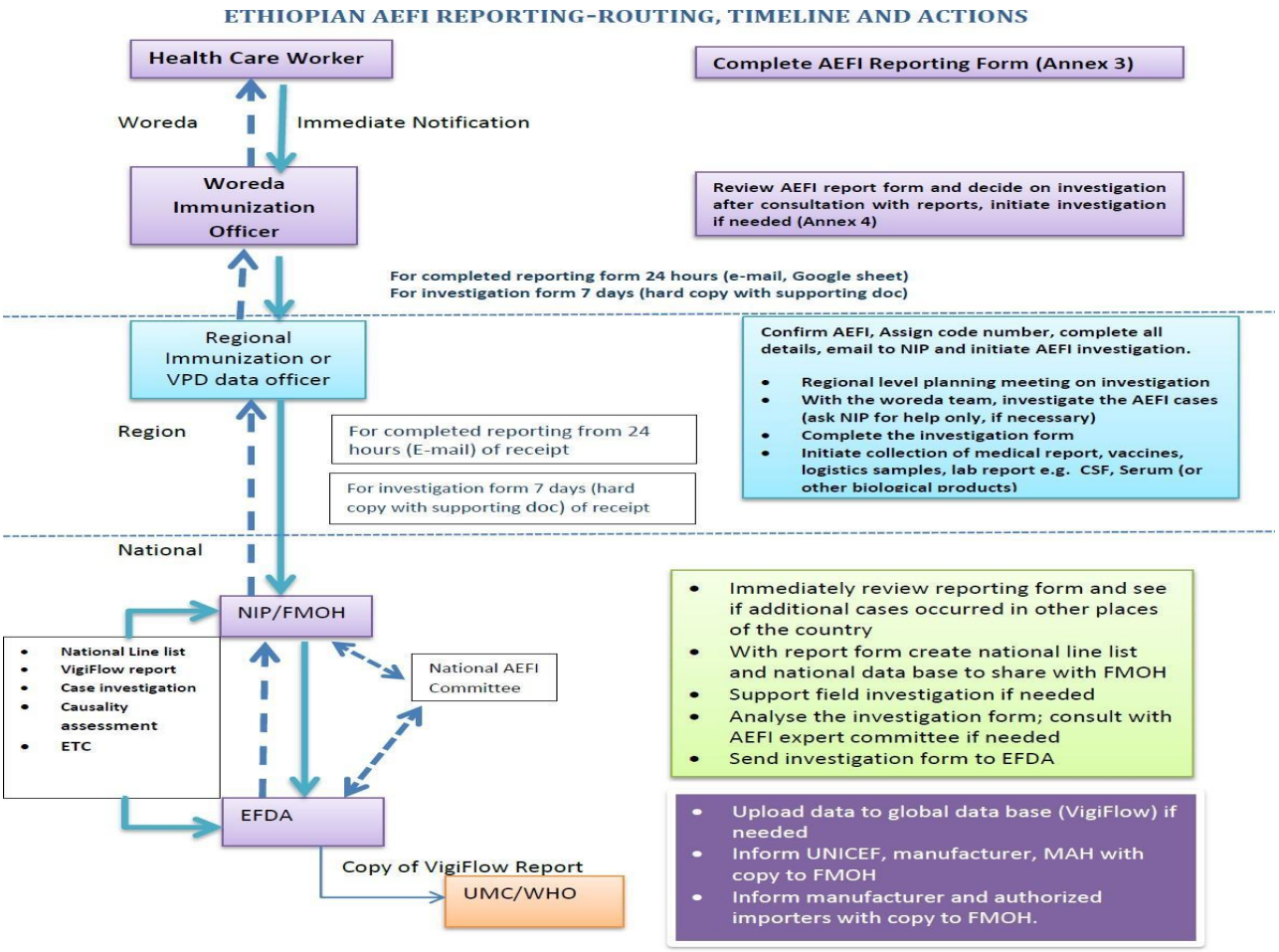


Figure 8: ETHIOPIA AEFI REPORTING AND FEEDBACK SYSTEM

Barriers of reporting AEFI

- Immunization service providers may not report AEFI for a number of reasons, such as;
- Considering that the event did not occur after immunization (however, all events
- following immunization as per the definition should be reported)
- Lack of knowledge about the reporting system and process
- Apathy, procrastination, lack of interest or time, inability to find the reporting form;
- Fear that the report will lead to personal consequences
- Guilt about having caused harm and being held responsible for the event and
- Diffidence about reporting an event when not confident about the diagnosis.

AEFI Investigation, Causality Assessment, and document sharing

Objectives of investigating AEFI are:

- To confirm diagnosis of a reported AEFI and determine the outcome(s)
- To investigate the link between the vaccine administered and the AEFI
- To determine the contribution of the operational aspects of the program to the reported AEFI

- To determine whether a reported event was isolated or part of a cluster
- To determine cause(s) of the AEFI to provide the best intervention/medical care and take any further action deemed necessary
- To determine whether un-immunized persons are experiencing the same medical event(s)

Not all AEFI reports need investigation. Once the report has been received, an assessment should be made to determine whether an investigation is needed.

The reported AEFI must be investigated if:

- It is serious
- It is part of a cluster
- It involves an increased number or rates of known cause
- Is a previously unrecognized event associated with an old or newly introduced vaccine
- It is a suspected immunization error
- It causes significant parental or public concern

Causality assessment is the systematic review and evaluation of available data about an AEFI to determine the likelihood of a causal association between the event(s) and the vaccine received.

The causality assessment of serious cases needs high levels of expertise and will be done by the National AEFI committee only.

The most important thing in causality assessment is the action that is going to be taken after the outcome of causality assessment.

Findings should be promptly and clearly communicated, and the messages should be clear on any next steps to be taken, including communicating reassurance or the need to act around the program including training, research, modifying systems, refining tools and recall of the vaccine to avoid and/or minimize recurrences.

The community also needs to be communicated about the issue and to address their concerns..

Data sharing and analysis

AEFI data (regularly) collected from HF on hard copy of Surveillance Report by HF staff should be shared to woreda.

Woreda directs the hard copy of serious cases to zone; zone to region and region to EFDA, EFDA will initiate investigation either from the center or through regional AEFI committee.

Non-serious cases will be line listed and shared (hard copy or excel or by other possible means)

All cases in the database will be kept by EFDA to share to WHO and conduct Data Analysis at the National level.

Documentation

1. Cases reporting form for all cases

3. Cases investigation form for cases that require investigation

3. Checklist to summarize the findings of the investigation of the case, algorism for decision of the causality and classification table should be filled for each investigated case.

4. The line list expected to be reported weekly for all cases (serious or non-serious) should be entered in the prepared data base for regular analysis interpretation and signal detection for action

Case study

Time: 5 minutes	A 30 years old female from Jimma town took the Janssen C-19 vaccine (First dose) around 10:00 in the morning. after 20 minutes of vaccination, she started to manifest wheezing, shortness of breath, uvular swelling along with tachycardia (PR=122 beats/min) and hypotension (Blood pressure of 80/50mmHg), epigastric pain, high-grade fever, headache, myalgia, chest pain, itching, cramping type of abdominal pain and rash starting from lower extremities which progressively involve all over the body. Based on the case; 5. What should be the clinical impression from this case? 5. Please write down the equipment/medicines you need to manage this client. 5. Once you stabilize this client, to whom do you report? 5. What important variables must be reported? which ones are already mentioned in the case study? 5. Please use a reporting format and fill it out.

Summary

- AEFI is any untoward medical occurrence that follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.
- AEFI can be categorized based on cause, and severity/ frequency
- There are 5 categories of AEFI as product defect , quality defect, immunization anxiety-related , immunization error related and coincidental,
  - Serious adverse events are AEFIs results in death, disability, hospitalization of patients or prolongation of hospitalization, congenital anomalies/birth defects.
- ALL COVID 19 vaccine related AEFI should be reported but all serious AEFI should be investigated, and the causality assessed.
- Vaccine safety monitoring is a shared responsibility between the NIP, NRA, VPD surveillance and other partners, and every partner would work together.

SESSION V

DEMAND GENERATION/PROMOTION FOR COVID-19 VACCINE

Course Duration: 150 min

Section description: This section aims to describe the effective communication methods, demand promotion strategies and approaches, and Risk and Crisis communication for successful COVID-19 vaccine implementation.

Learning objectives

By the end of the session, the participants will be able to:

- Describe the importance of communication for COVID-19 vaccine implementation,
- Describe and identify COVID -19 vaccine demand promotion strategies and approaches
- Identify target audience for advocacy, Social mobilization and community mobilization and risk / crisis communication for COVID -19 vaccine implementation,
- Build skills of HCWs and social mobilizers to effectively communicate with community members and stakeholders about the COVID-19 vaccination
- Promote the acceptance of COVID-19 vaccines and other routine immunization among the communities.

Training methods and Materials

- Training Methods
- Presentation
- Role Play
- Training Materials
- Training manual
- Audio-Visuals
- Posters

5.1. Basics of Communication and Demand Promotion

What is Communication?

Communication is described as - a process of transmitting and receiving idea, information and experience on a particular topic between two or more people that share the same code (verbal and non-verbal) aimed at reaching a mutual understanding.

Communication is one of the major components of COVID 19 Vaccination program.

Principles of effective communication

Principles of effective communication contains seven C's of effective communication

i. Completeness-The communication must be complete. It should convey all facts required by the audience.

- It is cost saving, gives additional information wherever required. It leaves no questions in the mind of receiver.
- Helps in better decision-making by the audience/readers/receivers of message as they get all desired and crucial information.
- It encourages the audience.

ii. Conciseness- is communicating what you want to convey in least possible words.

- It underlines and highlights the main message as it avoids using excessive and needless words.
- Concise message is more attractive and clear to the audience.

iii. Consideration- Consideration implies "stepping into the shoes of others". Effective communication must take the audience into consideration, i.e., the audience's view points, background, mind-set, education level, etc.

iv. Clarity- Clarity implies emphasizing on a specific message or goal at a time, rather than trying to achieve too much at once. Clarity in communication has following features:

- It makes understanding easier.
- Clear message makes use of exact, appropriate and concrete words.

v. Concreteness- Concrete communication implies being particular and clear rather than vague and general. Concreteness strengthens the confidence. Concrete message has following features:

- It is supported with specific facts and figures.
- It makes use of words that are clear and that build standing of audience..

vi. Courtesy- Courtesy in message implies the message should show the sender's expression as well as should respect the receiver.

- Courtesy implies taking into consideration both viewpoints as well as feelings of the receiver of the message.
- Courteous message is positive and focused at the audience.
- It makes use of terms showing respect for the receiver of message.
- It is not at all biased.

viii. Correctness- Correctness in communication implies that there are no grammatical errors in communication. Correct communication has following features:

Effective communication contributes to

- Increase knowledge and awareness of health care providers to disseminate appropriate messages on COVID-19 vaccines
- Build the confidence of healthcare workers to address rumors, misconceptions, and misinformation on COVID-19 vaccine

- Improve interpersonal communication skills of healthcare workers to facilitate discussions and provide counselling services to increase the uptake of COVID -19 vaccines
- Support communities to identify and report AEFIs

5.2. Communication Gaps on COVID-19 vaccines

Different reports indicate several COVID-19 vaccine communication gaps, among which the following are the major ones: -

- Poor interpersonal communication between health service provider and target population,
- Poor utilization of traditional, clan, religious and Kebele leaders for COVID -19 vaccine promotion
- Lack of knowledge of communities on adverse events following immunization
- Less use of mixed communication approaches (Channels)
- Lack of appropriate and timely action for circulating rumors, misconceptions and misinformation.

5.3. Demand Generation / Promotion Strategies

Communication encompasses the major communication strategies, namely Advocacy, Social Mobilization and Program Communication.

Advocacy, social mobilization, community engagement, and program communication play an important role in generating demand, building confidence and trust in COVID -19 vaccines.

Advocacy

Advocacy is one of COVID-19 vaccine communication strategies used to gain the support of stakeholders, community leaders and local politicians. It also helps to encourage community acceptance of and commitment to promote COVID -19 vaccines.

The advocacy can be done through:

- Advocacy meetings at different levels- woreda, kebele or facility level meetings (local politicians, kebele admins, etc.)
- Engaging influencers and role models (religious leaders, clan leaders, community leaders, women association, Youth association, etc…).
- Organize and conduct launching ceremonies at different levels.

Contextualized advocacy and communication plan should be developed to deliver tailored messages on COVID-19 disease, COVID-19 vaccine, vaccine safety to different intended audiences in geographically and socially hard to reach areas. Advocacy session with key stakeholders in conflict-affected areas and IDP camps can be organized to reach the unreached segment of communities on COVID -19 vaccines.

Social and Community Mobilization

Social and community mobilization is one of the main demand promotion strategies by engaging different stakeholders.

Social mobilization is a process of gaining and sustaining the involvement of stakeholders (GOs, NGOs, etc.) at societal level whereas community mobilization is gaining the involvement of everyone in the community for an action towards a particular goal.

Social and community mobilization includes local government leaders, regional and local media agencies, local non-government organizations, faith-based organizations, civil societies, private sectors, community-based organizations, professional associations, religious and clan leaders, and community leaders. This approach should be continuous to win their support and sustained engagement in the COVID-19 vaccine demand creation. This can be done through:

- Community dialogue or discussion
- Community engagement/empowerment (involve the community during planning, implementation and monitoring and evaluation).
- Dissemination of communication materials and messages
- Resource mobilization
- Mobilize local volunteers from organizations such as community and faith-based organizations to catalyze reaching every community, including communities from geographically or socially hard-to-reach areas to promote COVID-19 vaccines.

Program Communication

Program communication is a research-based consultative process of addressing knowledge, attitude, and practices through identifying, analyzing, and segmenting audience and participating in program and by providing them with relevant information and motivation through well-defined strategies, using an appropriate mix of interpersonal, group and mass –media channels, including participatory method.

The following are the key program communication activities to be conducted to properly respond to some of the major gaps of COVID-19 vaccine communication.

- Develop communication activity plan
- Conduct Kebele level focused Group Discussion with HDAs
- Conduct group education on COVID-19 vaccines
- Conduct interpersonal communication during COVID 19 vaccine sessions

Summary of COVID-19 vaccine communication strategies, target, objective and activities

Communication strategies	Targets	Objectives	Activities
Advocacy	Leaders at all levels, partners, religious and Clan/ community leaders, School head, Women Development groups	To gain local political will and commitment.	One to one meeting, Group Sensitization meeting, Lobby with local leaders.

Communication strategies	Targets	Objectives	Activities
Social mobilization	Kebele administration, religious institutions (mosques and churches), NGOs, Community members, traditional leaders, students and teachers, Women Development Agents	To build community participation and support To improve COVID 19 vaccine utilization To build trust of communities on COVID -19 vaccines immunization services To mobilize resources for immunization services	Sensitization onCOVID-19 Vaccines Message dissemination, Conduct community dialogue Community mobilization for COVID -19 vaccine promotion .
Program communication	Parents, Caretakers.	To improve their knowledge, attitude and practices on COVID-19 vaccines To improve demand for COVID-19 vaccines To complete the child full immunization schedule timely	Conduct Kebele focused Focus Group Discussion through HDA Facilitate immunization messages dissemination through different channels Conduct group education on COVID-19 vaccines Conduct interpersonal communication during COVID 19 vaccine sessions

Demand Generation Approach

To achieve high acceptance and uptake on COVID -19 vaccines, the below listed major demand generation approaches will be implemented:-

1. **Interpersonal Communication:** is face-to-face verbal or non-verbal exchange of information and feelings between two or more people. Each time a service provider has contact with a client, IPC is taking place.

   Having IPC for immunization technics /skill is crucial for health care workers where, professionals be able to convince educate their client , technics to follow IPC to be effective is active listening skill ,negotiation skill, storytelling skill , speaking skill, presentation skill, and conflict regulation skill.

Key Elements of Effective IPC

There are three main types of communication interactions that occur within a provider- client relationship. They are:

i. **Caring:** The goal is to establish and maintain a positive rapport with the patient

ii. **Problem solving:** The goal is for the patient and provider to share all necessary information for accurate diagnoses and appropriate treatment.

iii. **Counseling:** The goal is for clients to understand their condition and adhere to their treatment While they occur throughout an interaction, these types of communication often happen sequentially, with caring communication to establish a positive tone, problem solving to diagnose, and finally counseling to provide relevant health education. To communicate effectively through these different interactions, it can help to keep in mind some key elements of effective IPC. These are:

- Using verbal communication effectively
- Providing opportunities for patients to speak about their illness
- Fostering two-way dialogue
- Bridging of social distance
- Building partnerships with clients
- Creating a caring atmosphere

Case Scenario

Shitu is a 13 years old girl, a grade 5 student at one of the rural Primary school in the Kachabira woreda. The school sent consent letter to her families about vaccinating her for Covid-19. Both her mother and father were vaccinated for Covid-19 but they are worried about giving the vaccine to her daughter in this age. Shitu, brought her mother to her primary school to discuss about Covid-19 vaccination with the Health worker and after thorough dialogue the family agreed and shitu vaccinated for Covid-19.

HCW: I have been checking for all students, whose age is 12 years and above, whether they have been vaccinated against Covid-19?

HEW: Shitu, have you been vaccinated yet?

Shitu: No.

Mother: No, she hasn't. I got vaccinated and was fine. But I am worried about giving it to Shitu, because she is still growing.

HEW: I see. Could you tell me more about your concerns?

Mother: I am just unsure about giving it to children. Shitu is smaller than I am. I also held that it is has side effects.

HEW: I completely understand your concern. The good news is that Covid-19 vaccines are

safe and effective. All vaccines have some mild side effects, which may goes in few hours.

Currently millions of Ethiopian have already been vaccinated this is proof that the vaccine is safe and effective. The vaccines have been used under the most intensive safety monitoring and have been found to be safe and effective in adolescents as well.

Fortunately, there is no evidence that, any vaccine, including Covid-19 vaccines, cause fertility problems. And like all vaccines, scientists are studying covid-19 vaccines carefully for side effects.**Mother**: Ok, that is good now. Those were my biggest concerns. I am beginning to feel better now.

HEW: Shitu, What do you think? Do you want to get vaccinated today? Sure, I want to be vaccinated as my friends and protected myself from Covid-19.

Mother: Thanks for talking it through with us Sister.

HCW: My pleasure. We are always here if you think of any other questions after you go home.

2. **Community engagement** is a process of involving community in decision-making, with the goal of creating informed actions and shared visions. It helps to better engage them to achieve long-term and sustainable acceptance and uptake of Covid-19 vaccines among the community.

Community engagement is more successful when it is done within the community. Work with community and social mobilizers to meet with the community.

The major activities to be done for wider engagement of communities are:

- Conduct community dialogue or discussion by using existing community platforms like Idir, youth associations, women associations, religious leaders, school representatives, HDA and etc...
- Conduct community sensitization meetings with Women development Armies and other stakeholders
- Identify and train local mobilizers /town carries and distribute key message to community
- Use also other community gathering opportunities to mobilize the community (market days, youth centers, worship places, schools, festivals, Bazars and so on.

In all the approaches focus on the pressing community concern regarding the COVID- 19 vaccine and be able to motivate them to be vaccinated.

3. **Develop and disseminate multi-channel communication materials and messages** Target-specific and general communication materials and messages will be developed in different local languages for different audience segments such as youth, religious leaders, IDP, People with disability and refugee communities. These include print, audio, audio-visual and electronic messages. Therefore, messages and information on the COVID-19 vaccine will be disseminated using locally accessible communication channels such as mass media including TV, radio (including community radio), social media, megaphone, audio-mounted vehicles, print media including banners, posters and brochures etc. and interpersonal communication.

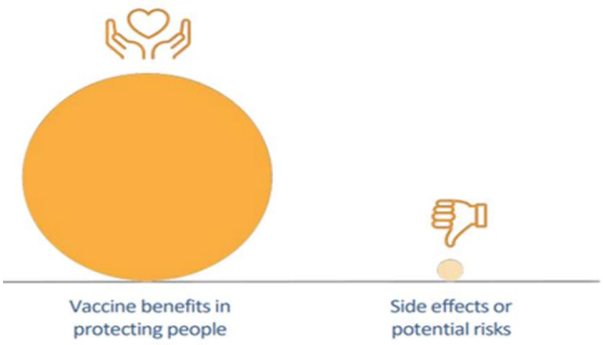
Ensure that the availability of these materials in disability friendly formats and disseminated through ethno-linguistic diversity approach to maximize vaccine uptake among the marginalized and hard to reach communities.

Key messages:

Key messages on COVID 19 vaccination focus on what communicators need to know about vaccine and pass on to client/beneficiaries, below are key messages that vaccine commentators needs to focus:

Benefits of COVID 19 vaccine to client and the community in general: We take vaccines to boost the immunity to protect from acquiring the disease, reduce severity of the disease/hospitalization and death due to COVID 19 vaccine.

Vaccine safety concern: The vaccine is safe, and it has gone through trials and found to be safe as per WHO's vaccine manufacturing protocols and continually monitor the safety through AEFI monitoring system as any other routine vaccination antigen, vaccine also given to client when only the benefit outweigh the risk as illustrated in below picture.



Eligibility: Target is all age 12 and above years for Pfizer antigen and age 18 and above for the remaining antigen (AstraZeneca, Sinopharm, Jansson) based on the current available vaccine antigens in Ethiopia. The vaccines are so helpful and recommended for those clients with comorbid cases, pregnant and lactating women.

Vaccination Site: Client can get the vaccine at health facility and temporary vaccination sites during campaign and mobile health and nutrition to reach for hard-to-reach community and IDPs.

Number of doses: Varies depending on the type of vaccine antigen you take E.g. Jansson one dose and booster after six months, the rest antigen currently available in Ethiopia be given two dose and booster dose after six months (health care workers need to explain why booster dose is requires).

Possible AEFI's: In some people, they may feel pain/redness on injection site or mild fever after vaccination which will go away after a few days. If they are persisting more than 3 days, please go to the nearest health center. Please stay and be observed at vaccination post about 30 minutes after receiving the vaccination.

COVID 19 prevention: Wash your hands frequently with soap and water to protect yourself and others from getting sick, use masks when going to public places and maintain physical distancing of at least 2 meters with others to prevent COVID-19 infection and transmission of the disease even after vaccination.

Contraindication: Acute illness, patient with seizer disorder for Sinapharm.

4. Capacity building will be done to frontline workers, volunteers, social mobilizer/town criers on demand generation plan of creation and risk communication plan. This can be done through: equipping with key messages, orientation of community and social mobilizers, women development army, volunteers, blocker leaders, CSO, FBOs.

5. Health care workers forum Health care workers are a reliable source of health information, their acceptance or rejection of COVID-19 vaccines can influence the general population's uptake of COVID-19 vaccines. People commonly rely on health care workers information and actions to guide their decision.

Create and facilitate health care workers forum for discussion on their concerns and information sharing, which will help to improve vaccine acceptance among the health care workers.

6. Social listening

These tools can be used to collect data from local area/community about rumors, mis-information and fake news across different social media, it is useful for understanding community concern regarding the vaccine

Steps for Conducting Effective Social Listening are

- Identify existing monitoring tools

- Set up a social and traditional media monitoring system

- Check your monitoring tools regularly

- Analyze and develop insights

In analyzing - answering the questions below can be a good start.

- What questions are people asking about COVID-19 vaccination?

- What are people's attitudes and emotions that may be linked to vaccination behavior?

- What rumors or misinformation are circulating and how quickly are they spreading?

-What overarching themes and narratives beyond individual pieces of content emerge from widely circulated rumors and misinformation?

-How are people responding to and interpreting vaccine-related communication from public health authorities?

5.5. Risk and crisis communication

Key definition and concepts

Risk: Chance or likelihood that something will harm or otherwise affect your health unless necessary measure and precautions taken this works for disease and services.

Risk communication: It refers to the exchange of real-time information,

The ultimate purpose of risk communication is to enable people at risk to take informed decisions to protect themselves and their loved ones.

Risk management is concerned with identifying, assessing and mitigating any activity or event that could cause harm to the business. Risks can be strategic or operational in nature.

Vaccine Risk communication

Many vaccine fears have some basis in reality. However, there is often mismatch between people's fear and reality. Moreover, there is little evidence on the knowledge of risk assessed by professional, which influence the way public perceives and responds to risks and dangers. Risk communication is communication process that the communicator hopes to provide service (for the audience) with information about the expected type (good or bad) and magnitude (weak or strong) of an outcome from a behavior or exposure.

It is the science of understanding scientific and technological risk and how it is communicated within a socio-political structure. Which attempted to offer a scientific basis for thresholds of risk which would be accepted by the public.

Crisis: Crisis can be defined as 'any situation that affects the trust or reputation of an institution, its products e.g. vaccine its services (e.g. immunization.,

Crisis communication

Crisis communication is defined as an adjusted response to an incident, that is aims at restoring public confidence in the institution's ability to manage the incident by keeping the public informed on what went wrong, why, and what is being done in response'

Crisis communication / management is concerned with responding to, managing, and recovering from an unforeseen event.

A crisis in immunization including for COVID-19 vaccine can occur for several reasons. Examples include:

- Increasing vaccine hesitancy amongst some groups due to various reasons
- An adverse event following immunization (AEFI): − A coincidence – an event that is perceived to be linked
- Poor communication in immunization e.g. an introduction of a new vaccine before addressing knowledge gap/ engaging relevant partners.
- Events including rumors or changes in the vaccination program in another country, even on a different continent. E.g. temporary cessation/suspension of the specific antigen (AZ in south Africa) vaccine
- Misinterpretation of new research reported in the media
- Misinformation from the Internet / social media that spreads in a community.
- Groups with their own, possibly unrelated agenda (e.g. political) spread rumors to destabilize a programme, or even take violent action against health workers .

To manage risk/Crisis

1. Get Prepared

-Create a crisis communication plan including sources for crises, ToR, identify fund source, SOPs etc.

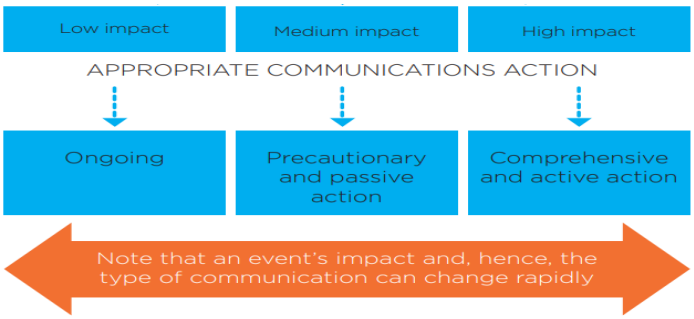
-Ensure training and orientation for key stakeholders including HWs, teachers, community leaders, journalists etc.

2. Implement: when crises occur

ANALYSE – When and where to respond, if the crises are a low, medium or high impact event, and if its getting public attention and affecting public trust in vaccines?

No.	Type of Event	Low Impact	Medium Impact	High Impact
1	Vaccine Reaction	• Reaction is not serious or dramatic • Reaction is serious but not relevant to the public (e.g. in another country with a vaccine not used in the country EPI program)	• Serious reaction in the country • Serious reaction with some relevance to public (e.g. in another country with a vaccine used in the program) • Anticipated media attention • Reaction among children, teenagers, or pregnant woman	• Actual media attention • Serious reaction(s) with unknown cause • Reaction that is dreaded, memorable, or dramatic • Serious reaction during a mass campaign • Serious reactions with a new vaccine
2	Rumors, Fake News or Media Report	• Story receives little to no public attention • Story does not play upon emotions and/or fears • Story is not believable	• Story receives some public attention • Story triggers some emotional fears • Story is plausible	• Story receives significant public attention; taps into emotional fears • Source has high readership/viewership • Source is credible and influential • Story is relevant

Actions to be taken based on the analysis result.



Be proactive – Aim to stop the crises before it gets large

ACTIVATE the crisis communication committee and plan.

TAILOR your message to the situation in the existing communication strategy

DESIGNATE a respected and trained spokesperson if the crisis requires a public response.

COORDINATE • Between technical and communication experts • With other relevant parties – such as local health units and schools

Principles of trust building during crisis management

-Communicate first: People are more likely to believe the first source and message that they receive.

-Be frequent in updating the public: Let the community know when you will share updated information

-Be transparent and honest: about what has happened, including if there are things you don't yet know. Share what you are doing to find out more information.

-Avoid over-reassuring people: acknowledge that serious AEFIs do occur, which is why there are safety monitoring systems in place

-Be empathetic - show that you care and that you understand that people may be concerned.

-Respond to commonly raised questions and concerns, even if the answer is just to say, 'we don't know that yet'. Address misunderstandings and rumors

-Let people know how they can get in touch for further information or to raise concerns (such as through a hotline, website or social media account)

Role of health Care worker in community communication on AEFI

Once crisis has occurred, responses should include the following communication elements:

- Communicate immediately with the PHCU/Woreda officials and EPI experts

- Provide the parents with factual information. Remember that some parents may seek information elsewhere and you may lose credibility if you do not provide a trustworthy and technically sound response. The public and the other stakeholders have a right to know exactly what happened.

- Reassure parents, caregivers and adults that necessary measures are being taken so that the members of the community and caregivers are informed of what is happening.

- Communicate the results of the investigation to the programme managers and to the EPI officers at all levels.

- If the AEFI was caused by immunization error, tell the public what steps are being taken to prevent similar events in the future.

- Use local radio, community platforms to brief about the event with the engagement of Woreda officials

- Repeat the message to dispel all fears

- Constantly reassure the public of the safety of vaccines.

Dealing with rumors and misinformation

Rumors and misinformation about immunization are amongst the most serious threats to the success of any immunization programme. Once rumors start, they can be very hard to stop. Unless the rumor can very easily be contained and addressed you must refer the matter to your supervisors as quickly as possible. You will need to work under their direction - action may even need to be taken at the national level. The consequences of rumors can be serious and, if unchecked, they can travel quickly beyond your local area.

3. Monitor the impact of the crisis management

- Assess the impact of communication messages/ strategy to inform next steps/ potential changes based on the collected information (new) or as evidences emerges).

- Revise your communications plan accordingly

- Document the steps and activities done to manage the situation/event, which will help in the future, if another related event happens.

Session VI

Coordination and Planning for COVID-19 Vaccine Rollout

Session duration: 90 minutes

Session description: This session outlines the necessary coordination mechanisms and planning process for COVID-19 vaccines rollout, which enable the participants to acquire the necessary knowledge, skill and attitude on coordination and planning.

Primary objective

By the end of this session participants will be able to describe the overall COVID-19 vaccine rollout planning and coordination mechanism

Enabling objectives

After completing this session, the participants will be able to:

- Explain the required coordination mechanisms for COVID-19 vaccine rollout
- Describe the COVID-19 vaccine rollout micro planning and preparation process
- Outline the important planning components for the COVID-19 vaccine rollout

6.1. COVID-19 vaccination coordination mechanism

COVID-19 vaccination rollout will require key national decisions to be made both prior to, and during, vaccine deployment. The deployment of the COVID-19 vaccine in the country is based on epidemiological need, assessed through rigorous scientific review and respects population safety.

For this purpose, there is a need to:

- Apply and strengthen inter-institutional and multi-sectoral coordination mechanisms.
- Ensure coordination with local governments (Presidents, secretariats, parliamentarians, mayors, Bureau heads, Zonal department, woreda office heads, PHCU head, Kebele leaders and key public figures)
- Coordinate participation from institutions or advisory bodies: task force (TF), technical working group (TWG), professional associations, academics institutions, NGOs, Bureau of education, bureau of transportation, bureau of social and labor affairs, bureau of women and children affairs, civil society organizations (CSO), religious institutions, community representatives, peace and security office, and people with disability associations.
- Engage institutions dealing with populations of concern like; IDPs, refugees and returnees. Engage with director of MCH, EPHI/PHEM, EPSS, and EFDA

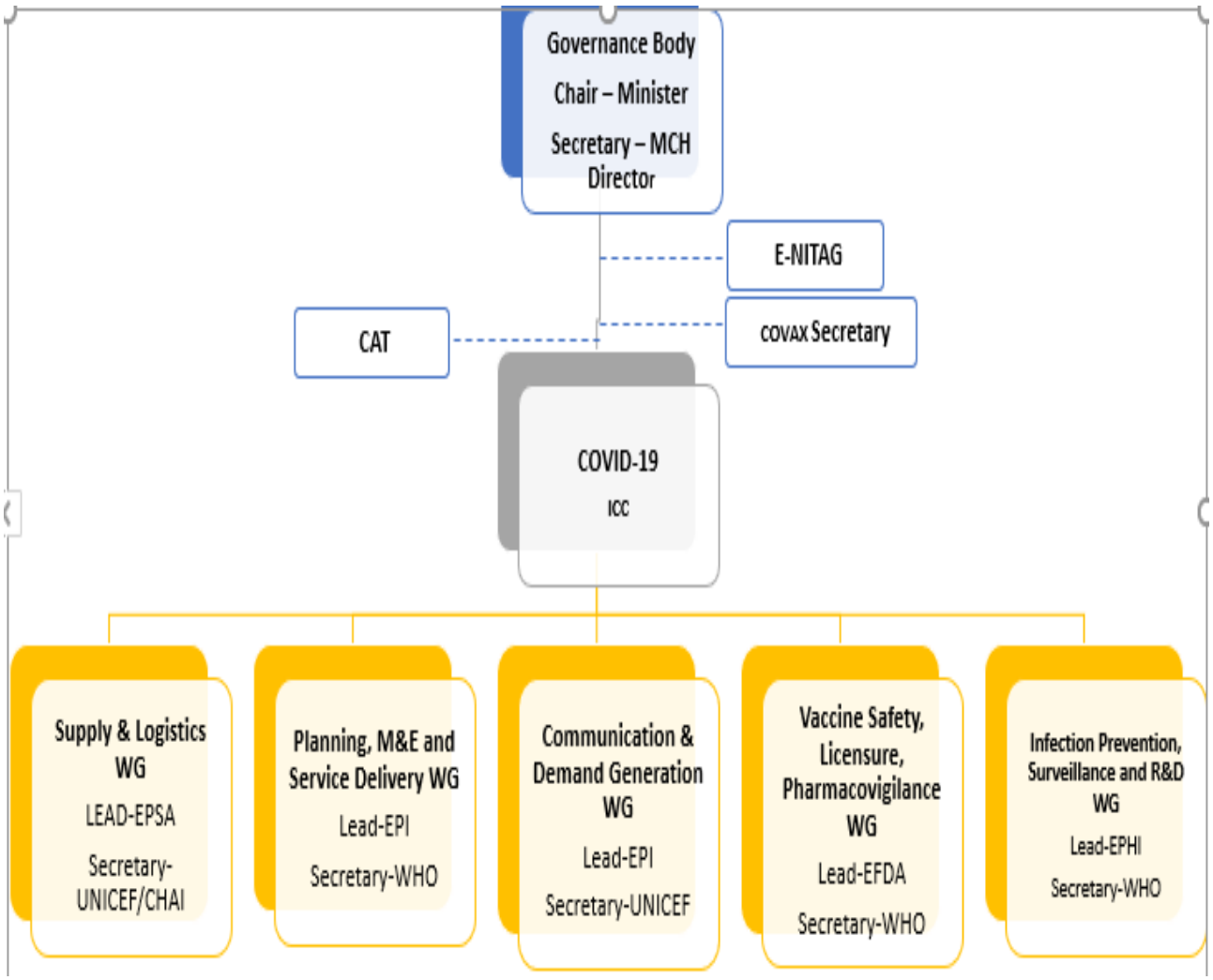
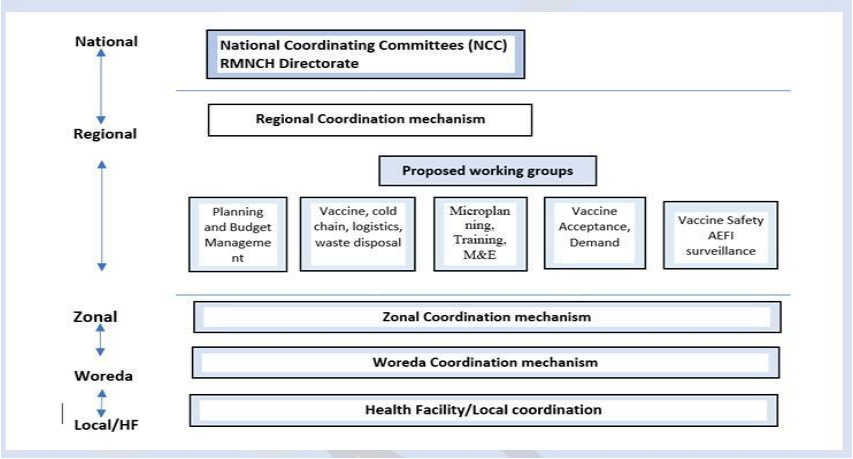


Figure 3: Organizational Chart of Interagency Coordination Structure and Technical Working Groups for COVID-19 Vaccine Planning

Sub-national Coordination

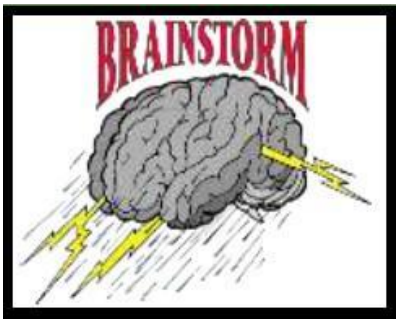
The Technical Working groups are revitalized at regional and lower levels to facilitate the effective implementation of the COVID-19 Vaccine rollout (Fig 4). Planning and coordination of COVID-19 vaccination rollout at regional, zonal and woreda levels emulated and adapted national level mechanisms and contextualized guiding principles to the respective levels as appropriate.

Figure 4: Sub-National Coordination Structure



6.2. Micro-plan development

Brainstorming Exercise



A) **What is micro planning (MP)?**

B) **How is MP developed?**

C) **Who is responsible for developing the MP?**

D) **What are the key considerations to develop MP?**

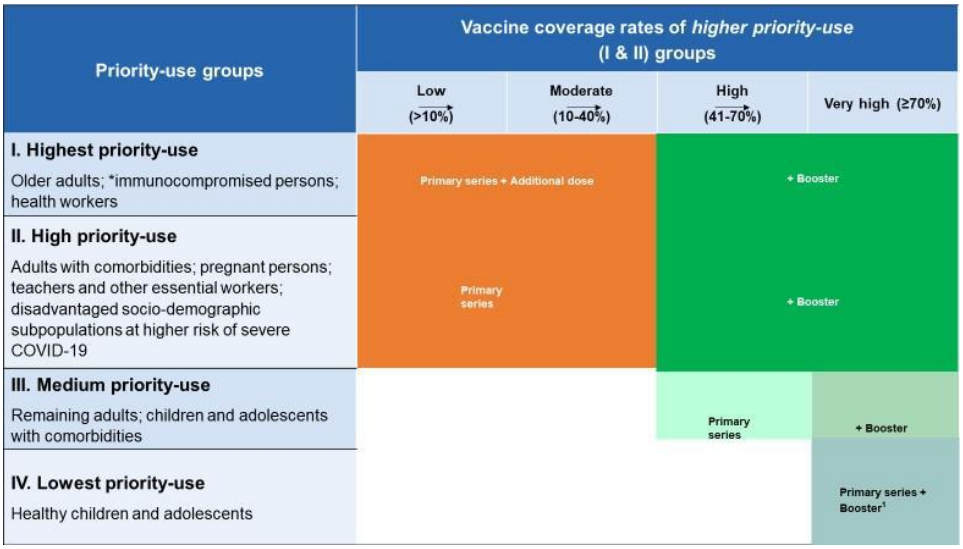
Micro planning is one of the tools that health workers use to ensure that immunization services reach every community. Micro planning is used to identify priority communities, to address barriers, and to develop work plans with solutions.

Micro planning exercise is a detailed bottom- up approach of planning and should start at the Kebele and HF levels. Micro planning at woreda levels should be developed using head count of unvaccinated target population or conversion factor of the target population. The bottom-up micro planning should use a standard micro-planning template and should include detail map of the Kebele.

This exercise should provide valid and realistic estimates of resources needed and information regarding existing and locally available resources (e.g., human resource, functional and non-functional cold chain equipment, transport, financial resource).

PLAN FOR PRIORITY TARGET GROUPS

As summarized in the figure below, WHO SAGE roadmap for prioritizing use of COVID-19 vaccines considers increasing vaccine availability, vaccine coverage rates, and the evolving epidemiological situation including COVID-19 variants of concern.



COVID-19 vaccination for pregnant and lactating women

The pregnant woman and lactating woman should be prioritized as target population for COVID-19 vaccination which is recommended in the SAGE recommendation and indicated in the national deployment and vaccination plan.

PHCU level Micro-plan Development Process

PHCU level micro-plan development overall process is expected to plan the required human, financial and logistic resources for COVID-19 vaccine rollout. The planning shall include health facilities in-charge and other key stakeholders like the Woreda level sector offices such as Education, finance, trade and industry office, transport, municipalities, law enforcement, IDP, refugees, community representatives, development Partners and CSOs (NGOs, Associations, developmental organization) working on health system area in the PHCU/Woreda.

At the micro-planning meeting, each stakeholder will be responsible to provide the required information for the micro-plan development with an age group of 12 years and above.

During this estimation of targets for vaccination, we need to make sure that,

- There should not be double consideration of targets in the micro plan.
- All stakeholders participated in this MP development will be assigned with the responsibility of announcing the vaccination dates in respective sector offices.
- The health sector will be the responsible body to take the lead to coordinate and officially submit the micro-plans to the next level.

Required Data/ information to develop the PHCU Micro-plan

- Inventory of cold chain equipment (cold boxes, ice packs for cold boxes; vaccine carriers, ice packs, ice pack freezing facilities etc.)
- Inventory of transportation facilities
- List of targets aged 12 years and above at their PHCU.
- List of high-risk populations including IDPs, refugees, returnees, and differently abled people.
- Copies of planning forms for each HFs and stakeholders
- PHCU map (physical and social map)
- List of hard-to-reach target areas
- Information about the local stakeholders; level of participation and their contact person and Identification of health facilities where the waste will be disposed (indicated on map).
- Information on vaccine and dry supply requirements
- Information on required recording and IEC/BCC materials.

Key activities to be accomplished while developing the micro-plan at PHCU level

- Identification and quantification of target groups
- Determine the number of vaccination posts and duration of vaccination
- Determine the required amount of vaccine, syringes, safety boxes, tally sheets, registration books, immunization cards, PPEs/IPC supplies (gloves, masks, and sanitizer), and waste disposal points.
- Estimate recording and reporting formats
- Estimate the required human requirement and training needs (coordinators, supervisors, vaccinators, screeners, volunteers, cold chain personnel, waste management personnel).
- Identifying strategies to reach hard to reach area
- Determine the transportation needs to prepare and implement the vaccination.
- Plan for advocacy, social mobilization and communication and IEC/BCC materials needs.
    - Identification and mapping of hesitant/ refusal groups, and design strategies
- Explore ways to strengthen inter-sectoral collaboration
- Plan vaccine and supply storage and distribution points
- Plan for waste management
- Costing of activities and supplies

Note: The micro planning development process should consider the training, logistics, communication activity and monitoring & evaluation planning which is indicated in each session.

Micro plan compilation and reporting

The PHCU in collaboration with all stakeholders should:

- Verify the data developed with all stakeholders,
- Supplement the missing data if any,
- Aggregate the data and officially submit to woreda.

Group Micro planning exercise

Case scenario

You are a HW working in Kebele X with a total of 10,000 populations; the kebele has 1 HP & 7 gots. Two of the gots do live in a mountainous area 8km away from the HP. Within the kebele, there are 1 Christian & 1 Muslim religious institution, 2 primary schools. When you look at updated head count data, 6541 individuals are found aged 12 years and above. Among these, 2114 individuals received 1st dose of AstraZeneca vaccine three months back and 1581 individuals completed primary vaccination series Seven month back and 252 of them received booster dose Nationally, COVID-19 vaccination campaign is planned to happen within the three-month time for 7 days to vaccinate the remaining total unvaccinated target individuals.

1) Calculate the target population for the coming campaign?
2) Estimate the amount of vaccine & supply required?
3) What service delivery strategies will be used to address the vaccine to all target groups?
4) Identify major stakeholders & plan for social mobilization and communication activity
5) Prepare the micro plan using the standard C-19 vaccination micro planning template in annex **VI.**

Assumption

- 150 individual/team/day at fixed site
- 100 individual/team/day at OR and mobile site

The available vaccine types for the upcoming campaign are Astrazeneca and Pfizer.

Session Summary

- Ensure the engagement of all stakeholders to strengthen the planning and coordination mechanism at PHCU level
- MP must be bottom-up
- MP preparation should be participatory-involve all stakeholders
- Focus should be given to identifying the targets/community members for COVID-19 vaccine
- Identify strategies to reach hard to reach & special group of population
- Accurately estimate human and vaccine and supplies needs
- Address all pillars/components of the COVID
- Responsibility for each component should be delegated to a specific team/person 19 vaccine rollout

SESSION VII

VACCINE DELIVERY STRATEGIES

Session duration: 120 minutes

Session description

This session aims to provide basic knowledge and skill on the COVID 19 vaccination delivery strategies and organizing vaccination sessions.

Primary objective

By the end of this session participants will be able to describe the COVID 19 vaccination delivery strategies and organizing vaccination sessions.

Enabling objectives

By the end of the session, participants will be able to:

1. Identify vaccine delivery strategies for the different priority groups
2. Outline how to organize COVID-19 vaccination sessions
3. Demonstrate COVID 19 vaccine administration

Think Pair Share Activity

Time allowed: 10 Minutes

A) What types of COVID-19 vaccine delivery strategies are you familiar with?

B) What strategy works best for COVID-19 vaccination better uptake?

C) Identify which health service programs could be integrated with COVID-19 vaccination?

7.1. Vaccine delivery strategies

The potential strategies for COVID-19 vaccination delivery are

1.Fixed/static posts: fixed posts established in health facilities (Hospital, HC & HPs). As per FMoH standard, engagement of private and NGO health facilities can be considered to enhance vaccine uptake at fixed posts.

2. Temporary fixed posts: Temporary posts established at schools, workplaces, religious areas, industrial parks, bank & insurances, cross-border points, universities, transport hubs, and other institutions. At IDPs sites, similar posts established as appropriate to the size of target population living in the IDPs.

3. **Outreach posts:** based on local contexts and to ensure adequate access to the target communities, outreach posts used in areas with limited access to health services, such as remote or hard to reach areas.

4. **Mobile health and nutrition teams:** Mobile health and nutrition teams, when available, will be used in areas with limited access to health services, in conflict affected areas, and pastoralist communities.

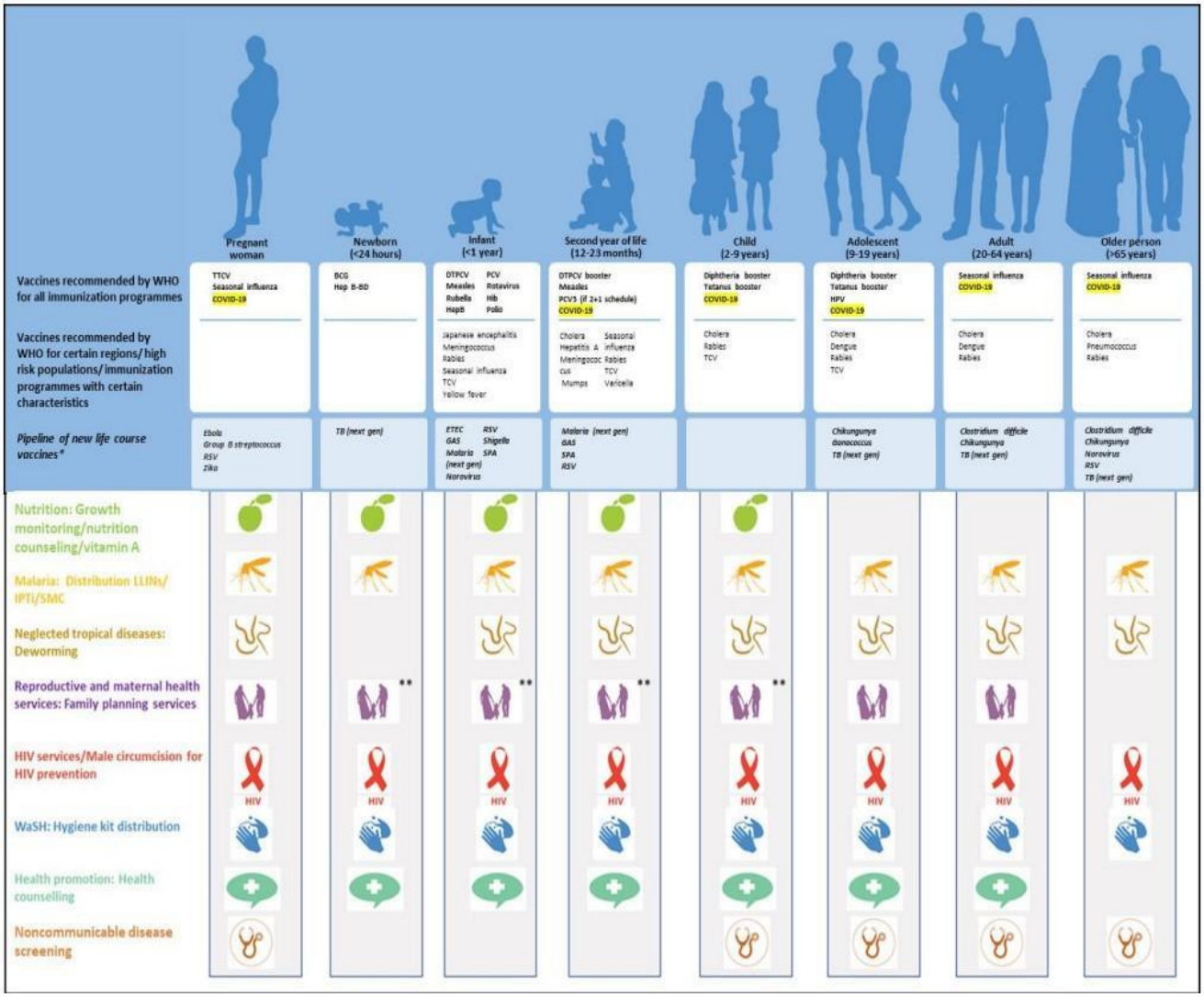
Additional approaches and considerations

Even though the above-mentioned service delivery strategies are in place, the modalities could vary in different areas and contexts. As listed below, additional approaches can be considered.

A. Vaccination campaigns: considering addressing large target population within short period of time, to increase the herd immunity of the community, and with the continued existence of COVID 19 pandemic, frequent rounds of campaign modes is the preferred and proven approach.

B. COVID-19 Service integration with RI & other service: The most likely scenario is that SARS-COV2 is continued to evolve but the severity of the disease reduces over time. However, periodic spikes in cases and deaths may occur as immunity declines which may require periodic boosting for high-risk population. Besides this, for the purpose of efficient utilization of resources and ensuring the sustainability of essential services, integrating COVID-19 vaccination with routine immunization and other essential PHCU services will be crucial including planning to integrate zero dose identification, under immunized and default tracing for routine immunization.

Even though the routine vaccination activities majorly focus to an age group below two year, COVID-19 vaccination targets the adult age group, provides opportunities to integrate other existing health service targeting adults more easily (e.g., Nutrition, screening for NCDs, reproductive health education, delivery of bed nets for malaria prevention) targeting these adult groups in the figure below.


Pregnant woman
Newborn (<24 hours)
Infant (<1 year)
Second year of life (12-23 months)
Child (2-9 years)
Adolescent (9-19 years)
Adult (20-64 years)
Older person (>65 years)
Vaccines recommended by WHO for all immunization programmes
TTCV
Seasonal influenza
COVID-19
BCG
Hep B-BD
DTPCV
Measles
Rubella
HepB
PCV
Rotavirus
Hib
Polio
DTPCV booster
Measles
PCV3 (if 2+1 schedule)
COVID-19
Diphtheria booster
Tetanus booster
COVID-19
Diphtheria booster
Tetanus booster
HPV
COVID-19
Seasonal influenza
COVID-19
Seasonal influenza
COVID-19
Vaccines recommended by WHO for certain regions/high risk populations/immunization programmes with certain characteristics
Japanese encephalitis
Meningococcus
Rabies
Seasonal influenza
TCV
Yellow fever
Cholera
Hepatitis A
Meningococcus
Mumps
Seasonal influenza
Rabies
TCV
Varicella
Cholera
Rabies
TCV
Cholera
Dengue
Rabies
TCV
Cholera
Dengue
Rabies
Cholera
Pneumococcus
Rabies
Pipeline of new life course vaccines*
Ebola
Group B streptococcus
RSV
Zika
TB (next gen)
ETEC
GAS
Malaria (next gen)
Norovirus
RSV
Shigella
SPA
Malaria (next gen)
GAS
SPA
RSV
Chikungunya
Bonococcus
TB (next gen)
Clostridium difficile
Chikungunya
TB (next gen)
Clostridium difficile
Chikungunya
Norovirus
RSV
TB (next gen)
Nutrition: Growth monitoring/nutrition counseling/vitamin A
Malaria: Distribution LLINs/ IPTI/SMC
Neglected tropical diseases: Deworming
Reproductive and maternal health services: Family planning services
**
HIV services/Male circumcision for HIV prevention
HIV
WaSH: Hygiene kit distribution
Health promotion: Health counselling
Noncommunicable disease screening

7.2. Organizing COVID-19 vaccination session

A well-organized vaccination session will enable the efficiency and effectiveness of the overall vaccination service delivery through commencing of below major activities.

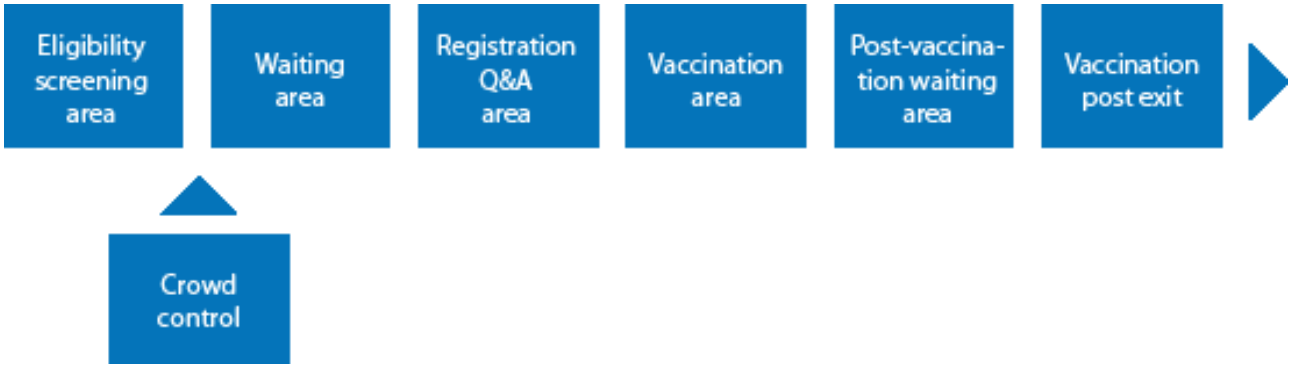
Preparation for session: For any vaccine delivery strategy, inform the community and target groups in advance of the location and time of vaccination, set up safe vaccination sites and ensure adequate quantities of vaccines and supplies, adequate cold-chain equipment, appropriate injection equipment, appropriate PPEs, safety box and reporting and recording tools.

Team composition and target for each session: Each HFs will identify the number of vaccinators, vaccination teams and targets for each session as per the national guide. Vaccination post will be organized as per the standard lay outs and with assigned trained persons with specific assigned roles. For the static vaccination session adequately trained vaccinator should be availed during the whole working days and hours.

Ensure standard infection prevention and control strategies for vaccination sessions: The necessary arrangements for COVID 19 infection prevention should be in place, including screening for COVID 19 infection, physical distancing, use of PPEs/IPCs, establishing hand hygiene/washing facilities, establishing the vaccination sites in well ventilated areas, and ensuring proper health care waste management. Hand hygiene - use alcohol-based hand rub or running water and soap before and after contact with each vaccine recipient; PPEs - wear a face mask; environmental cleaning - maintain a clean environment, especially high-touch surfaces (e.g. chairs, tables, door handles) and Apply safe injection; and physical distancing; and COVID 19 screening at immunization sites, and proper health care waste management.

Setting up vaccination sites/sessions:

- Ensure good ventilation: open windows in indoor space, if outdoors, pick a well- ventilated area,
- Screen for respiratory symptoms: before those to be vaccinated enter the vaccination site,
- Limit the number of individuals: to avoid crowding and long waiting times, ensure one-way flow through the vaccination site and maintain 1 meter between each caretaker. (Refer diagram below).
- Give sideways positioning: avoid positioning yourself face-to-face with the vaccine recipient and
- Advise the client: to return for second dose of vaccine after as per recommended interval, about possible side effects of the vaccine and what to do if happens, on COVID 19 prevention measures, and to keep the vaccination card. Do not miss information, keep all necessary recordings.



7.3. Vaccine administration

Proper vaccine administration is critical to ensure that vaccination is safe and effective. It is recommended that all health care personnel who administer vaccines receive comprehensive, competency-based training on vaccine administration policies and procedures. The recommended practices for COVID-9 injections include:

- Check the expiry date of the vaccine
- For vaccine requiring dilution use separate syringe to dilute single vial only.
- Ensure the right match for vaccine with diluent as per the manufacturer recommendation
- Prepare each injectable vaccine using a separate syringe immediately before vaccination
- Label each vaccine vial with the date and time immediately when opened
- Return the vaccine vial to the vaccine carrier, put the vial on foam pad
- Ensure you are wearing face mask, position the vaccine recipient and use aseptic technique
- Provide vaccine on the left deltoid intramuscular
- Discard the used needle and syringe without recapping in the safety box
- Record on tally sheet, vaccination card and registration
- Provide advice on AEFIs and when to return

Table 24: SUMMARY OF COVID19 VACCINES CHARACTERISTICS AND PRESENTATION.

COVID-19 Vaccine Type	Target age group	Route	Dosage	Number of doses	Schedule
AstraZeneca	18 years and above	IM	0.5ml	2 doses	1st dose at start 2nd dose 8-12 weeks after the 1st dose
SinoPharm	18 years and above	IM	0.5ml	2 doses	1st dose at start date 2nd dose 3 to 4 weeks after the 1st dose
Janssen (J&J)	18 years and above	IM	0.5ml	Single	Single
Sinovac	18 years and above	IM	0.5ml	2 doses	1st dose at start date 2nd dose 2-4 weeks after the 1st dose
Pfizer	12 years and above	IM	0.3ml	2 doses	1st dose at start date 2nd dose 3-4 weeks after the 1st dose

Additional Considerations

A)Mix and match the use of COVID-19 vaccines

Mix & Match is a situation in which using of heterologous vaccine in first and second dose.

Rationale for mix and match

- Vaccine shortage for the 2nd dose
- Increasing immunogenicity
- Enhancing vaccine effectiveness
- Contraindication to a specific vaccine after the first dose

- Changes in guidance for vaccine usage mRNA vaccines can be used as subsequent doses after initial doses of vectored vaccine and vice versa. AstraZeneca and any of the mRNA vaccines can also be used after initial doses of inactivated vaccines. However, it is not recommended to use the mix and match of the vaccines if the facility has adequate stock of the same vaccine to complete the primary series.

Table 28: Summary of Mix and match

Mix and Match	
1st dose	**2nd dose**
AstraZeneca	Pfizer
Pfizer	AstraZeneca

B) Booster Dose

Booster dose is required when the immunity that we achieved because of being vaccinated starts to wane or deteriorate and if the performance of the vaccines is less or inadequate against some of the variants of concern that have emerged. Hence, Booster dose is an extra dose of vaccine which will be given for the target who completed the primary vaccination series.

Booster dose can be homologous which same vaccine series is or heterologous which is different type of vaccine from the primary series.

Table 29: summary of Booster dose vaccination in Ethiopia

Homologous Boosting (Same vaccine series)			Heterologous Boosting		
1st dose	**2nd dose**	**Booster dose**	**1st dose**	**2nd dose**	**Booster dose**
AstraZeneca	AstraZeneca	AstraZeneca	AstraZeneca	AstraZeneca	Pfizer
J & J		J & J	J & J		Pfizer
Pfizer	Pfizer	Pfizer	Pfizer	Pfizer	AstraZeneca
Sinopharm	Sinopharm	Sinopharm	Sinopharm	Sinopharm	Pfizer

Closing the vaccination session

During closing the vaccination session, the healthcare personnel in charge should:

- Discard any used reconstituted COVID-19 vaccine vials in a separate waste bag or container
- Count the unopened COVID-19 vaccine vials and diluents and write down the number on the tally sheet.
- If in outreach/campaign, return opened and unopened COVID-19 vaccine vials and diluents, the vaccine carrier, and coolant- packs to the distribution point.

Demonstration exercise

Time Allowed: 30 Minutes

Demonstrate how COVID-19 vaccine is administered following the standard methods.

- Your facilitator will give the guide and provide appropriate materials

Session Summary

Fixed, temporary fixed, outreach and mobile health & nutrition teams are the potential COVID-19 service delivery strategies

Vaccination campaigns and COVID-19 Service integration with RI & other service are the additional approaches for better vaccine uptake

A well-organized vaccination session will enable the efficiency and effectiveness of the overall vaccination service delivery

Proper vaccine administration is critical to ensure that vaccination is safe and effective

SESSION VIII

MONITORING AND EVALUATION OF COVID-19 VACCINATION

Session duration: 180 minutes

Session Description

This section describes the importance of monitoring and evaluation during the COVID 19 vaccine introduction so that to enable the participants to acquire the necessary knowledge, skills and attitude on monitoring and evaluation of the COVID 19 vaccine introduction. This section also discusses the major monitoring and evaluation indicators and tools to be used during the COVID 19 vaccine introduction.

Learning Objective

By the end of this session, the participants will be able to:

- Describe monitoring and evaluation approaches of COVID-19 vaccination
- Explain and use the set indicators for COVID 19 vaccine monitoring
- Describe and use COVID-19 vaccination campaign monitoring system
- Identify and use COVID-19 vaccine monitoring and evaluation tools

Session Topics

- Introduction to COVID-19 vaccine monitoring
- Indicators to monitor COVID-19 vaccination progress
- COVID-19 Vaccination monitoring Tools
- COVID-19 Vaccination campaign monitoring
- Evaluation of COVID-19 vaccine rollout

8.1. Introduction to COVID-19 vaccine monitoring

Brainstorming

What is monitoring?

Why do we monitor COVID-19 vaccination?

Monitoring is the process of continuous observation and collection of data on immunization programs to ensure that it is progressing as planned and objectives are met. The purpose of monitoring is to assess performance, coverage, and implementation to identify problems/bottlenecks, develop solutions, and guide further implementation.

After COVID-19 vaccine introduction there is an intense demand for data by:

- Public health decision-makers, national and subnational, authorities' regulatory bodies
- Public, communities, civil society organizations, and the media
- National, regional, and global immunization partners, including donor organizations; and vaccine manufacturers , health researchers and academics.

The COVID-19 vaccination monitoring system is designed to: -

Measure equitable uptake and coverage over time by geography, and high-risk population groups

Ensure that the necessary records and documentation are in place for use in surveys, AEFI and safety monitoring, disease surveillance and vaccine effectiveness studies.

Ensure that individuals can be monitored for the full course, in the likely case that a multidose schedule is required, to reduce the incidence of dropouts.

Provide the data needed for fast and efficient course corrections in the planning, micro planning and roll-out of vaccines.

The COVID-19 vaccine is not yet part of the national routine immunization program, nor part of the HMIS. A separate monitoring system is designed, and monitoring tools are also developed to ensure proper monitoring of the COVID-19 vaccination.

COVID-19 Vaccination Monitoring Systems

Brainstorming

Which sources of COVID-19 vaccine monitoring systems do you know?

The following systems will be used to monitor COVID-19 vaccination planning, implementation, and post implementation phases

- Vaccine logistic and coverage administrative reports
- Vaccine safety monitoring (Adverse Event Following Immunization)
- COVID-19 surveillance report
- Campaign readiness assessments
- Supportive supervision
- Review meeting
- Survey

The information obtained from monitoring will be used to undertake corrective measures as well as for documenting lessons to be used for future programming.

8.2. Indicators to monitor COVID-19 vaccination progress

Brainstorming

What is Indicator?

Which COVID-19 vaccination indicator do you know?

Definition of Indicators:- An indicator is a variable that measures one aspect of a program or project that is directly related to the program's objectives. It measures the value of the change in meaningful units that can be compared to past and future units. This is usually expressed as a percentage or a number

The following indicator groups will be used to monitor the COVID 19 vaccination in Ethiopia:

The COVID-19 vaccination monitoring system is designed to monitor: -

- Vaccine uptake and coverage
- Vaccine supply and logistic
- Demand promotion and communication
- AEFI
- COVID-19 surveillance
- Information system
- Planning, coordination, and system related

Vaccine uptake and coverage monitoring

Calculating COVID-19 vaccine coverage is necessary for monitoring the impact of vaccine on a population, as well as for evaluating the performance of a vaccine program toward meeting objectives. As with other EPI vaccines, administrative coverage can be supplemented by community-level coverage surveys as deemed necessary.

The difference between these two concepts is that uptake expresses vaccination activity over time, while coverage expresses the resulting protection among a population.

- **Vaccine Uptake:-** Vaccine uptake or vaccination rate: the number of people vaccinated with a certain dose of the vaccine in a certain time (e.g., during a month or year), which can be expressed as an absolute number or as the proportion of a target population
- **Vaccination Coverage:-** The vaccinated proportion of a target population. Coverage can be estimated by accounting for vaccination in previous time periods (weeks, months, years)

Example

Consider a country with a total population of 10 million people that manages to vaccinate 4,000, 000 people with two doses each year in 2021, and 2022. What is uptake and coverage in each of these years?

Answer:- In 2021, 4,000,000 people received a second dose, representing 40% of the population (uptake). This is also the best estimate for coverage in 2021. In 2022, again 4,000,000 people received a second dose, representing 40% of the population. But the resulting coverage is certainly higher than 40%. Coverage may be close to 80% (cumulative uptake).

Coverage of COVID-19 vaccines should be tracked by administered doses as follows:

Core Coverage Indicators

- ***People received at least one dose:*** *- The number of people received at least one dose of any vaccine (J&J, AstraZeneca, Pfizer or Sinopharm)*
- ***First dose Coverage:*** *- Proportion of people received at least one dose of COVID-19 vaccine from the target population (12+ years of age)*
- ***People received second dose:*** *- The number of people received second dose of either Pfizer, AstraZeneca or Sinopharm vaccine including mix and match*
- ***People Completed Vaccination series (Fully Vaccinated):*** *- the number or proportion of people who received the last recommended dose for the respective vaccine type (one dose of J&J vaccine or two doses of Pfizer, Sinopharm and AstraZeneca).*
- ***People Received Booster Dose:*** *- The number of people received booster dose* of any vaccine type
- ***Partially Vaccinated:*** *The proportion of people who received one dose of either Pfizer, Sinopharm or AstraZeneca vaccine but not receive the second dose*
- ***Total dose administered:*** *- The total number of vaccine doses administered, including the first, second, and booster doses*
- ***Drop Out Rate*** *= (COVID 19 Doses 1 - COVID 19 Doses 2) *100 / COVID 19 Doses 1*

Data Source: - Performance *Report (DHIS2)*

Disaggregation: *- Geography (Region, Zone, Wo reda), Age (12-17, 18-64 and 65+), Sex (Male, Female), special population groups (Health workers, people with disability, IDPs/Refugees, People with comorbidity, old age)*

Reporting Period: - Daily

Vaccine supply and logistic indicators

Brainstorming

How do you calculate Vaccine wastage rate?

Monitoring the distribution and utilization of vaccines and ancillary supplies such as syringes, safety boxes, vaccination cards and PPE, to the service delivery points provide a sense of the vaccine sufficiency and fair distribution of vaccines in a country.

Core Vaccine Supply Indicators

- **Vaccines allocated:** - *the number doses of vaccines allocated to a certain region or district as a percentage of the total population.*
- **Vaccine Utilization: -** *The proportion of vaccines doses administered over vaccine doses received*
- **Number and proportion of Woredas received vaccine supply on time and in full (OTIF): -** *The number of woredas that received full supply on time over the total number of woredas*
- **Vaccine Wastage Rate**: *traditionally, some wastage is expected and accepted as a price to pay for achieving high coverage, especially for vaccines that are presented in multi-dose vials. In the context of limited supply however, every wasted dose represents a missed opportunity for vaccination, and the target for wastage should be close to zero.*
  - **Vaccine Wastage Rate =** *100 – Vaccine usage Rate*
    - Vaccine Usage Rate = *Number of Doses Given/Sum of Doses Opened, damaged/expired*
    - Open Vial Wastage= *percentage of doses that were discarded after vials were opened*

Data source: - *administrative report*, *VITAS*, OTIF monitoring sheet

Reporting Period: - Monthly

Disaggregation: - Geography, Vaccine type

Demand promotion and communication indicators

Brainstorming

What is the importance of monitoring demand promotion and communication indicators?

Monitoring and supervision of communication activities will be important to show the effectiveness of communication interventions during the vaccine rollout and to make course corrections as needed. Therefore, demand planning should include plans and activities for the monitoring and evaluation of relevant activities linked with the national deployment and vaccination plan (NDVP) and performance indicators. This will also include developing a monitoring checklist and rapid surveys to assess the effectiveness of communication activities.

Core Demand Promotion and Communication Indicators

Number of advocacy meetings/workshops organized and conducted

Number of sensitization meetings organized and conducted

Number of community dialogue organized and conducted

People Reached by COVID-19 vaccination messages: - *Number of people reached through mass media and social media with COVID-19 vaccine-related messaging*

Data source: - *administrative report*

Reporting Period: - *Monthly*

Disaggregation: - *Geography*

Vaccine Safety (AEFI) Monitoring Indicators

Brainstorming

What is the importance of monitoring AEFI indicators? Which AEFI indicators do you know?

As with any vaccine roll-out, it is very important to monitor vaccine safety. This involves recording, investigating, and reporting any AEFI. Typically, case investigation reports are made for serious cases, while a full line list of all detected cases is used by PHCU, woreda, Zone, and regional levels, and shared with the national regulatory authority (EFDA).

Monitoring these numbers can provide early warnings about safety concerns with a certain vaccine or vaccine batch, or about unsafe administration practices.

Core AEFI Indicators

Number of active surveillance sites: - *The number of active surveillance sites conducting active AEFI case search*

Number of Adverse Events following Immunization reported to EFDA: - *Number of timely detected COVID-19 vaccines adverse events following immunization (AEFI) cases reported to EFDA*

Number of SAE investigated and classified: - *Number of serious adverse events (any undesirable experience-life-threatening events, hospitalization or death associated with the COVID-19 vaccination in a person vaccinated) investigated and classified by EFDA.*

Disaggregation: - Vaccine type

Reporting period: - Monthly

Data source: - *administrative report, Case investigation forms,*

Reporting Period: - *Monthly*

Disaggregation: - *Geography, Surveillance site (Active, Passive), vaccine type*

COVID-19 Surveillance Indicators

Brainstorming

How do you monitor COVID-19 morbidity and mortality?

Surveillance data is very important to inform policy changes, guide new program interventions, sharpen public communications, and help agencies to assess investment areas

Core Surveillance Indicators

Number of COVID-19 cases reported: - *Number of confirmed coronavirus disease (COVID-19) cases reported*

Number of deaths due to COVID-19: - *Number of confirmed deaths reported due to COVID-19 disease*

Data source: - *Performance Report (DHIS2 tracker)*

Reporting Period: - *Monthly*

Disaggregation: - *Geography (Region, Zone, Wereda), Sex (Male Female), Vaccination status*

Planning, coordination, and system related Indicators

Monitoring system related indicators helps to inform the prioritization of actions and decision-making at health facility, subnational and national levels.

Core Planning and coordination Indicators

- Availability of COVID-19 vaccine multisectoral coordination mechanisms that meet regularly with MOH/RHB, WoHo
- Number of woredas with vaccine delivery micro plan
- Number of Woredas implementing DHIS2 COVID vaccination reporting system
- Number of and proportion of woredas reporting monthly stock status data
- Number of trained health workers: - *Number of health workers trained on COVID-19 vaccine-related topics with FMOH, RHB or partners support.*
- Number of supportive supervision visits conducted
- Number of COVID-19 vaccination review meetings conducted

Data source: - *Administrative report*

Reporting Period: - *Monthly*

Disaggregation: - *Geography (Region, Zone, Woreda)*

Group Exercise

Assume you are an EPI focal person in Jigjiga health center. The total catchment population is 45,000. In 2022, Jigjiga health center received 20,000 vaccine doses and administered 15,000 doses and stock on hand 4,600. Use the information below and calculate

- Total doses administered
- People completed vaccination series
- Vaccine utilization and wastage rate

Vaccine Type	1st dose administered	2nd dose administered	Open vial wasted
Pfizer	2000	1000	150
Sinopharm	3000	1500	100
J&J	5300		50
AstraZeneca	1000	1200	100

8.1. COVID-19 Vaccination monitoring Tools

> **Brainstorming**
>
> What should we consider in recording and reporting COVID-19 vaccination data?

Data Collection and Reporting Principles

- Every vaccination given at any visit will be recorded/updated in the COVID-19 vaccination register and COVID-19 vaccination card
- All vaccination given will be tallied based on the appropriate disaggregation (Age group, Gender, Dose, special population group and vaccine type)
- Vaccination data will be aggregated daily and reported to the next level
- Data will be entered to DHIS2 COVID-19 vaccination reporting system at Woreda level

Recording and Reporting Tools

> **Brainstorming**
>
> List and explain the recording and reporting tools used for COVID-19 vaccination?

The following tools will be used to record and report COVID-19 vaccination administrative data (Refer COVID-19 vaccination data management SOP for detail)

COVID-19 vaccination card

This is the individual's vaccination record/certificate. It is kept by the individual and therefore is the only immunization record that is found in the community. This card should be brought to the vaccination sites during each visit. The vaccination card is important for many reasons:

- It serves as a reminder for the individual to return to the health facility/vaccination site for the next dose(s)
- It helps the health worker determine an individual's vaccination status.
- Allows continuity of service when the person moves to another area
- During coverage surveys, the card is used to verify vaccination status of the individual
- It is important to generate electronic vaccine certificate (QR code)

Who updates: - *Health care workers completes the information required by the COVID-19 vaccination card as service is provided*

Where to Keep: *The COVID-19 Vaccination card should always be kept* by the individual

When to use: *Whenever the individual comes for vaccination to a vaccination site of any capacity – facility/outreaches/mobile sites*

The following steps will be used to complete the COVID-19 vaccination card

- For an individual visiting the vaccination site for the first time, health care workers will issue COVID-19 vaccination card and fill the demographic data as well as vaccination information
- For revisit client, health workers will update the vaccination status

The following information should be recorded in the COVID-19 vaccination card

ID.NO:- Write the individual ID Number. This should be the same with the ID number recorded in the COVID-19 vaccination register

Passport Number:- Write the passport number of the individual (if applicable)

Full Name:- Write the full name of the individual legibly

Age:- Write age in full years Sex: - Write sex of the individual in full format (Female, Male)

Occupation:- Write the Occupation of the person

Region, Zone/Sub City, Woreda, Kebelle, Village:- Write the residential region, zone/ sub city, Woreda, kebelle, village, of the individual. This can be cross referenced with the information in the individual ID

On the second page of the COVID-19 vaccination card record the following information

First Dose

- **Vaccine type:-** Write the full name of the vaccine type administered
- **Batch Number:-** Write the batch number of the vaccine administered legibly
- **Date Vaccinated:-** Write the date of vaccination legibly in DD-MM-YYYY format. Primarily use Ethiopian calendar
- **Next Vaccination Date:-** Write the next vaccination date for subsequent doses (2nd dose or booster) in DD-MM-YYYY format Follow the same procedure for 2nd and booster doses.

Follow the same procedure for 2nd and booster doses

8.1.2. COVID-19 vaccination register

The COVID-19 Vaccination Register is a longitudinal register with each row covering full course of vaccination data for one individual. Each dose of COVID-19 vaccine given to every eligible target is recorded next to their names in the register. The register is being used as an additional tool for health workers to be aware of who have missed doses and allow for tracking defaulters. The data in the register can be also used as a source of information during program evaluation and surveys.

How to use COVID-19 Vaccination Register

The facility should ensure availability of a revised version of COVID-19 Vaccination Register – contain all the variables to be recorded to avoid lumping together of information by the service provider

- When HF staff go to outreach/ mobile immunization service, they need to carry the register
- All vaccination data should be recorded in the COVID-19 Vaccination Register as soon as the individual received the first dose at the health facility or outreach sites
- For every new person (never vaccinated) create a new entry in the register and create a new COVID-19 vaccination card
- Once registered in the COVID-19 Vaccination Register do not create a new entry in the register each time the individual visits the facility for subsequent doses

In subsequent visits locate the individual's entry by Serial Number or ID number in the register and update data for each dose provided

- If the COVID-19 vaccination card is not available, ask the individual the details of the first immunization to locate his/ her entry in the register

For an individual who has come to your health facility for the first time but has received the first dose in another health facility, create a new entry in the register, ask for the COVID-19 vaccination card and mark on the register that the individual has already been vaccinated for the first dose. Provide the second dose or Booster Dose, record in the register and tally for reporting.

DO NOT TALLY and REPORT VACCINATION GIVEN BY ANOTHER FACILITY

COVID 19 Immunization Register

Region (1): _____ Zone (2): _____ Woreda (3): _____ Kebele: (4) _____ Name of vaccination post/HF/IDP/Refugee: (5) _____

S. N (6)	ID No.(7)	Full Name(8)	Age(9)	Sex(10)	Occupation (11) (Insert code nubmer indicated at the bottom)	Comorbidity (12) (insert code number indicated at the bottom)	Pregnant/ Lactating (13)	Others (14) (insert code number indicated at the bottom)	Village/Got/ Residence (15)	House No (16)	COV 1 (1st Dose)			COV 2 (2nd Dose)			Booster dose			Phone No. (26)
											Vaccine Name(17)	(DD/MM/YY)(18)	Batch No (19)	Vaccine Name (20)	(DD/MM/YY) (21)	Batch No (22)	Vaccine Name(23)	(DD/MM/YY) (24)	Batch No (25)	
1																				
2																				
3																				
4																				
5																				
6																				
7																				
8																				
9																				
10																				
11																				
12																				
13																				

How to record information on the register

When an individual comes for the very first time, fill in all information in the register except the space provided for vaccinations (The column for each dose should be completed after the vaccinations are provided)

Region, Zone, Woreda, Kebele:- Write the respective region, zone, woreda, and Kebelle where COVID-19 Vaccine canter is located

Name of Vaccination Post:- Write the official name of the health facility, IDP (internally displaced people) & Refugee camps where COVID-19 Vaccine centre is located

S.N:- Write serial number starting from 001 in a consecutive order. This is a continuous number given once for every individual registered in the COVID-19 vaccination register according to their order This will continue to the last page of the register. The serial number should also be recorded in the individual COVID-19 vaccination card for easy retrieval during the next vaccination schedule

ID Number:- Write the person's identification number (ID)

- There should be a unique identification number (serial number or ID number) on the register for each individual and use the same number on the COVID-19 vaccination card. This way, for the next vaccination, it will be very easy to locate the individual's entry on the register

Full Name:- Write the names of the person's father & grand father

Age:- Write the person's age in full years

Sex:- Write the person's sex

Occupation:- Write the person's occupation code as indicated at the bottom of the registration book

Co-morbidity:- Write the person's disease code as indicated at the bottom of the registration book

Pregnant/Lactating:- Ask if she is pregnant or lactating write the status as "pregnant " or "Lactating" if not leave it blank

Others:- Write the codes indicated at the bottom of the registration book

Village/Gote:- Write the village/Gote where the person lives

House Number:- Write the house number of the home where a person lives

Vaccine Name:- Write the full name of COVID-19 Vaccine for each dose

(DD/MM/YY):- Write the date, month and year for each dose provided with full date format DD-MM-YY

Batch Number:- Write the Batch number of the booster dose of the vaccine

Phone Number:- Write the person's mobile phone number

- Doses administered should be recorded legibly in the vaccination register immediately after administration of the vaccine (and not before or much later)

COVID-19 vaccination Tally sheet

Brainstorming

What is the purpose of tally sheet?

When should we tally COVID-19 vaccination data?

Tally sheets are forms that are marked every time a health worker administers a dose. They are used to collate and complete reports

- The main body of tally sheet has dose number, age, and gender disaggregation for each vaccine type
- Use a separate tally sheet for each day of vaccination and category
- Tally sheets should be used for all sessions whether fixed, outreach or mobile. When HF staff go to outreach/ mobile immunization service, they need to carry a tally sheet
- All vaccinators in a health facility should use the same type of tally marks (/) to make it easier to count the totals

Doses administered should be tallied immediately after administration (and not before or much later)

Who updates:- Health care workers tally every single vaccination as service is provided. If this instruction is not observed, there is a high risk that vaccines that have been administered will be miscounted because of the complexity of counting administered vaccines for a specific time from a longitudinal register

Where to Keep:- The COVID-19 vaccination tally sheet should always be filed and kept at the vaccination site

When to use:- Whenever there is vaccination session in the vaccination site of any capacity-facility/outreach/mobile site

How to use COVID-19 Vaccination Tally Sheet

In first upper part of the tally sheet

- Use a separate tally sheet for each vaccine type and each vaccination session
- write the name of the region, zone, Woreda, Kebelle and health institution
- Write the date of vaccination in DD-MM-YYYY format
- Type of COVID-19 vaccine given: - Write the full name of the vaccine type in the tally sheet

For each vaccination you perform, ***strike the printed zero vertically*** at the correct line on the tally sheet next to the dose you have just given (1st dose, 2nd dose or Booster dose) according to age group and sex of the individual (12-17 years, 18-64 years, >=65 years for both Female and Male),

- Tally ALL vaccinations given to ALL population including special population groups by age and sex disaggregation, then Tally number of special population groups (Health workers, IDPs, refugees, people with disability and people with medical condition) vaccinated out of the total vaccination.

TALLY SHEET FOR COVID 19 VACCINATION (Routine and Campaign)

Region: _____ **Zone:** _____ **Woreda:** _____ **Kebelle:** _____ **Name of vaccination post/HF:** _____ **Date of vaccination:** ____/___/____

- *Use a separate tally sheet for each vaccine type and each vaccination session*
- *Tally* **ALL vaccinations** *given to* ***ALL population*** *including special population groups* ***by age and sex*** *disaggregation, then Tally number of special population groups (Health workers, IDPs, refugees, people with disability and people with medical condition) vaccinated out of the total vaccination*

Vaccine Type _____

Dose	Age 12-17		Age 18-64		Age ≥ 65 years		Special population groups				
							Health Workers	IDPs	Refugee	People with medical condition	People with disability
	Female	Male	Female	Male	Female	Male					
First Dose	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____
Second Dose	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____
Booster dose	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000
	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____
Mix-Match dose	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000	00000 00000					
	Total_____	Total_____	Total_____	Total_____	Total_____	Total_____					

After completing each tally sheet for the day, the total number of tallied should cumulate at the end of each age/Gender category and in the last column of each sheet by gender. This gives the total number of vaccinations given with each dose for the day

At the end of the tally sheet, write

Doses Received:- Write the number of doses Received for the vaccination session

Stock at hand:- Write the number of doses available in the stock

Open Vial Wasted:- Write the number of open vials wasted

Closed Vial Wasted:- Write the number of closed vials wasted

COVID-19 vaccination daily reporting forms

The daily reporting form is the reporting format used to collate and report all vaccinations given at the vaccination site. At the PHCU level this is the primary reporting tool for summarizing all vaccinations provided from all vaccination sites.

Who updates:- Team supervisors, PHCU coordinator compiles, check, and review data, then forward one copy to their designated administrative office according to their level.

Where to Keep:- The COVID-19 vaccination daily reporting forms should always be kept at the vaccination sites and each administrative level health offices

How to use COVID-19 Vaccination Daily Reporting Forms

It is completed by summarizing the data from the daily tally sheets for a particular day. Each day when you finish your vaccination session

- Fill Name of the vaccination post or PHCU or Woreda or Zone according to your level of reporting
- Count the number of vaccinations recorded on the tally sheet for each age group, gender (12-17 M/F, 18-64 M/F, 65+ M/F), population group and vaccine type and enter the daily totals on the reporting form
- Make sure that you enter the totals from the COVID-19 vaccination tally sheet in the correct column

(Summarized the data from the tally sheet and put the numbers by vaccine type, age, and sex. This includes all people vaccinated including health care workers, IDPs, people with underlying conditions and others)

Vaccine logistics

- Complete the vaccine logistic information as follows
- Doses Received: - Write the number of doses Received for the vaccination session
- Stock at hand: - Write the number of doses available in the stock
- Open Vial Wasted: - Write the number of open vials wasted
- Closed Vial Wasted: - Write the number of closed vials wasted

Reporting on any adverse events following immunization (AEFI)

If there have been any adverse events following immunization during the session, the health care provider should compile from the tally sheet accordingly. But, if there is any serious adverse event, it should be reported immediately.

After completing both sections of the form, send the reporting form in the same day to the next administrative level. Remember to put the date and your name in the space provided at the bottom.

*NB. The health worker should ensure that all fields in the daily reporting form are filled appropriately before sending to the next level.

COVID-19 Vaccination daily Reporting Form

Region_____ **Zone**_____ **Wereda**_____ **PHCU**_____
Date of Vaccination____/____/____ **Report Compiled by**_____ **Report Approved by**_____

COVID-19 Vaccine Doses Administered by Age, Sex and Vaccine Type

(Summarized the data from the tally sheet and put the numbers by vaccine type, age, and sex. This includes all people vaccinated including health care workers, IDPs, people with underlying conditions and others)

Doses administered	12-17 Years		18-64 Years		>= 65 Years		*Health Workers*	*IDPs*	*Refugee*	*People with medical condition*	*People with disability*
	Male	Female	Male	Female	Male	Female					
AstraZeneca 1st dose given											
AstraZeneca 2nd dose given											
AstraZeneca booster dose given											
Johnson & Johnson 1st dose given											
Johnson & Johnson booster dose given											
Pfizer 1st dose given											
Pfizer 2nd dose given											
Pfizer booster dose given											
Mix-Match dose given											
Sinopharm 1st dose given											
Sinopharm 2nd dose given											
Sinopharm booster dose given											

Vaccine Supply

Vaccine Type	Doses received	Open Vial Wasted (in dose)	Closed Vial wasted (in dose)	Stock at Hand
AstraZeneca				
Sinopharm				
Johnson and Johnson				
Pfizer				

Adverse Effect Following Immunization (AEFI)

Vaccine Type	Serious AEFI	Non-Serious AEFI
AstraZeneca		
Sinopharm		
Johnson and Johnson		
Pfizer		

- **AEFI line listing, reporting/notification, and investigation forms:** AEFI forms, such as, line listing, notification, and investigation forms are printed and universally distributed to all levels, including immunization sites as appropriate. Those forms are developed to be used for recording, reporting, and investigation of all COVID 19 vaccine related AEFIs. Paper based and electronic reporting of AEFI is explained in the Vaccine Safety section of this manual

DHIS2 aggregate reporting module

DHIS2 aggregate reporting module is the primary reporting tool for COVID-19 vaccination data. Aggregated data from each vaccination site will be compiled and entered to DHIS2 on daily basis. Data will be accessible to use by higher level structure based on the defined user privilege. (Refer the DHIS2 training manual fordetails)

ALL COVID-19 VACCINATION DATA SHOULD BE CAPTURED IN THE DHIS2 SYSTEM

Who updates:- PHCU/Wereda Health Information Technician or EPI focal person who is trained on COVID-19 vaccination data reporting using DHIS2

Where to Keep:- The DHIS2 COVID-19 vaccination data reporting system is a web-based system designed to collect an aggregate data based on the daily reporting format. The data should be kept at the health facility or Wereda health office

When to use:- Daily in the PHCU or Wereda health office where the DHIS2 system is implemented

8.3. COVID-19 Vaccination campaign monitoring

Brainstorming

What makes mass campaign vaccination different from the routine vaccination?

When should we monitor campaigns?

COVID-19 vaccination campaign is one of the strategies in COVID-19 vaccination delivery.

COVID-19 vaccination campaigns should be monitored during:-

- Pre campaign phase
- Intra Campaign phase
- Post Campaign phase

Pre-Campaign monitoring:- campaign readiness assessment tool (RAT) will be implemented at national regional and Woreda level to assess campaign readiness status of all levels. The Readiness assessment tool includes planning and coordination, cold chain and logistics management, demand generation and communication, training and monitoring and evaluation components. Data from RAT will be analysed, visualized, and shared with regions, partners and other stakeholders for timely action and preparation.

Intra-Campaign monitoring:- intra-campaign team monitoring checklist will be applied during the campaign to monitor and take on site action based on identified gaps. The data will be collected using ODK tool and visualized in Power BI dashboard for visibility and tracking of urgent issues. Regional, zonal and Woreda level taskforces shall meet every day to discuss performance, identify challenges and sharing of experiences.

Post Campaign monitoring:- Post campaign administrative and technical report will be prepared by Zone, Region, and National EPI unit to document achievements, challenges, and best practices for future planning.

8.4. Review meetings

COVID-19 vaccination review meetings shall be conducted at all levels (woreda, zone, region, national). National, regional, zonal and Woreda level officials, program managers, partners and other stakeholders will participate in the review meeting. The review meeting will be used to share best experiences, identify challenges, and discuss way forwards.

8.5. Supportive Supervision

Supportive supervisions will be conducted on quarterly basis by all levels to identify gaps and provide technical support at all levels on a regular basis. Both integrated and COVID-19 vaccination specific supportive supervision checklists shall be used to all levels to standardize the supportive supervisions. Hard copy and digital checklist will be used to collect and analyze the supportive supervision data. Findings from the supportive supervision will be summarized and shared to lower levels.

8.6. Evaluation of COVID-19 vaccine rollout

Brainstorming

What is Evaluation? What makes it different from Monitoring?

Evaluation refers to the systematic assessment of whether a project/program is achieving its stated goals and objectives as determined at the planning stage and/or the extent to which the program has resulted in the anticipated outcomes and impact among the target population.

The following evaluation methods will be implemented to assess the outcomes of COVID-19 vaccination

Programmatic post-introduction evaluation of COVID-19 vaccines (cPIE):- The purpose of a post-introduction vaccine evaluation is to evaluate the impact of the vaccine introduction on the country's immunization programme and to rapidly identify problems needing correction as vaccination expands in the country. The evaluation can not only lead to improvements in the implementation of the new vaccine and overall immunization programme but can also provide valuable lessons for other countries for future vaccine introductions.

In the context of COVID-19 vaccine introduction, the classical post-introduction evaluation will likely require adaptation, where multiple COVID-19 vaccine products are introduced or where products are targeted at different population groups.

Intra Action Review:- The process consists of a desk review followed by a discussion around a small number of pre-selected questions addressing key programmatic areas relevant to the country's vaccine introduction situation. Unlike cPIE, it relies on review of available routine monitoring data rather than new data collection. The aim of IAR is to identify lessons learned and actionable results to improve the COVID-19 vaccine roll- out.

Summary

- COVID-19 vaccination monitoring system is designed to measure equitable uptake and coverage over time by geography, and high-risk population groups
- Administrative reports , supportive supervisions, review meetings and surveys are the main monitoring and evaluation systems for COVID-19 vaccination
- Vaccination cards, immunization registers, tally sheets, AEFI forms, daily reporting formats and DHIS2 system are the main recording and reporting tools for COVID-19 vaccination monitoring
- Every single vaccination data should be recorded in the COVID-19 registration book, tally sheet and reported through the daily reporting form and DHIS2
- COVID-19 vaccination campaign should be monitored during the pre campaign, intra campaign and post campaign phases
- Core coverage, demand promotion, vaccine logistic , AEFI , surveillance and other system related indicators should be analysed and interpreted in regular basis for timely and evidence based decision making

Id. No. (from registration book) **መለያ ቁጥር**

_____

Passport No (Optional)/
የፓስፖርት ቁጥር

_____

Full Name/ **ሙሉ ስም**

_____

Age / **ዕድሜ** _____

Sex/ **ጾታ** _____

Occupation/ **ስራ**

_____

Region/ **ክልል** _____

Zone/Subcity/ **ዞን**_____

Woreda/ **ወረዳ** _____

Kebele/ **ቀበሌ** _____

Village/Got/ **ጎጥ**_____

Place of vaccination/ **የመከተቢያ ቦታ**

_____

Dose ዶዝ	Vaccine type የክትባቱ አይነት	Batch No. ባች ቁጥር	Date vaccinated E.C(G.C optional) የተከተቡበት ቀን	Next vaccination date E.C(G.C optional) ቀጣይ መከተቢያ ቀን
መጀመሪያ ዶዝ Dose 1				
ሁለተኛ ዶዝ Dose 2				
ማጠናከሪያ ክትባት Booster Dose				

ከኮሮና ቫይረስ በሽታ ለመጠበቅ አስፈላጊዉን የክትባት መጠን ይዉሰዱ።
You must take full doses of the vaccine to be protected; in line with the Vaccine type.

Annex II: COVID-19 Vaccination Register

COVID 19 Immunization Register

Region (1): **Zone (2):** **Woreda (3):** **Kebele: (4)** **Name of vaccination post/HF/IDP/Refugee: (5)**

S. N (6)	ID No.(7)	Full Name(8)	Age(9)	Sex(10)	Occupation (11) (Insert code nubmer indicated at the bottom)	Comorbidity (12) (insert code number indicated at the bottom)	Pregnant/ Lactating (13)	Others (14) (insert code number indicated at the bottom)	Village/Got/ Residence (15)	House No (16)	COV 1 (1st Dose)			COV 2 (2nd Dose)			Booster dose			Phone No. (26)
											Vaccine Name(17)	(DD/MM/YY)(18)	Batch No (19)	Vaccine Name (20)	(DD/MM /YY) (21)	Batch No (22)	Vaccine Name(23)	(DD/M M/YY) (24)	Batch No (25)	
1																				
2																				
3																				
4																				
5																				
6																				
7																				
8																				
9																				
10																				
11																				
12																				
13																				
14																				
15																				
16																				
17																				
18																				
19																				
20																				
21																				
22																				

Comorbidity codes: *1. Chronic heart disease 2. Hypertension 3 . Diabetic 4. Cancer 5. Hepatic failure 6 . Pulmonary diseases (COPD, Asthma, Severe Respiratory diseases, TB) 7 . Renal failure 8. Autoimmune diseases (SLE, Rheumatoid Arthritis) 9. Morbid obesity 10. HIV/AIDS 11. Mental illness .*

Occupation codes: *- 1. Health Care Workers 2. Security workers 3. Teachers 4. Bank workers 5. Others*

Others codes: *- 1 People with disability, 2. IDP 3. Prisoner, 4.Refuge*

Annex III:- COVID-19 Vaccination Tally sheet

E. TALLY SHEET FOR COVID 19 VACCINATION (Routine and Campaign)

Region: _________ Zone: _________ Woreda: _________ Kebelle: ______________ Name of vaccination post/HF: ____________

Date of vaccination: ______/____/_____

- Use a separate tally sheet for each vaccine type and each vaccination session
- Tally ALL vaccinations given to ALL population including special population groups by age and sex disaggregation, then Tally number of special population groups (Health workers, IDPs, refugees, people with disability and people with medical condition) vaccinated out of the total vaccination

Vaccine Type _______________________

Dose	Age 12-17		Age 18-64		Age ≥ 65 years		*Special population groups*				
							Health Workers	**IDPs**	**Refugee**	**People with medical condition**	**People with disability**
	Female	*Male*	*Female*	*Male*	*Female*	*Male*					
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
First Dose	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	*Total*_____	*Total*_____	*Total*_____	*Total*_____	*Total*_____	*Total*_____	*Total*_____	*Total*_____	*Total*_____	*Total*_____	*Total*_____

Second Dose	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	Total_____	*Total_____*	*Total_____*	*Total_____*	*Total_____*	*Total_____*	*Total_____*	*Total_____*	*Total_____*	*Total_____*	*Total_____*
Booster dose	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000	00000
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	Total_____	*Total_____*	*Total_____*	*Total_____*	*Total_____*	*Total_____*	*Total_____*	*Total_____*	*Total_____*	*Total_____*	*Total_____*
Mix-Match dose	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	00000	00000	00000	00000	00000	00000					
	Total_____	*Total_____*	*Total_____*	*Total_____*	*Total_____*	*Total_____*					

	Vaccine Supply						
	Doses Received	**Open Vial Wasted (in dose)**					
	Stock at Hand	**Closed Vial Wasted (in dose)**					

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Annex IV: COVID-19 Vaccination Daily Reporting Form

COVID-19 Vaccination daily Reporting Form

Region_____ **Zone**_____ **Woreda**_____ **PHCU**_____

Date of Vaccination____/_____/____ **Report Compiled by**_____ **Report Approved by**_____

COVID-19 Vaccine Doses Administered by Age, Sex and Vaccine Type

(Summarized the data from the tally sheet and put the numbers by vaccine type, age, and sex. This includes all people vaccinated including health care workers, IDPs, people with underlying conditions and others)

Doses administered	12-17 Years		18-64 Years		>= 65 Years		*Health Workers*	*IDPs*	*Refugee*	*People with medical condition*	*People with disability*
	Male	Female	Male	Female	Male	Female					
AstraZeneca 1st dose given											
AstraZeneca 2nd dose given											
AstraZeneca booster dose given											
Johnson & Johnson 1st dose given											
Johnson & Johnson booster dose given											
Pfizer 1st dose given											
Pfizer 2nd dose given											
Pfizer booster dose given											
Mix-Match dose given											
Sinopharm 1st dose given											
Sinopharm 2nd dose given											
Sinopharm booster dose given											

Vaccine Supply

Vaccine Type	Doses received	Open Vial Wasted (in dose)	Closed Vial wasted (in dose)	Stock at Hand
AstraZeneca				
Sinopharm				
Johnson and Johnson				
Pfizer				

Adverse Effect Following Immunization (AEFI)

Vaccine Type	Serious AEFI	Non-Serious AEFI

Health facility (or vaccination centre) name:					
Name of Vaccines Received	***Date of vaccination***	***Time of vaccination***	Dose (e. g. 1st, 2nd, etc.)	***Batch/ Lot number***	Expiry date

Adverse event (s):

☐ Severe local reaction ☐ *>3 days* ☐ *beyond nearest joint*

☐ Seizures ☐ *febrile* ☐ *afebrile*

☐ Abscess

☐ Sepsis

☐ Encephalopathy

☐ Toxic shock syndrome

☐ Thrombocytopenia/bleeding disorder

☐ Anaphylaxis

☐ Fever≥38°C

☐ Other (specify).....

Date & Time AEFI started (DD/MM/YYYY):__ __ / __ __ / __ __ __ __☐☐Hr☐☐Min

Was the patient hospitalized? ☐Yes ☐No

Date patient notified event to health system (DD/MM/YYYY):

__ __ / __ __ / __ __ __ __

Describe AEFI (Signs and symptoms) including and medical measures taken elsewhere; it could be traditional or modern:

Outcome:

☐ Recovering ☐Recovered ☐ Recoveredwith sequelae ☐Not Recovered ☐Unknown

☐Died If died, date of death (DD/MM/YYYY):__ __ / __ __ / __ __ __ __Autopsy done: ☐Yes ☐No ☐Unknown

Past medical history (including history of similar reaction or other allergies), concomitant medication and other relevant information (e.g. other cases). *Use additional sheet if needed:*

First Decision making level to complete:

Annex VI: - Micro planning template

										Name of Kebele
										# Of HP **Total population**
										1st dose
										2nd dose
										Booster
										total # of vaccination team
										# Of team supervisor
										# Of coordinator
										# Of vaccinator
										# volunteer
										Vaccine in dose
										AD syringe (target popn*1.05)
										Safety Box (AD syringe* 100/1.05)
										# of refrigerator
										# of Cold box (1 per supervisor)
										# of vaccine carrier (1 per team)
										# of Ice pack 4 per Vaccine carrier
										# of adrenaline (2 per team)
										Sanitizer
										Face mask
										# of Vaccination card
										# of register
										# of tally sheet
										# of AEFI line list
										# AEFI reporting format

Target population

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