

UNITED REPUBLIC OF TANZANIA



**MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY
AND CHILDREN**

GUIDELINES FOR COVID-19 VACCINATION

VERSION ONE

JULY 2021

Foreword

Coronavirus disease (COVID-19) has caused millions of deaths with increasing number of recorded cases on daily basis globally. The health care systems in most countries has been stretched beyond their capacity, causing their paralysis. Though people with comorbidities and the elderly are most affected, younger people are also affected due to emergence of new SARS-CoV-2 variants of concern such as the alpha, beta, gamma and delta variants which are more transmissible and virulent than the Wuhan-Hu-1 strain.

The impact of COVID-19 pandemic economically, socially and culturally has been vivid in many countries. Tanzania like other countries has also been affected economically and socially, and has experienced three waves of the disease since its first recorded case in March 2020.

Despite various control measures and strategies taken by different countries as advocated by WHO, vaccination has proven to be effective in reduction of disease severity, hospitalization and deaths, especially in countries that have introduced COVID-19 vaccines and vaccinated a large number of its population.

The Government is in the process of introducing COVID-19 vaccines starting with health care workers, adults aged 45 years and above, people with comorbidities aged 18 years and above, special groups like pilgrims, international travellers and UN staff, non-residents and diplomats.

The guidelines have been developed to provide guidance on the provision of COVID-19 vaccines in the country and will be revised from time to time as need arises.

It is my expectation that users may find it useful and the Ministry will revise it on regular basis depending on the need.



Prof. Abel N. Makubi

Permanent Secretary

ACKNOWLEDGEMENT

The development of the Guidelines for Covid-19 Vaccination was possible through the commitment and dedication offered by officers from the Ministry of Health, Community development, Gender, Elderly and Children (MOHCDGEC) and other stakeholders.

On behalf of the management of the MOHCDGEC, I would like to extend my appreciation to the leadership of Dr. Leonard Subi, the Director of Preventive Services and coordinator of the vaccine pillar, for his guidance during the entire period of development of this guideline. Secondly, I wish to acknowledge for a tireless leadership and stewardship shown by Mr. Ngwegwe Bulula, the Program Manager for Immunization and Vaccine Development (IVD) Program and his team, specifically Dr. Furaha Kyessi and Dr. Mwendwa Mwenesi for their valuable contributions towards the completion of this work.

The Ministry would also like to acknowledge the inputs and comments provided by members of the pillars of the COVID-19 Response, Dr. Michael Kiremeji, Dr. Angela Samwel, Dr. Azma Simba, Mr. Daudi Msasi and other members, for their comments and refining of these guidelines.

The development of this guidelines was possible through a financial support from immunization group of partners, which include the World Health Organization (WHO) United Children's Fund (UNICEF) and Clinton Health Access Initiative (CHAI). The Ministry would like to acknowledge and thank for their highly needed support.

Lastly, I value all contributions provided by the members of the National Immunization Technical Advisory Group lead by Prof. Stephen Mshana, and immunization technical officers from IVD Technical Working Group (TWG) and some of the members of the National Taskforce team.



Dr. Aifello W. Sicalwe
Chief Medical Officer

ABBREVIATIONS

AEFI	Adverse Events Following Immunization
NIS	National Immunization Strategy
CHMT	Council Health Management Team
CVS	Central Vaccine Store
CHAI	Clinton Health Access Initiative
DMO	District Medical Officer
DTP	Diphtheria Tetanus Pertussis
COVID-19	Coronavirus Disease 2019
GAVI	Global Alliance on Vaccine Immunization
GNI	Gross National Income
GPSA	Government Procurement Services Authority
IEC	Information Education and Communication
IPC	Infection and Prevention Control
ITN	Insecticides Treated Nets
ICC	Inter-Agency Coordinating Agency
IMCI	Integrated Management of Childhood Illnesses
IVD	Immunization and Vaccine Development program
MSD	Medical Stores Department
NITAG	National Immunization Technical Advisory Group
NTF	National Task Force Team
PMTCT	Prevention of Mother to Child Transmission
PIE	Post Introduction Evaluation
RHMT	Regional Health Management Team
RMO	Regional Medical Officer
RTM	Remote Monitoring Devices
TMDA	Tanzania Medicines and Medical Devices Authority
UNICEF	United Nations Children's Fund
WHO	World Health Organization
WICR	Walk In Cold Room

Table of Contents

FOREWORD	II
ACKNOWLEDGEMENT.....	III
ABBREVIATIONS	IV
LIST OF FIGURES.....	VIII
LIST OF TABLES	VIII
1.0 INTRODUCTION.....	1
1.1 BACKGROUND INFORMATION	1
1.2 IMMUNIZATION SERVICES IN TANZANIA.....	2
1.3 OVERVIEW OF CORONAVIRUS DISEASE 2019.....	4
1.4 TYPES OF COVID-19 VACCINES.....	5
1.4.1 INACTIVATED VACCINES:	7
1.4.2 PROTEIN SUBUNIT VACCINES:	7
1.4.3 ADENOVIRUS VECTOR VACCINES:.....	7
1.4.4 MRNA VACCINES:	7
2.0 PLANNING AND COORDINATION FOR COVID-19 VACCINATION	8
2.1 NATIONAL COORDINATION TO DISASTERS AND EMERGENCIES	8
2.2 NATIONAL COORDINATION TO COVID-19 VACCINATION	9
2.2.1 INTER-AGENCY COORDINATING COMMITTEE (ICC).....	9
2.2.2 IVD TECHNICAL WORKING GROUP	9
2.2.3 NATIONAL IMMUNIZATION TECHNICAL ADVISORY GROUP.....	9
2.3 REGIONAL AND COUNCIL COORDINATION	10
2.3.1 EXTENDED RHMTs AND CHMTs	10
2.3.2 NATIONAL TECHNICAL COORDINATORS FOR THE REGIONS	11
2.3.3 REGION HEALTH MANAGEMENT TEAM	12
2.3.4 COUNCIL HEALTH MANAGEMENT TEAM.....	14
2.4 HEALTH FACILITY COORDINATION.....	17
2.4.1 HEALTH FACILITY GOVERNING COMMITTEE	17
3.0 VACCINATION DELIVERY STRATEGY	19
3.1 TARGET GROUPS FOR VACCINATION	19
3.2 COVID-19 VACCINE SELECTION PREFERENCES	19

3.3	VACCINATION DELIVERY STRATEGY, TACTICS AND PROPOSED VACCINATION SITES...	20
3.3.1	VACCINATION DELIVERY STRATEGY AND TACTICS	20
3.3.2	VACCINE ACQUISITION IN THE COUNTRY	21
3.3.3	VACCINATION OF INTERNATIONAL TRAVELLERS	21
3.3.4	VACCINATION OF UN STAFF AND DIPLOMATS	21
3.3.5	VACCINATION OF NON-RESIDENTS	22
4.0	REGULATORY PREPAREDNESS.....	23
4.1	REGULATION OF VACCINES	23
4.2	EMERGENCY USE REGULATORY PROCEDURES.....	23
4.3	PATHWAYS FOR EMERGENCY REGULATORY APPROVAL.....	24
4.4	FACILITATIVE IMPORT PROCEDURES AND EXPEDITED LOT/BATCH RELEASE OF COVID-19 VACCINES.....	25
4.5	TRACEABILITY OF VACCINES IN THE CONTEXT OF COVID-19 PANDEMIC.....	25
5.0	SUPPLY CHAIN MANAGEMENT, COLD CHAIN AND LOGISTICS	26
5.1	PROCUREMENT.....	26
5.2	DONATION OF COVID-19 VACCINES	27
5.3	IMPORTATION PROCEDURES FOR COVID-19 VACCINES.....	27
5.3.1	SPECIAL PERMIT APPLICATION PROCEDURES	28
5.3.2	ADVISE TO IMPORTING INSTITUTIONS	29
5.4	VACCINATION SERVICE DELIVERY	29
5.5	CUSTOMS CLEARANCE	30
5.6	VACCINE STORAGE.....	31
5.6.1	STORAGE REQUIREMENT/CONDITIONS FOR EACH VACCINE	31
5.7	ESTIMATING VACCINE NEEDS AND STORAGE CAPACITY	33
5.7.1	ESTIMATING VACCINE NEED.	33
5.7.2	ESTIMATING COLD CHAIN STORAGE SPACE REQUIREMENT	33
5.8	DISTRIBUTION AND LOGISTICS MONITORING	35
5.9	INVENTORY MANAGEMENT	36
6.0	HUMAN RESOURCE AND TRAINING.....	37
6.1	HUMAN RESOURCE	37
6.2	TRAINING PLAN	37
7.0	VACCINE ACCEPTANCE AND UPTAKE	38
8.0	VACCINE ADMINISTRATION	40
8.1	REGISTRATION OF CLIENT'S/VACCINATION RECIPIENTS	40

8.2	ADMINISTRATION OF CONSENT FORMS.....	40
8.3	OCCUPATIONAL HEALTH AND SAFETY.....	41
8.4	VACCINE ADMINISTRATION PROCEDURES.....	41
9.0	DATA MANAGEMENT TOOLS.....	44
9.1	VACCINATION REGISTERS.....	44
9.2	TALLY SHEETS.....	44
9.3	VACCINATION CARDS.....	44
9.4	DAILY AND MONTHLY VACCINATION REPORTS.....	44
9.5	VACCINE MANAGEMENT INFORMATION SYSTEM.....	45
10.0	VACCINE SAFETY MONITORING, MANAGEMENT OF AEFI, AND INJECTION SAFETY.....	46
10.1	AEFI SURVEILLANCE.....	46
10.2	AEFI DETECTION.....	47
10.3	AEFI DOCUMENTATION.....	47
10.4	AEFI REPORTING FLOW.....	47
10.5	EVENT BASED SURVEILLANCE – EBS.....	51
10.6	COVAX NO-FAULT COMPENSATION PROGRAM.....	51
11.0	WASTE MANAGEMENT AND DISPOSAL.....	52
11.1	SAFE DISPOSAL OF INJECTION MATERIALS.....	52
11.2	HANDLING AND DISPOSAL OF SAFETY BOXES.....	52
11.3	IMMUNIZATION WASTES DISPOSAL AT POSTS IN URBAN AREAS.....	53
11.4	DISPOSAL OF OTHER IMMUNIZATION WASTES.....	53
12.0	MONITORING AND EVALUATION.....	54
13.0	ANNEXES.....	55
13.1	ANNEX 1: CONSENT FORM.....	55
13.2	ANNEX 2 (A): COVID-19 TALLY SHEET WITH HCW.....	56
13.3	ANNEX 2 (B): COVID-19 TALLY SHEET WITHOUT HCW.....	57
13.4	ANNEX 3: COVID-19 CLIENT VACCINATION CARD.....	58
13.5	ANNEX 4: KEY VACCINE SAFETY DEFINITIONS AND THEIR IMPLICATIONS IN THE COVID-19 CONTEXT.....	60
13.6	ANNEX 5 (A): HEALTH FACILITY DAILY REPORT.....	64
13.7	ANNEX 5 (B): HEALTH FACILITY MONTHLY REPORT.....	66
13.8	ANNEX 6: DISTRICT DAILY/MONTHLY REPORT.....	68
13.9	ANNEX 7: COVID-19 VACCINATION NATIONAL PERIODIC REPORT.....	70

List of figures

Figure 1: Map of The United Republic of Tanzania.	1
Figure 2: Policy Level Coordination	8
Figure 3: Tanzania AEFI reporting -routing, timelines and action	48
Figure 4: Tanzania AEFI surveillance cycle	50

List of tables

Table 1: Projected Trends of Population Growth in Tanzania.....	2
Table 2: Routine Immunization Schedule in Tanzania.....	3
Table 3: Types of COVID-19 vaccines	6

1.0 INTRODUCTION

1.1 Background Information

The United Republic of Tanzania is a union between Tanzania Mainland and Zanzibar. It is the largest country in East Africa occupying a surface area of about 945,087 km² with a projected population of about 60 million people. Tanzania mainland is divided into 26 regions (**Figure 1**) and 184 councils. Approximately 75% of the population resides in rural areas. The health system is organized in a pyramidal structure, with tertiary health facilities at the top and the primary health facilities at the base. Tanzania has recently been classified as a lower-middle-income country with a gross national income (GNI) per capita of 1,080 USD, and is one of the fastest growing population in Africa (Table 1).

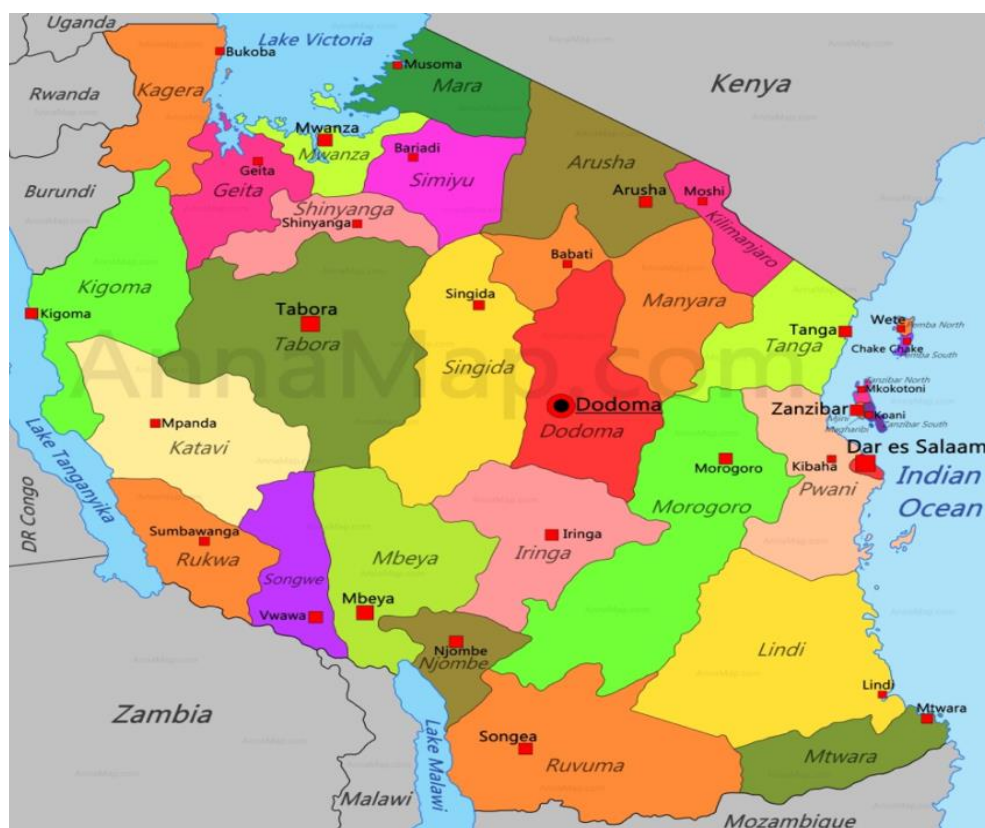


Figure 1: Map of The United Republic of Tanzania.

Table 1: Projected Trends of Population Growth in Tanzania

	2020	2021	2022	2023
Total Population	57,637,628	59,441,988	61,280,743	63,150,477
Total under <15 yrs	24,984,932	25,652,960	26,367,472	27,048,131
15 - 49 years	27,289,943	28,417,503	29,006,123	30,079,782
50 years and above	5,362,753	5,371,525	5,907,148	6,022,564

Source: NBS Population Projection Report - 2013 to 2035

1.2 Immunization services in Tanzania

Routine immunization services in the country for children under five years of age, woman of child bearing age, pregnant women and girls aged 9-14 years of age, are provided free of charge countrywide in both public and private health. There is no significant geographical, economic, policy, cultural, gender and social barriers to immunization. The Constitution of The United Republic of Tanzania amended in 1984 to provide for the Bill of Rights. Article 14 of the Bill of Rights stipulates that every person has a right to life and to the protection of life by society which include immunization.

The routine immunization services are managed and coordinated by the Immunization and Vaccine Development (IVD) Program. IVD Program is under Reproductive and Child Health Section of the Directorate of Preventive Services of the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC). At subnational level, IVD works with the Regional and Council Health Management Teams (RHMT & CHMT), which are under the Regional and District Medical Officers (RMOs & DMOs), respectively. The Regional and District Immunization and Vaccination Officers (RIVOs & DIVOs) at the regional and district level are immunization focal persons, responsible for coordination and implementation and of all immunization activities

At service delivery level, Public Health Nurses (PHN) are responsible for provision of immunization services. Immunization services are integrated with other child survival and adolescent health interventions such as integrated management of childhood illnesses (IMCI), Vitamin A, deworming, prevention of mother to child transmission (PMTCT), insecticide-treated nets (ITNs), School Health Programme and Focused Guidelines for COVID-19 Vaccination

Antenatal Care. A total of 6,777 health facilities (87% of the total number of facilities) provide immunization services and about 80% of the population lives within five (5) kilometres of a primary health facility.

There are currently nine antigens for prevention of thirteen vaccine-preventable diseases (VPDs), since the establishment of immunization program in 1975 (Table 2). In addition, the MoHCDEG through Epidemiology Section provides yellow fever vaccines for international travellers and Hepatitis B vaccine to health care workers at ports of entry or regional referral hospitals and other designated health facilities.

Table 2: Routine Immunization Schedule in Tanzania

Antigen	Timing
BCG, OPV 0	At birth or first contact
OPV1, DTP-HepB-Hib1, PCV 1, Rota 1	6 Weeks of age
OPV2, DTP-HepB-Hib2, PCV 2, Rota 2	10 Weeks of age
OPV3, DTP-HepB-Hib3, PCV3, IPV	14 Weeks of age
MR 1	9 months of age
MR 2	18 months of age
TT/Td 1	First contact
TT/Td 2	1 Month after the 1st dose
TT/Td 3	6 months after the 2nd dose
TT/Td 4	1 Year after the 3rd dose
TT/Td 5	1 Year after the 4th dose
HPV 1	14 years
HPV 2	6 months after 1st dose

1.3 Overview of Coronavirus Disease 2019

Coronavirus disease 2019 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The COVID-19 outbreak was first reported in Wuhan, China and was declared a Public Health Emergency of International Concern (PHEIC) in January 30, 2020. The World Health Organization (WHO), as of 11:30am CEST, 12th July 2021, has reported a total of 186,411,011 confirmed cases and 4,031,725 deaths globally¹. The disease has continued to affect all countries around the world impacting health, economies and social functionality of communities around the World. African countries have also been affected by the pandemic which cost many lives, economies and social functionality of communities.

Tanzania has also been impacted by the COVID-19 epidemic both economically and socially with the first case reported on 16th March, 2020. The country has experienced three waves of the epidemic, with an increased impact of subsequent waves.

Several efforts and strategies have been advocated and implemented to control the pandemic by countries, including adherence to infection prevention control (IPC) protocols by health care workers, physical distancing, wearing of face masks, hand hygiene and vaccination, but vaccination has proven to be one of effective strategy to control the pandemic. Studies have indicated that countries like UK, Israel and Qatar with reported increasing population vaccination coverage for COVID-19, had notable impact in reducing symptomatic infection, disease severity, hospitalization and deaths among vaccinated individuals even in the settings with emerging variants compared to unvaccinated population.²⁻⁶

¹ WHO Coronavirus (Covi-19) Dashboard: covid19.who.int

² Haas et al 2021. Impact and effectiveness of mRNA BNT162b2 vaccine against SARS-CoV-2 infections and COVID-19 cases, hospitalizations, and deaths following a nationwide vaccination campaign in Israel: an observational study using national surveillance data. *Lancet* DOI: [https://doi.org/10.1016/S0140-6736\(21\)00947-8](https://doi.org/10.1016/S0140-6736(21)00947-8),

³Bernal et al 2021. Early effectiveness of COVID-19 vaccination with BNT162b2 mRNA vaccine and ChAdOx1 adenovirus vector vaccine on symptomatic disease, hospitalisations and mortality in older adults in England. *medRxiv* preprint doi: <https://doi.org/10.1101/2021.03.01.21252652>

⁴Pritchard et al 2021. Impact of vaccination on new SARS-CoV-2 infections in the UK. *medRxiv* preprint doi: <https://doi.org/10.1101/2021.04.22.21255913>

⁵Public Health England 2021.

⁵https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/977249/PHE_COVID-19_vaccine_impact_on_mortality_March.pdf

⁶Abu-Raddad, Chemaitelly, Butt, 2021. Effectiveness of the BNT162b2 Covid-19 Vaccine against the B.1.1.7 and B.1.351 Variants DOI: 10.1056/NEJMc2104974

Tanzania, like any other country in the world, considers immunization as one of the components to control the pandemic. Implementing the disease control measures is important to ensure restoration of community wellbeing. Introduction of COVID-19 vaccine will benefit the population by preventing people from getting seriously ill or dying from COVID-19. This will supplement to the main COVID-19 control interventions; physical distance, use etiquette, frequently hand hygiene, wearing a mask and conducive environmental factors.

Introduction of COVID-19 vaccine in Tanzania is in line with the National COVID-19 Response Plan which recommends the use of COVID-19 vaccine as part of preventive measures against COVID-19 pandemic. This is due to increase in morbidity and mortality due to COVID-19, inadequate capacity for the country to handle severe and critical cases, emergence of new viral variants and as part of the global response. But also, the introduction of COVID-19 in the immunization services is in line with the National Immunization Strategy (NIS) of Tanzania 2021 to 2025. COVID-19 vaccine management in the country will follow the existing vaccination mechanisms.

While there are several COVID-19 vaccines under development and use, the country will only use COVID-19 vaccines that have been approved and registered by Tanzania Medicines and Medical Devices Authority (TMDA).

1.4 Types of COVID-19 Vaccines

There are four types of COVID-19 vaccines; inactivated, protein sub-unit, Adenovirus vector and mRNA vaccines (Table 3). With the exception of the inactivated vaccines which utilize the whole virus, the rest of the COVID-19 vaccines are based on the SARS-CoV-2 spike (S) protein. The spike (S) protein (particularly in its prefusion [native] conformation) is the immunodominant antigen of the virus that elicits neutralizing antibodies against the virus.

Table 3: Types of COVID-19 vaccines

Types of COVID-19 Vaccines				
	Inactivated	Protein Subunit	Adenovirus Vector	mRNA
Examples of COVID-19 vaccines	Sinopharm Sinovac	Novavax	Janssen AstraZeneca Sputnik V	Pfizer-BioNTech Moderna
Mechanism	Contains a chemically-inactivated version of the whole SARS-CoV-2 virus	Contains a purified SARS-CoV-2 S protein produced using cells in the laboratory	Uses a harmless altered Adenovirus to deliver genetic information of the SARS-CoV-2 S protein ³	Synthetic mRNA containing genetic information of the SARS-CoV-2 S protein
Route of administration	Intramuscular (deltoid muscle; upper left arm)	Intramuscular (deltoid muscle; upper left arm)	Intramuscular (deltoid muscle; upper left arm)	Intramuscular (deltoid muscle; upper left arm)
Dose volume	Sinopharm: 0.5 ml Sinovac: 0.5 ml	0.5 ml	Janssen: 0.5 ml AstraZeneca: 0.5 ml Sputnik V: 0.5 ml	Pfizer: 0.3 ml Moderna: 0.5 ml
Number of doses	Sinopharm: 2 doses, 21 to 28 days apart Sinovac: 2 doses, 28 days apart	2 doses, 21 days apart	Janssen: 1 dose AstraZeneca: 2 doses, 28 days apart Sputnik V: 2 doses, 21 days apart	Pfizer: 2 doses, 21 days apart Moderna: 2 doses, 28 days apart
Storage	Sinopharm: 2 to 8 °C for 24 months Sinovac: 2 to 8 °C for 36 months	2 to 8 °C for 6 months	Janssen: 2 to 8 °C for 3 months; 25 °C for 12 hours AstraZeneca: 2 to 8 °C for 6 months; 25 °C for 6 hours Sputnik V: ready to use solution -20 °C for 6 months; Freeze-dried powder at 2 to 8 °C for 6 months	Pfizer: -80 °C for 6 months; 2 to 8 °C for 31 days; 25 °C for 2 hours Moderna: -20 °C for 6 months; 2 to 8 °C for 30 days; 25 °C for 2 hours
Other vaccines	HPV/cervical cancer (virus-like particles) Whooping cough Hepatitis A Rabies	Hepatitis B	Ervebo (rVSV-ZEBOV) Ebola vaccine that uses vesicular stomatitis virus vector	

³ Janssen: Adenovirus 26 (Ad26) on both doses; AstraZeneca: chimpanzee adenovirus (ChAd) on both doses; Sputnik V: Adenovirus 26 (Ad26) in first dose and Ad5 in second dose.
Guidelines for COVID-19 Vaccination

1.4.1 Inactivated vaccines:

These are based on the creation of inactivated viruses derived from virus grown in culture that are afterwards chemically inactivated. These vaccines deliver stably expressed and conformational native antigenic epitopes that elicit the production of neutralizing antibodies against the virus. Examples of COVID-19 inactivated vaccines are those manufactured by Sinopharm and Sinovac by growing the virus in Vero cells.

1.4.2 Protein Subunit Vaccines:

These vaccines deliver the S protein as a recombinant protein sub-unit within one of several cell-based systems that support protein expression. In turn, the body produces neutralizing antibodies against the virus. Examples of COVID-19 inactivated vaccines are those manufactured by Novavax which has developed a sub-unit vaccine delivered using the saponin-based Matrix-M adjuvant.

1.4.3 Adenovirus vector vaccines:

Adenoviral vector vaccines use replication-deficient viruses engineered to contain the genetic sequence of the SARS-CoV-2 S protein, in order to express the S protein in host cells. Once expressed, the body produces neutralizing antibodies against S protein which prevent virus infection. Examples of COVID-19 vector vaccines carrying the S protein include Ad26.CoV2. S vaccine by Johnson & Johnson (based on Adenovirus serotype 26 vector), ChAdOx vaccine by AstraZeneca (based on chimpanzee adenovirus vector) and Sputnik V by Gamaleya Research Institute (based on Adenovirus serotype 26 in the first dose and Adenovirus serotype 5 in the second dose).

1.4.4 mRNA Vaccines:

In these vaccines, lipid nanoparticles are used to deliver the S protein-encoding mRNA into the cytoplasm of the cell. Since the delivered mRNA does not enter the nucleus where the human genetic is stored, the vaccine cannot alter our genetic material (DNA). The host uses the delivered mRNA to make the S protein, which induces a coordinated immune response against the virus. Pfizer-BioNTech (BNT162b2) and Moderna (mRNA-1273) have developed mRNA-based vaccines. The mRNA vaccines can be manufactured in weeks and could be easily tailored to deliver mRNA coding for viral variants.

2.0 PLANNING AND COORDINATION FOR COVID-19 VACCINATION

2.1 National Coordination to Disasters and Emergencies

The GoT has established three coordination committees in response to COVID 19 outbreak, two at policy level constituting of National Task Force led by the Prime Minister and Inter-Ministerial Committee led by the Chief Secretary.

The Prime Minister's Office is responsible for overall National coordination and is leading the multi-sectoral National Task Force (NTF).

However, all technical guidance is through the Technical Task committee led by the Permanent Secretary (Health).

The CMO is designated to chair all technical meetings and is the overall coordinator of the country response to the pandemic.

Key roles of the committee, is to ensure the country contain the outbreak while ensuring essential health services are provided.

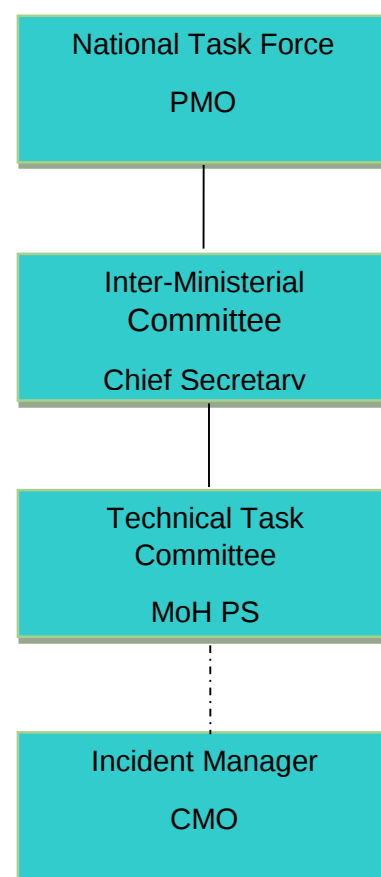


Figure 2. Policy level Coordination

Under the technical task committee, there are 10 pillars, including vaccine pillar responsible for COVID-19 vaccine introduction, with the CMO as the Incident Manager, and DPS as the coordinator of the vaccine pillar.

2.2 National Coordination to COVID-19 vaccination

2.2.1 Inter-Agency Coordinating Committee (ICC)

The ICC is the national coordination committee for immunization program under the chairmanship of the Permanent Secretary of Health and is responsible for policy, resource mobilization and endorsement of new vaccines introduction in the country. It composed of members from immunization partners such as WHO, UNICEF, PATH, CHAI, JSI, Senior officer from ministry of finance and planning, PORALG, TMDA, MSD, GPSA, and directors of preventive services, human resources, chief accountant and chief internal auditor of the MoHCDGEC.

2.2.2 IVD Technical Working Group

Under ICC, there is IVD Technical Working Group (TWG) made up of technical immunization officers from immunization partners, IVD and PORALG. The IVD-TWG provides recommendation to ICC on all matters pertaining to improvement of immunization services provision as well as new vaccine's introduction.

2.2.3 National Immunization Technical Advisory Group

The NITAG is an independent technical committee that advises the MoHCDGEC on immunization and vaccination related matters.

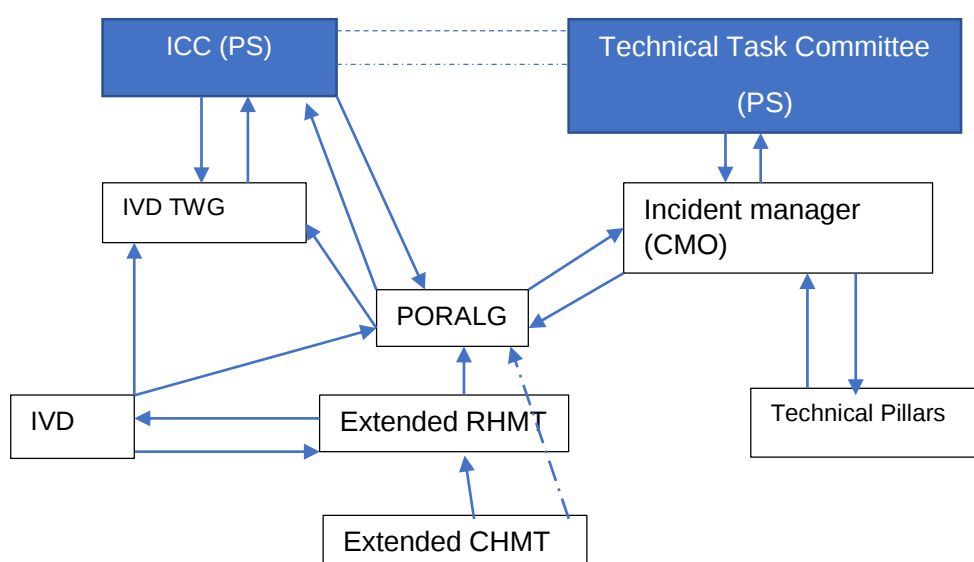


Figure 3. Immunization services coordination

Roles and Responsibilities

The MoHCDGEC through its IVD program in collaboration with the President's Office Regional Administration and Local Government Authority (PO-RALG) and Immunization Partners in the country will be responsible for overseeing the introduction of COVID-19 vaccination.

The national level is responsible for:

- i. Setting standards for the vaccination implementation guidelines and microplanning,
- ii. Advocacy and resource mobilization,
- iii. Setting standards for training, supervision, monitoring using standard tools and methods,
- iv. Training and supporting the development of micro plans,
- v. Ensuring the presence of adequate cold chain and logistics arrangement for vaccine storage, distribution and administration to the target population, and
- vi. Ensuring robust adverse events following immunisation (AEFI) surveillance, AEFI case management and causality assessment.

2.3 Regional and Council Coordination

2.3.1 Extended RHMTs and CHMTs

The Regional and District levels will closely coordinate preparedness and implementation of COVID-19 vaccination at their respective level, including:

- i. Development of macro/microplans and plan of action for the region,
- ii. Coordination and implementation of training, microplanning, supervision and monitoring,
- iii. Analysis and synthesis of microplans from Councils to guide appropriate strategies,
- iv. Distribution of vaccines and other supplies including IPC supplies,
- v. Social mobilization and communication to generate demands in the region,
- vi. Monitoring administrative vaccination data and logistics supplies at the operational level,
- vii. Monitoring and addressing vaccine hesitancy, and
- viii. Supervision of vaccination activities.

Roles and responsibilities of Regional/Council Health Management Teams

- Ensure there is a comprehensive Council/Health Facility micro plan in all councils/facilities in the region
- Ensure the Council Team conduct stakeholders meeting at the Council level to discuss on the implementation of COVID-19 vaccination
- Ensure the availability of vaccines, related supplies and cold chain and logistics materials
- Ensure the availability of protocol of handling rumors and providing statements in case AEFI occur to assure the public is discuss in the District PHC and Health facilities meetings
- Ensure the availability of AEFI report forms and emergency drugs for AEFI
- Ensure data are properly collected, compiled and shared to the next higher level on daily basis
- Ensure the availability and implementation of Advocacy and Social mobilization plan
- Support Council team to manage properly the financial resources provided for implementation COVID-19 vaccination
- Respond to any unforeseen issue that may raise during the implementation of COVID-19 vaccination

2.3.2 National Technical Coordinators for the Regions

The availability of COVID-19 vaccine will determine whether the routine, campaign or a mix of routine and campaign delivery mode will be used in the region during COVID-19 vaccination. In campaign delivery mode, each Region will have a National Technical Coordinator posted from MoHCDEGEC. The person must be Senior Health Worker preferably with previous experience in the organization and management of immunization activities.

Role and responsibility of National Technical Coordinator

- Support Regional Team to develop a comprehensive Regional micro plan
- Ensure there are regional maps showing all Councils and Health Facilities service areas
- Ensure the Council level implementation plans are displayed at the Region
- Ensure the availability of vaccines, cold chain and logistics materials
- As part of the Regional team, monitor and supervise implementation of Council Supervisors
- Ensure the personnel involved in the implementation are selected per criteria given
- Ensure the Council Supervisor and Vaccinators are health workers qualified to give injection
- Ensure the recorders are Extension Workers who can easily screen the age of children and record
- Ensure the availability of emergency drugs for AEFI in the region
- Ensure the protocol of handling rumours and providing statements in case AEFI occur to assure the public is discuss in the Regional and District PHC Meetings
- Monitoring and auditing all Adverse Events Following Immunisation (AEFI)
- Ensure the waste management plan is clear to all Council Supervisors and monitor the waste management at the implementation level
- Ensure data collection and compilation is done inclusive of daily report and shared among stakeholders and feedback provided using the data; use the administrative reports to ensure logistics supply is adjusted
- Support regional team to manage properly the financial resources provided for implementation of COVID-19 vaccination
- Support Regional Team to conduct the Regional level stakeholders meeting to discuss on COVID_19 vaccination

2.3.3 Region Health Management Team

Region Health Management Teams supported by immunization stakeholders and partners based in the regional level are responsible for developing regional macro plan, coordinate, supervise and monitor the planning and management of the implementation of the COVID-19 vaccination in their respective regions. The Regional Technical Team will work under guidance of the Regional Commissioner and Regional Administrative Secretary through Regional Primary Care Committee

Composition of Region Technical Team

1. Regional Medical Officer- Chairperson
2. Regional Administrative Secretary
3. Regional Immunization and Vaccine Officer
4. Regional Health Secretary
5. Regional RCH Coordinator
6. Regional Nursing Officer
7. Regional Health Officer
8. Regional Pharmacist
9. Regional Dental Surgeon
10. Regional Bureau of Statistics
11. Regional Nutrition Officer
12. Regional Education Officer

Regional Technical Coordinators

Each Council will have two Regional Technical Coordinators from the Regional Technical Team posted from the regional level to the Council. One must be a Senior Health Workers in the region or Tutors of schools of health technology/ nursing/ midwifery/ allied health training institutions in the region.

Role and responsibility of Regional Technical Coordinator

- Support Council Team to develop the comprehensive Council COVID-19 micro plan
- Support Council Team to conduct the Council level stakeholders meeting to discuss on COVID-19 vaccination
- Ensure there are **Council maps** showing all the Health Facility service areas, villages/streets, vaccination post fixed and temporary, roads with distance and population.
- Ensure the Health Facility service area level implementation plans are displayed at the Council Ensure the personnel involved in the implementation are selected per criteria given
- Ensure the Council Supervisor and vaccinators are health workers qualified to give injection
- Ensure the recorders are Extension Workers who can easily screen the age of children and record
- As part of the Council team, monitor and supervise implementation of Local Supervisors and Vaccination Teams
- Ensure the availability of vaccines, cold chain and logistics materials
- Ensure the protocol of handling rumors and providing statements in case AEFI occur to assure the public is discuss in the District PHC Meetings
- Ensure the availability of emergency drugs for AEFI
- Monitoring and auditing all AEFI
- Ensure the waste management plan is clear to all Local Supervisors and Vaccination Teams and monitor the waste management at the implementation level
- Data collection and compilation including sharing of reports to next higher level on daily basis
- Support Council team to manage properly the financial resources provided for implementation of COVID-19 vaccination

2.3.4 Council Health Management Team

Council Health Management team supported by other immunization stakeholders based in the district Council their main responsibility is to develop council micro plan, coordinate, supervise and monitor the planning and management of the implementation in the council. The District Technical Team will work under guidance of the District Commissioner and District Executive Director through District Primary Care Committee.

Composition of District Technical Team

District Medical Officer - Chairperson

District Immunization and Vaccine Officer

District Health Secretary

District RCH Coordinator

District Nursing Officer
District Health Officer
District Pharmacist
District Planning officer
District Educational Officer
District Nutritional Officer
District Social Welfare Officer

Council Supervisor

A cluster of vaccination post depending on the accessibility and terrain will have a Council Supervisor posted from the Council level. Such persons must be Senior Health Workers in the Council.

Role and responsibility of Council Supervisor

- Support the Health Facility in charge to conduct the stakeholders meeting to discuss on COVID-19 vaccination
- Supervise Vaccination Post Supervisor and Community Leaders to conduct house to house mobilization prior to implementation
- Ensure there is a **Health Facility service area map** showing all the villages, settlements/ streets, vaccination post, roads and population
- Ensure the Posts daily implementation plans are displayed at the Health Facility (movement of teams for each day)
- Ensure the hard to reach areas and priority group population are reached
- Ensure the Post vaccinators are health workers qualified to give injection
- Ensure the recorders are Extension Workers who can easily screen the age of children and record
- Ensure the availability of vaccines, cold chain and logistics materials
- Ensure the availability of emergency drugs for AEFI
- Monitoring and auditing all AEFI
- Ensure the waste management plan is clear to all Vaccination Teams and monitor the waste management at the ward level
- Monitor the collection of the waste (safety boxes) from the wards to the burn and bury areas every day.
- Monitoring and supervision of the implementation
- Data collection and compilation and sharing of daily report to the next higher level
- To attend daily implementation meetings at District level
- Ensure there is proper supervision and administration of the financial resources

Vaccination Post Team

Each Vaccination Post Team will be under the supervision and coordination of one senior Health Worker as a Post Supervisor.

Role and responsibility of Vaccination Post Team Supervisor

- Responsible with immunization activities in the Post service area
- Coordinate the post activities
- Ensure house to house mobilization is done prior implementation within the post service area.
- Ensure the volunteers are mature and respected persons selected within the service area who can influence change in the community
- Ensure the post is functioning according to the vaccination post implementation plan
- Ensure all eligible people under priority group are vaccinated voluntarily
- Ensure the availability of vaccine, cold chain and logistics materials
- Ensure the availability of emergency AEFI drug kit
- Monitor, manage and audit all AEFI cases and report to the Council Supervisor immediate
- Data collection, compilation and submission to the Council Supervisor on daily basis
- Collect the safety boxes from the post to the designated burn areas every day.
- Monitoring and supervision of the implementation
- Monitor the waste management issues in the out post

The following are the personnel in the Vaccination Post team

Composition of a Post team

Personnel	Total Number
Vaccinators	1
Recorder	1
Community Leader	1

This composition of the team is designed to allow the vaccinators the optimum environment to be able to vaccinate an acceptable number of children and allows for greater flexibility in responding to the situation in the field.

Vaccinator must be Health Worker qualified to give injection selected by the Council Team.



Remember

- *Don't post two qualified and experienced health workers in the same post*
- *Qualified and experienced health workers be assigned to give injection*

Recorder must be:

- Extension Worker who can easily identify the eligible group and record properly
- Endorsed by Council Team
- Community Leaders must be selected by community within post service area



Remember – Team selection

- *Poor team selection is a major problem of the failure in immunization activities*
- *Vaccinators must be health workers who can give injection.*
- *Recorder must be extension workers*
- *Community Leader must be a respectable person selected by community*

2.4 Health Facility Coordination

Provision of immunization services are usually done at health facilities, therefore proper plans and coordination at this level is important for provision of better services to the community

2.4.1 Health Facility Governing Committee

Health Facilities Governing Committee and community healthcare workers will be responsible in ensuring that all eligible population receive the recommended dose regimen of COVID-19 vaccines. Moreover, they will be responsible for:

- i. Development of microplans and appropriate strategies to reach all target groups,
- ii. Mobilization of targeted groups for vaccination,
- iii. Implementation of vaccination activities,
- iv. Documentation of doses provided and vaccine stocks, and reporting to the next level,

- v. Monitoring and managing AEFIs, and
- vi. Supervision of vaccination activities.

Roles and responsibilities of Health Facilities

- Responsible with immunization activities in the service area
- Ensure house to house mobilization is done prior implementation within the post service area
- Ensure the volunteers are matured and respected persons selected within the service area who can influence COVID-19 vaccination in the community
- Ensure the post is functioning according to implementation plan
- Ensure all eligible population are given COVID-19 vaccine as needed
- Ensure the availability of vaccine, cold chain and logistics materials
- Ensure the availability of emergency AEFI drug kit
- Monitor, manage and audit all AEFI cases and report to the Council Supervisors immediate
- Data collection, compilation and submission to the Council Supervisors on daily basis
- Collect the safety boxes from the post to the designated burn areas every day
- Monitoring and supervision of the implementation
- Monitor the waste management issues in the post

3.0 VACCINATION DELIVERY STRATEGY

3.1 Target Groups for Vaccination

The Government aims to protect all its people against COVID-19 by giving effective and scientifically acceptable preventive measures including provision of safe, efficacious and quality vaccines. Recognizing the global COVID-19 pandemic we have prioritized the vaccination of COVID-19 to priority and special group population and therefore, Health care workers should identify those eligible for vaccination.

Priority groups include

- i. Frontline health care workers,
- ii. People with comorbidities aged 18 years and above,
- iii. Adult 45 years and above, and
- iv. Frontline essential workers including those at ports of entry, security and defence forces, lecturers, and primary and secondary school teachers.

Special groups include;

- i. International travelers,
- ii. Pilgrims,
- iii. UN Staff, and diplomats,
- iv. Non-residents, and
- v. Essential workers from tourism industry.

3.2 COVID-19 Vaccine Selection preferences

The critical literature review of COVID-19 vaccines conducted on vaccine and immunization characteristics (safety, efficacy, storage, type, dosage, price, neutralization of variants, population studied), disease epidemiology, economic and operational considerations and health policy and programmatic issues, led the Government to introduce COVID-19 vaccines, in the following order of preference; BioNTech/Pfizer BNT162b2, Moderna mRNA 1273, Novavax NVX-CoV2373, Johnson & Johnson (Janssen) Ad26. COV2. The list will be updated from time to time based on the available scientific information as recommended by NITAG.

3.3 Vaccination delivery strategy, tactics and proposed vaccination sites

3.3.1 Vaccination delivery strategy and tactics

COVID -19 vaccination is voluntary to eligible individuals. A consent form shall be signed prior to vaccination (Annex 1).

The country will employ combined campaign and routine delivery mode strategies to deliver COVID-19 vaccines to targeted population. Health facilities (Dispensaries, Health Centers, and Hospitals) will be the main points for provision of such vaccines alongside other vaccines in the routine immunization services.

- i. **Campaign strategy:** This approach will be applied when vaccines are received in bulk with a short shelf life. Vaccination will be conducted in specific time period preceded by announcement to the public.
 - The vaccination posts will be identified and announced to the public.
 - Clients will be required to register online or upon arrival at the health facility and be allocated to a specific vaccination site and will be assigned with a date, place and time of vaccination.
- ii. **Routine vaccination:** In this delivery mode, COVID-19 vaccination services will be administered at the health facility level and clients will be vaccinated at any time based on facility arrangement. This strategy will be used mostly for international travellers, pilgrims, elderly, those with comorbidities and other eligible client at their respective clinics during visit or outreach posts.
- iii. **COVID-19 Vaccination On-Demand:**

Vaccination of eligible population (priority group) will be **free of charge**. These vaccines will be sourced through the COVAX facility. However, for international travellers mandated to be vaccinated before travelling, a cost sharing mechanism may be applied based on the vaccine's funding source. The Government will announce the posts for the COVID -19 vaccination on demand and issue clear guidelines regarding the requirements (including: Passport, VISA, Tickets) before vaccination is offered. The client will be required to meet the cost of vaccination which will be revised from time to time.

3.3.2 Vaccine acquisition in the Country

(i) Access of vaccines through the COVAX Facility

COVAX facility provides vaccines to vaccinate 20% of the population. The country has prioritized the use of vaccines under COVAX facility to vaccinate priority groups free of charge as per section 3.1 above.

Depending on the vaccine availability that will be allocated by COVAX for Tanzania population, the vaccine will be distributed and administered to priority groups based on equity and risk assessment.

(ii) Access of vaccines through donation, bilateral agreements or AVATT

Beyond vaccinating 20% of the population covered through COVAX Facility donation, the Government can obtain additional vaccines to achieve herd immunity. This could be done through its own funding, donations, bilateral agreement with financial institutions like World Bank, International Monetary Fund (IMF), African Development Bank (AfDB) and/or through African Vaccine Acquisition Task Force Team (AVATT) of the African Union.

Under very special circumstances the Ministry responsible for health may allow private institutions in accordance to TMDA regulations to import vaccines direct from manufacturers and provide them to the public based on government regulated prices.

3.3.3 Vaccination of international travellers

Pilgrims, business people, students studying abroad, people attending international sport games, treatments, meetings et cetera who are not eligible for the priority groups (Section 3.1) vaccination through the COVAX Facility donation will be vaccinated at designated facilities with cost sharing as per cost sharing guidelines. Funds collected will be used as a revolving fund to procure vaccines through Medical Store Department (MSD). The MSD will procure the COVID-19 vaccines and supply to public and private health facilities designated to vaccinate international travellers or population in need.

3.3.4 Vaccination of UN staff and diplomats

This group will be vaccinated based on the agreed arrangements between the Government and their embassies or organizations. The delivery of COVID-19 vaccines

shall be supervised by the Government to ensure compliances to the country's immunization guidelines.

The following procedures shall be observed:

- i. Embassies/Organization shall write to the MoHCDGEC through the Ministry of Foreign Affairs expressing their intention to vaccinate their UN staff and diplomats.
- ii. The letter shall indicate the type of vaccine, number of staff to be vaccinated, their names, nationality, age and their risk status.
- iii. Vaccination may be carried out either at UN medical clinics or any designated public/private health facilities of their preference offering immunization services.
- iv. If the UN staff and diplomats intend to use vaccine not listed for emergency use by WHO, they shall write to MoHCDGEC for approval and shall make necessary arrangement to procure COVID-19 vaccines, adhering to country regulatory protocols.
- v. No vaccines will be imported without the import permit from TMDA.
- vi. Vaccine procured for UN staff and diplomats, shall be used for that purpose only, and not otherwise.
- vii. Tanzanian working under UN organization, will not hold the Government accountable for any detrimental effects resulting from vaccination, and will incur all costs for their treatment in case of detrimental effects from vaccination, since the indemnity clauses bind the manufacturer and the UN organization directly and not the Country.
- viii. The UN organization and diplomats shall furnish report to the MoHCDGEC indicating staff vaccinated, type of vaccines used, number of doses and batch number.

3.3.5 Vaccination of non-residents

International community that lives in Tanzania and working at different capacities as expatriates and want to be vaccinated with COVID-19 vaccines shall observe the following:

- i. May register their names to the designated public/private health facilities authorized to offer vaccination at their own cost. These facilities will be supplied by MSD, or receive donation that have been approved by TMDA and while observing all regulatory protocols.
- ii. May contact their respective embassies for vaccination depending on the arrangement that has been made.
- iii. Non-residents will not be allowed to import the COVID-19 vaccines by themselves.

4.0 REGULATORY PREPAREDNESS

4.1 Regulation of Vaccines

The Tanzania Medicines and Medical Devices Authority was established under the Tanzania Medicines and Medical Devices Act, Cap 219. The legislations provide a framework for regulation of quality, safety and effectiveness of medicines (including vaccines), medical devices and diagnostics. TMDA demonstrates its ability to consistently provide quality services through implementation of Quality Management System principles stipulated in the ISO 9001:2015 Quality management systems – Requirements from 2009 ISO 9001: 2008 certification and later recertified to ISO 9001:2015 in the year 2017.

4.2 Emergency use regulatory procedures

The Tanzania Medicines and Medical Devices (Registration of Medicinal Product) Regulations 2015 provides legal requirements for market authorization of vaccines in Tanzania Mainland.

In case of public health emergencies, the Authority shall publish a call for submission of applications for approval of required vaccine (by name, dosage form and strength) and prescribe minimum data package to be accepted at the time of the submission as stipulated in the “*TMDA, guidelines for guidance on processing of applications for registration of medicinal products through non-routine procedure in Tanzania March, 2020*”.

The applications shall be submitted online, and all the data uploaded in the TMDA electronic medicine registration submission portal available at the TMDA website

Guidelines for COVID-19 Vaccination

(www.tmda.go.tz). The submission procedure shall follow the administrative part of the “*TMDA Guidelines on Submission of Documentation for Marketing Authorization of Human Vaccines, Rev. No. 01, March 2020*”.

4.3 Pathways for emergency regulatory approval

TMDA participated or contributed to international or regional regulatory network or experts’ committees for East African Community Medicines Regulatory Harmonization (EAC –MRH) Programme, SADC Medicine Regulatory Harmonization, African Vaccine Regulatory Forum (AVAREF) and WHO Collaborative Registration Procedure (Including accessing scientific data of WHO Listing of Vaccines for Emergency Use for global review team).

TMDA will consider three regulatory pathways for approval of COVID-19 vaccine in the country;

- i. Vaccines that have already been submitted for the WHO prequalification EUL assessment, reliance method will be used whereby the access to the evaluation report and dossier from the WHO prequalification team will be requested. Vaccines currently listed for Emergence use by WHO will fall under this category and will be approved by TMDA for use in the country. Examples include Pfizer/BioNTech, Moderna, Johnson & Johnson (Janssen), AstraZeneca, Sinopharm, Sinovac.
- ii. Vaccines that have already been evaluated by Stringent Regulatory Authorities (SRAs) reliance method may be used after thorough evaluation including submission of report and dossier to the regulatory authority. Any additional queries regarding the product will be issued to the applicant.
- iii. Local applications that have not been subjected to the WHO EUL prequalification process or Stringent Regulatory Authorities Emergency Use Authorization will require the applicant to submit the application and agree to AVAREF/EAC/SADC joint review by experts from the member states. Queries will be issued to the applicant and a Joint review meeting will be called where the applicant will respond to the issues raised.

Recommendations to the meeting will then be presented to the Heads of

National Medicines Regulatory Authorities (NMRAs) for the final decision on authorization.

4.4 Facilitative import procedures and expedited LOT/Batch release of COVID-19 vaccines

The following procedures shall be adhered to:

- i. Applications for importation of vaccines in Tanzania shall be submitted to TMDA through the online trader portal. In case of donations special importation permit will be issued under section 57 of the Act to allow importation of unregistered vaccine on public interest.
- ii. To avoid storage problems, the application for importation should be made one week prior to loading the consignment. The applications shall be online via TMDA online importation portal.
- iii. TMDA issues import permit within 24hrs after receiving import applications (if there are no queries) for registered products and inspection and release of imported consignments at port of entries is done daily (24/7). Batch release certificates from manufacturer shall be available for quality verification. Import permits of unregistered products will be issued within 7 days after submission of applications.
- iv. Tanzania provides tax exemption for imported medicinal products including vaccines of which COVID-19 will follow the same conditions. The imported COVID-19 vaccine consignments shall be given priority in terms of inspection and release at the port of entry and where possible, they shall be given direct release and inspected at the warehouse.

4.5 Traceability of vaccines in the context of COVID-19 pandemic

Labelling the vaccines shall follow the TMDA “*Guidelines on Submission of Documentation for Marketing Authorization of Human Vaccines, March 2020*”.

Additionally, for vaccines that will be procured under COVAX Facility the WHO draft models for vials and packaging shall be used whereby the recommended two-dimensional (2D) bar codes applied to secondary packaging will facilitate traceability for the vaccines.

5.0 SUPPLY CHAIN MANAGEMENT, COLD CHAIN AND LOGISTICS

5.1 Procurement

Procurement and acquisition procedures of COVID-19 vaccines in the country are detailed below:

- i. COVID-19 vaccines under COVAX facility will be procured through UNICEF, while vaccines outside the COVAX facility will be procured through UNICEF or MSD depending on the bilateral agreement and the funding source.
- ii. Public/private hospitals and other designated centres for COVID-19 vaccination will access vaccines procured through UNICEF/MSD.
- iii. Public/Private institutions that intend to import COVID-19 vaccines, shall write to the Ministry of Health, and upon approval, shall make necessary arrangement for procurement while adhering to regulatory protocols of the country, provided the imported vaccine are for special group and not for sale.
- iv. The Ministry will not allow procurement or importation of COVID-19 vaccines in the United Republic of Tanzania by individuals, private institution or company.
- v. No COVID-19 vaccine(s) will be imported into the country without the import permit from TMDA.
- vi. The MoHCDGEC will establish need of the COVID-19 vaccine(s) to vaccinate groups outside COVAX facility or upon request from institutions, and shall procure and supply the vaccines at reasonable price through MSD.

5.2 Donation of COVID-19 vaccines

The Government may receive donation COVID-19 vaccine from various sources. Likewise, religious institutions, private hospitals and other organization may receive donation to vaccinate their community. The following should be considered when receiving or requesting donation for COVID-19 vaccines;

- i. All donated COVID-19 vaccines must abide to donation guidelines and Financial Act, Cap.134 on Government loans, grants and guarantee.
- ii. The Ministry will accept donation of vaccines that are under WHO emergency Use listing, and exceptions will be made depending on the country need.
- iii. All donated vaccine(s) shall be approved by TMDA before their importation into the country.
- iv. To avoid delayed clearance of donated vaccine(s), the donor or receiving institution other than the Government, must incur all costs of clearance. Or else, the donating organization/country shall submit the donation certificate and memorandum of understanding (MoU) signed between the Government and the donor.
- v. All institutions, companies or organization that intend to donate the vaccine to the Government, should consult the MoHCDGEC beforehand, and whenever possible, are advisable to disburse the equivalent funds to the Government for it to procure the vaccines of its preference under MSD.

5.3 Importation Procedures for COVID-19 vaccines

Section 73 of the Tanzania Medicines and Medical Devices Act, Cap. 219 gives mandate to TMDA to regulate importation and exportation of medicines, medical devices, *in vitro* diagnostics and biocidal. The categories of importers of regulated products include Government and non-government institutions such as embassies and religious institutions. All imported and exported regulated products need to be registered by TMDA.

However, a special permit may be issued under section 57 (1) of the Act to allow for the importation of unregistered regulated products which include COVID-19 vaccines.

The special permit may be issued to Government and non-government institutions such as religious institutions and embassies. Therefore, embassies and religious institutions which intends to import COVID-19 vaccines for their employees and members may use the special permit window.

5.3.1 Special permit application procedures

Conditions and documentation required for a special permit are outlined under section 1.5 of the Guidelines for the Importation and Exportation of Pharmaceutical Products. However, in summary, the importing institution will need to:

- i. Submit the letter to the MoHCDGEC showing the intention to import COVID-19 vaccine(s). The letter should mention intended group to be vaccinated, quantity to be imported, name and brand of the vaccine and indemnification documents or WHO commitment for UN organisations;
- ii. Create a trader portal account available on the TMDA website www.tmda.go.tz
- iii. Lodge an import application online on TMDA website accompanied by a supporting letter from the MoHCDGEC;
- iv. In case of COVID-19 vaccine donations, importers must have a donation certificate and prior approval from the Ministry responsible for Health. The donated vaccine should be among the WHO listed and country approved vaccine for emergency use and must be fit for human consumption, good quality, safe and not prohibited in the country of origin and in line with the Donation Guideline of the United Republic of Tanzania Mainland;
- v. Labelling the vaccines shall follow the TMDA “Guidelines on Submission of Documentation for Marketing Authorization of Human Vaccines, March 2020”;
- vi. Declare the appropriate COVID-19 vaccine storage locations accessible for inspection

5.3.2 Advise to importing institutions

To avoid storage problems, institutions are advised to apply for the import permit at least seven days before loading the consignment. TMDA will process and issue the import permit within 24 hours after receiving the import application (if there are no queries to the application).

The imported COVID-19 vaccines consignments shall be given priority in terms of inspection and release at the port of entry and where possible, they shall be given direct release and inspected at the warehouse of the importer.

5.4 Vaccination service delivery

i. Human resource

Each vaccinating facility must indicate number of vaccinators available as per guidelines.

Vaccination shall be provided by qualified health care workers only.

ii. Storage

Each vaccination facility must indicate availability of functional cold chain equipment, temperature monitoring devices and adequate storage capacity for freezing or refrigeration. Each facility must develop a contingency plan for vaccination service delivery.

iii. Viability

Each facility must be supplied with vaccines with longer shelf life. However, since most COVID-19 vaccines are supplied with shorter shelf lives, it's important to establish a well detailed plan with appropriate delivery strategy, especially using campaign delivery mode. If consumption is low, you should communicate with your district immunization focal person for redistribution of the vaccines to other facilities to avoid expiry.

Healthcare workers should ensure temperature is continuously monitored using temperature monitoring devices to avoid spoilage of the vaccines due to heat excursions. All health facilities should adhere to storage conditions for each type of vaccine to ensure viability.

iv. Documentations

Each facility should use data monitoring tools provided to record COVID-19 vaccination as per Section 9 of these guidelines.

v. **Waste management**

Refer to section 11 of the guide for waste management protocols of the waste management.

vi. **Reporting**

Each vaccinating facility must record daily summary of the vaccinations and submit to the district level for compilation, especially when using paper-based tools. However, when using electronic tools like electronic immunization registry, reporting will be automated.

vii. **Reporting of Adverse Events Following Immunization (AEFI)**

Each facility shall record all AEFI for each vaccine. Refer to Section 10 of these guidelines for further guidance.

- i. Vaccine recipients themselves and/or parents/guardians of immunized infants/children, health care providers at immunization facilities shall notify TMDA in case of adverse events following immunization.
- ii. A standard paper-based reporting form for AEFI is available. A web based portal will be made available at the TMDA website www.tmda.go.tz or through the Adverse Events reporting phone application (APP) (TMDA ARRT).

Detailed guidance on reporting of AEFI can be obtained from “*Guidelines for surveillance of adverse events following immunization*”.

5.5 Customs Clearance

Clearance of COVID-19 vaccines will be under Government Procurement Services Agency (GPSA) except for vaccines procured for UN Staff and diplomats, or other private entities with approval from the Government.

Prior to arrival of the vaccine, the mandatory shipping documents like Airway Bill, Packing List, Commercial Invoice and certificate of analysis must be delivered to relevant authorities (TMDA and GPSA) in advance for processing and issuance of importation permit for customs clearance to avoid delays in clearance processes.

Upon arrival, relevant authorities shall make sure:

- i. Vaccines are cleared within 24 hours.
- ii. Soon after clearance, vaccines are transported to the Central Vaccines Store (CVS) for storage.

5.6 Vaccine Storage

Upon arrival, vaccines should be cleared within 24 hours. Vaccines should be stored in a standby Walk in Cold Room (WICR) at the port of entry for emergency storage should there be delays in customs clearing process. Cleared vaccine consignments will be transported to the CVS in Dar es Salaam, for storage.

For the vaccines requiring Ultra Cold Chain (UCC) storage conditions, expedited clearance has to be done to ensure viability of vaccines. Arrangement of immediate transfer of vaccine consignment to the CVS pending clearance have to be in place.

5.6.1 Storage requirement/conditions for each vaccine

Recommended storage and handling of each COVID-19 vaccine will be in accordance to the manufacturer's instructions. For example, the following are current manufacturer's instruction on storage for vaccines listed below;

(a) Pfizer/BioNTech BNT162b2

- i. Maximum shelf life is 6 months when stored in a freezer at -80°C to -60°C
- ii. 31 days at 2°C to 8°C after thawing (indicate/label date and time immediately after removing from freezer).
- iii. Once removed from the fridge, shall be stored between 2°C to 25°C for 2 hours prior to dilution.
- iv. Once diluted shall be stored between 2 to 25°C for a further 6 hours.
- v. Once thawed, the vaccine cannot be re-frozen
- vi. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

(b) AstraZeneca ChAdOx1-S

- i. Maximum shelf life is 6 months stored in a refrigerator between 2 to 8°C.
- ii. Once removed from the fridge, may be stored between 2 to 25°C for up to 6 hours.

- iii. Once opened, the vial must be used within 6 hours or at the end of immunization session whichever comes first.
- iv. Must not be frozen.
- v. Protect from direct sunlight during storage.

(c) Moderna mRNA-1273

- i. Maximum shelf life is 7 months stored in a freezer at -25°C to -15°C
- ii. Do not store on dry ice or below -40 °C
- iii. 30 days at 2 to 8°C after thaw (assign immediately after removing from freezer).
- iv. Once removed from the fridge, may be stored between 8 to 25°C for up 12 hours.
- v. Once opened, the vial must be used within 6 hours or at the end of immunization session whichever comes first.
- vi. Once thawed, the vaccine cannot be re-frozen
- vii. Protect from light during storage.

(d) Johnson & Johnson (Janssen) Ad26. COV2

- i. Store the vaccine between 2°C and 8°C until the expiration date (shelf life is 3 months).
- ii. Once opened, the vial must be used within 6 hours or at the end of immunization session whichever comes first.
- iii. Protect from light during storage.

(e) Sinopharm BBIBP-CorV

- i. Store in a refrigerated condition of 2°C and 8°C
- ii. It is supplied as pre-filled syringe or vial.
- iii. Have a shelf life of 24 months
- iv. Protect from light and
- v. Do not freeze

5.7 Estimating vaccine needs and storage capacity

5.7.1 Estimating vaccine need.

Estimate the vaccine need at national, regional and district level using target population method. Due to short shelf life of COVID-19 vaccine, estimate vaccine need on monthly basis except at central vaccine stores which could be estimated at 3- or 6-months period depending on the type of vaccine. With expectation of vaccination coverage of 90% and wastage rate of 5% and buffer stock of 5% for all vaccines, monthly vaccine need will be;

$$= \frac{\text{Target population} \times \text{No. of doses} \times 1.11 \text{ (wastage factor)} \times 1.05 \text{ (buffer stock)} \times 0.9 \text{ (coverage)}}{12}$$

= monthly doses of COVID-19 vaccine needed.

Example: Dar es Salaam has target of 50,000 people, what will be the monthly vaccine need for Pfize/BioNTech?

$$= (50,000 \times 2 \times 1.11 \times 1.05 \times 0.9) / 12$$

$$= 8,741 \text{ doses}$$

$$= 8,741 / 6 = 1,457 \text{ vials.}$$

5.7.2 Estimating Cold chain storage space requirement

The following two calculations are needed at each level to verify whether there is a sufficient cold storage space for COVID-19 vaccines: -

i. **Calculate the total cold chain space available by;**

- Obtaining an inventory (number) of the functional cold chain equipment available\
- Multiply the number of CCE by the volume of that particular CCE

ii. **Subtract space used for routine immunization.**

To calculate the amount of cold chain space available for vaccine supplies for COVID-19, subtract the estimated amount of space used for routine immunization services from the total space available.

If there are problems of inadequate space at all levels the following options should be applied:

- iii. Use a **“fast chain”**. This means sending vaccine with plenty of cool water packs rapidly to the vaccination sites with inadequate storage space.
- iv. **Strategically time delivery/collection quantities for routine immunization vaccines.**

Distribution of routine vaccines should be portioned and the remaining delivered soon after COVID-19 vaccination where space is not adequate at Council or some health facilities.

To estimate storage space for each vaccine, take 4.6 cm³ per dose, as packed volume for all COVID-19 vaccines, except Pfizer/BioNTech which is 1.79 cm³ per dose.

To estimate cold storage space required;

= Vaccine doses x packed volume per dose.

Example: Monthly vaccine need at facility Z is 5,200 doses of Janssen vaccine.

What is the storage space required?

= 5,200 doses x 4.6

= 23,920 cm³

= 23.9 liters.

If facility Z has RCW50EG refrigerator for routine immunization, does the facility have adequate storage space to accommodate COVID-19 vaccine?

Note. RCW50EG has net storage capacity of 24 liters, and vaccine in routine immunization occupy 50% of the storage space (12 liters).

Therefore, total required storage space at facility Z = 12 liters + 23.9 liters for COVID-19 vaccine = 45.9 liters.

The available storage space is inadequate, and the facility will require additional refrigerator to accommodate;

= 45.9 – 24 = 21.9 liters.

Therefore, this facility need to be supplied with additional refrigerator in order to store 5,200 doses of Jansen vaccine.



Remember

- *To estimate the vaccine, need and storage space required before receiving vaccine.*
- *Always keep the vaccine at the recommended temperature during storage.*

5.8 Distribution and logistics monitoring

Distribution matrix should be established at each level. The CVS will distribute the vaccine to Regional Vaccine Stores (RVS), and each region will be responsible for distribution to respective regional hospital vaccination sites or to districts vaccine stores.

- Each region will submit the total number of target population to be vaccinated with COVID-19 vaccine.
- The region will estimate the total doses that will be required and submit the requisition to the National logistic subcommittee of the Ministry of Health and IVD for verification and approval, and then submit to the approved requisition to CVS for distribution.
- The CVS will distribute COVID-19 vaccines and its related safety injection materials respectively to all regions within 10 days.
- Each region will require one (1) ultra-cold freezer for storage of Pfizer/BioNTech vaccine in case is to be used. If no ultra-cold freezers at regional level, distribution of Pfizer/BioNTech vaccines will be restricted to Dar es Salaam.
- Distribution of Pfizer/BioNTech vaccine to the districts and Health Facilities will be done using temperature monitored standard cold boxes.
- Remote Temperature Monitoring (RTM) devices installed to CVS and all RVS and 80% of the district/council vaccines stores will monitor temperature excursions for supervisors to mitigate.



Remember

- *COVID-19 Vaccines are very sensitive to heat and sunlight, distribution to vaccination sites should be done close to vaccination days depending on delivery strategy.*

5.9 Inventory Management

Ensure adequate stock is available for vaccination by daily physical counting at the end of the vaccination session. Understand your daily consumption and contact your immunization focal person for replenishment if you anticipate any shortage. Each vaccination sites should have maximum stock for 4 weeks only.

If you are supplied with vaccine with short expiry and your consumption is low, contact immediately your immunization focal person to plan for re-distribution.

6.0 HUMAN RESOURCE AND TRAINING

6.1 Human resource

Each vaccinating facility must identify human resources involved in the vaccination exercises.

Vaccination will be administered only by qualified health care workers, preferably registered, enrolled, or nurse attendants.

- i. In campaign delivery mode, each vaccination site whether fixed or mobile shall have at least three staff, namely the vaccinator, the recorder and crowd controller.
- ii. In campaign delivery mode, the maximum number to vaccinate per day will be 200 in urban and 150 in rural areas.
- iii. In routine delivery mode, each fixed post must have at least one vaccinator, who will be responsible for vaccination and recording.

6.2 Training Plan

Each region should aggregate the total number of health care workers from councils that require training of COVID-19 vaccination.

- i. Plan for cascaded training from central level to facility level
- ii. Identify national facilitators and regional and council facilitators
- iii. Indicate training schedules for all personnel
- iv. Training will be cascaded from central level to facility level

7.0 VACCINE ACCEPTANCE AND UPTAKE

For effective execution of the communication plan, the MoHCDGEC through Risk Communication and Community Engagement (RCCE) technical working group shall design and develop communication materials and tools to enhance public awareness and promote uptake of COVID-19 vaccine(s). The following will be prepared in advance for public advocacy and sensitization:

- i. Radio & TV shows including content influencing vaccine acceptance.
 - Radio and TV jingles and adverts.
 - Maximize utilization of free programs in electronic media.
- ii. Short training video(s) to support capacity building for training of trainers.
- iii. Media assets including graphics, texts and short videos for engagement on digital platforms.
- iv. Public announcements and advertisements messages.
- v. IEC materials: brochures, posters and billboards.
- vi. Bulk messaging to target facilitators and internal stakeholders' mobilization.
- vii. 24-hour Hotline manned by health workers to answer vaccination related questions from access, administration and adverse events.
- viii. Leveraging on existing campaigns which involve the general public such as "NYUMBA NI CHOO"; existing sports arena such as gyms, jogging clubs, marathons, football game; and where politicians, religious leaders and other influencers attend as well as the community health workers who are the linkage between the community and service delivery point.

Key considerations to support risk communication and community engagement activities to address vaccine hesitancy:

- i. Listening to communities and gathering social data to understand their concerns and beliefs and addressing them through timely and targeted communication and other strategies.
- ii. Use of channels, including media and social media, to proactively share information about vaccination in general, the COVID-19 vaccine development process,

- iii. Sharing of information from trusted sources.
- iv. Engagement of media, religious, policy, community and influential leaders
 - Working with community, religious and influential leaders for physical dialogue
- v. Engaging frontline health workers as change agents in the community
 - 1. Build communication skills- interpersonal communications and community dialogue that will help to equip them to hold difficult conversations both in the face of demand from those not eligible to receive the vaccine and those who are hesitant about receiving the vaccine.
 - 2. Demand creation activities should initially focus on health workers and other high-risk groups (e.g. older adults) that have been prioritized by the National Program
 - 3. Utilization/leveraging other platforms such as Sports arena (Gyms, marathons, Bonanzas, Football matches, NYUMBA NI CHOO platform, CHWs etc.
 - 4. Developing contents for people with special needs (blind, deaf and all with disabilities).

8.0 VACCINE ADMINISTRATION

8.1 Registration of client's/vaccination recipients

COVID-19 vaccination is voluntary to eligible group, and each recipient should register to the respective vaccination sites through an online application or by physically visiting the designated health facility/vaccination post providing COVID-19 vaccines. Each region will share information on where vaccination is provided. The client will be notified on the vaccination date and place.

8.2 Administration of consent forms

Before vaccination, clients will be required to provide their written informed consent on COVID-19 vaccination (Annex 1).

The health care provider should:

- i. Provide appropriate information on COVID-19 vaccine safety, efficacy, and potential side effects,
- ii. Vaccinate the eligible client as per COVID-19 vaccine administration Standard Operation Procedures (SOPs).
- iii. Ensure the client;
 - a) Is 18 years and above with ability to consent,
 - b) Contribute the cost of vaccination as prescribed under the Cost Sharing Guidelines for non COVAX vaccines.
 - c) Is among the target group for vaccination at that time as per Tanzania list of target population.

The healthcare worker must document relevant information in the relevant data tools for COVID-19 vaccine. S/he must ensure completeness of all information as required in the register and vaccination card. If the client agrees to vaccinate and has signed the consent form, proceed with the vaccination procedure.



Remember

- *Client must be able to consent by filling the form.*
- *Each vaccination site must have at least one vaccinator and a recorder*
- *Vaccines will be administered by a qualified health care worker*

8.3 Occupational Health and Safety

Health workers and service users must be protected during vaccination. All health workers providing vaccination services must;

- i. Use infection and prevention measures as per IPC guideline National Guidelines for Prevention of COVID-19.
- ii. Keep the vaccination area neat, clean and free of materials that are not related to the work.
- iii. Observe all injection safety procedures.
- iv. Report immediately to the supervisor all adverse events following immunization (AEFI), accidents and any potential exposures to infectious materials.

8.4 Vaccine administration procedures

Every vaccine provider at health facilities and designated vaccination centres/posts should ensure appropriate vaccination procedures as per COVID-19 vaccine administration SOP. Vaccines that will be used include BioNTech/Pfizer BNT162b2, Moderna, Novavax NVX-CoV2373, Johnson & Johnson Ad26. CoV2 and any other vaccines that will be listed for emergency use by WHO and approved for use in the United Republic of Tanzania.

i. **Route of administration**



The vaccine should be administered through Intramuscular injection at the upper left arm into the deltoid muscle.

ii. **Vaccination dose and schedule**

- **Pfizer- BioNtech**

The vaccine is available as 6 dose-vial after dilution.

Give 0.3 mls of Pfizer-BioNtech vaccine Intramuscular injection (I.M) into the upper left arm. Vaccination should be two doses and the interval between 1st and 2nd dose should be 21 – 28 days. If the second dose is accidentally given earlier than 21 days, the dose need not to be repeated. The second dose should not be given beyond 42 days (6 weeks) after the first dose.

- **Johnson & Johnson**

The vaccine is available as a 10-dose vial liquid.

Give 0.5 mls of Johnson & Johnson vaccine I.M into the upper left arm. The vaccine is given as a single dose vaccine.

- **Moderna mRNA-1273**

The vaccine is available as a 10-dose vial liquid.

Give 0.5 mls Moderna vaccine I.M into the upper left arm. The vaccine is given as a two dose and the interval between first and second dose should be 28 days. If the second dose is accidentally given earlier than 28 days, the dose need not to be repeated. The second dose should not be given beyond 42 days (6 weeks) after the first dose.

- **Oxford – AstraZeneca ChAdOx1-S**

The vaccine is available as a 2 and 10-dose vial liquid.

Give 0.5 mls of Oxford – AstraZeneca vaccine I.M into the left upper arm. It is given as two doses, with the second dose given 8 -12 weeks after the first dose.

If the second dose is inadvertently administered 4 weeks earlier after the first dose, the dose need not to be repeated.

If the second dose inadvertently delayed, it should be given at the earliest possible opportunity.

Note: The second dose is more preferred to be provided on the 12th week from the first dose.

- **Sinovac (CoronaVaC)**

Give 0.5 mls of CoronaVaC I.M into the left upper arm. It is given as a two dose, with the second dose given one month (28 days) after the first dose. Shake well before use.

- **Sinopharm BBIBP-CorV**

Give 0.5 mls of Sinopharm BBIBP-CorV I.M into the left upper arm. It is given as a two dose, at the recommended interval of 21 – 28 days after the first dose.

9.0 DATA MANAGEMENT TOOLS

Routine immunization data management tools (including electronic tools) will be used to record all eligible vaccine recipients.

- i. Data management tools should be updated to include COVID-19 Vaccine.
- ii. Conduct daily and monthly monitoring for COVID-19 vaccination.
- iii. Supply performance monitoring chart to all designated Health Facilities to monitor to COVID-19 vaccination for both single and two doses administration.
- iv. Monitor monthly coverage with dropout rate.
- v. Monitor Vaccine utilization closely at all levels.

9.1 Vaccination registers

This is a health facility-based data collecting tool. Use both electronic and manual COVID-19 vaccination registers to capture physical address of the vaccine recipient, full name, age in years, sex, history of COVID-19 infection, comorbidities, occupation, allergy and information on doses.

9.2 Tally sheets

Use tally sheets for COVID-19 vaccination to record all doses administered at the vaccination facilities on daily basis (Annex 2). There are tally sheets with and without health care workers, that will be used to record doses administered on daily basis.

9.3 Vaccination cards

Electronic and/or hard copies of vaccination cards will be provided to all client, and will contain his/her unique identification number (National ID, Passport, bar code/QR code), full name, date of vaccination of first and second dose, name of the vaccine, batch and lot number (Annex 3).

9.4 Daily and monthly vaccination reports

Each vaccination facilities at the end of vaccination session, will record the total number of people vaccinated on daily basis. All AEFIs will be recorded for each vaccine (Annex 5 (a)(b)). The daily summary form will be submitted to the DMO's office. At the DMO's office, vaccination reports from all vaccination facilities will be aggregated on District daily vaccination report (Annex 6) and then shared to the RMO's office, who will then share with the national level (Annex 7).

9.5 Vaccine Management Information System

The Vaccine Information Management System (VIMS) will be used to monitor vaccine stock management, routine COVID-19 vaccination data and cold chain equipment functionality, temperature monitoring and inventory at district, region and national level. A separate dashboard will be created to indicate the daily vaccination data and will be aggregated from vaccination sites using electronic registries, or daily tally sheets vaccination summary.

10.0 VACCINE SAFETY MONITORING, MANAGEMENT OF AEFI, AND INJECTION SAFETY

10.1 AEFI surveillance

Surveillance for Adverse Events Following Immunization (AEFI) is an integral part of the Immunization and Vaccine Development (IVD) Program, and reinforces the safe use of all vaccines in the country while also helping to maintain public confidence in its immunization program.

Objectives of AEFI surveillance:

- i. To rapidly detect and respond on time to the occurrence of an AEFI.
- ii. To identify, correct and prevent immunization error related reactions.
- iii. To facilitate AEFI causality assessment.
- iv. To recognize clusters or unusual high rates of AEFI.
- v. To identify potential safety signals (including previously unknown vaccine reactions), and generate hypotheses that may require further investigation.
- vi. To generate information with which to effectively communicate with public the community, media and other stake holders, regarding the safety of vaccines used.
- vii. To analyse adverse reactions and identification of risk factors.

To control safety and quality of COVID-19 vaccines, TMDA should do the following:

- i. Monitor/receive AEFI from the healthcare workers and the community; and conducting causality assessment of the received reports,
- ii. Educate the public on safety and quality of vaccines,
- iii. Sensitize the public and healthcare workers on reporting of suspected Adverse Events associated to the use of vaccines,
- iv. Review of safety reports of medicines like Periodic Safety Update Reports (PSURs), Periodic Benefit Risk Evaluation Reports (PBRERs) and Risk Management Plans (RMP),
- v. Communicate with Marketing Authorization Holders on all matters related to safety and quality of vaccines,

- vi. Strengthen and coordinate 8 zones and 28 regional pharmacovigilance centers for active surveillance of AEFI
- vii. Collaborate and align with stakeholders (universities, research institutes, public health programmes -PHPs) in strengthening pharmacovigilance system including COVID-19 vaccine.

10.2 AEFI Detection

- i. Should be conducted through passive surveillance when vaccine recipients, healthcare providers and staff in immunization or health care facilities detect the AEFIs and notify them to high authority
- ii. Should be detected through active surveillance, via selected sentinel sites.
- iii. Should be detected in phase IV clinical studies of COVID-19 vaccines.

10.3 AEFI documentation

- i. Reporting should be done using the standard AEFI reporting form.
- ii. All efforts should be taken to complete the reporting form as details as possible at the first point of contact

10.4 AEFI reporting flow

The AEFI reporting flow is summarised in the Figure below.

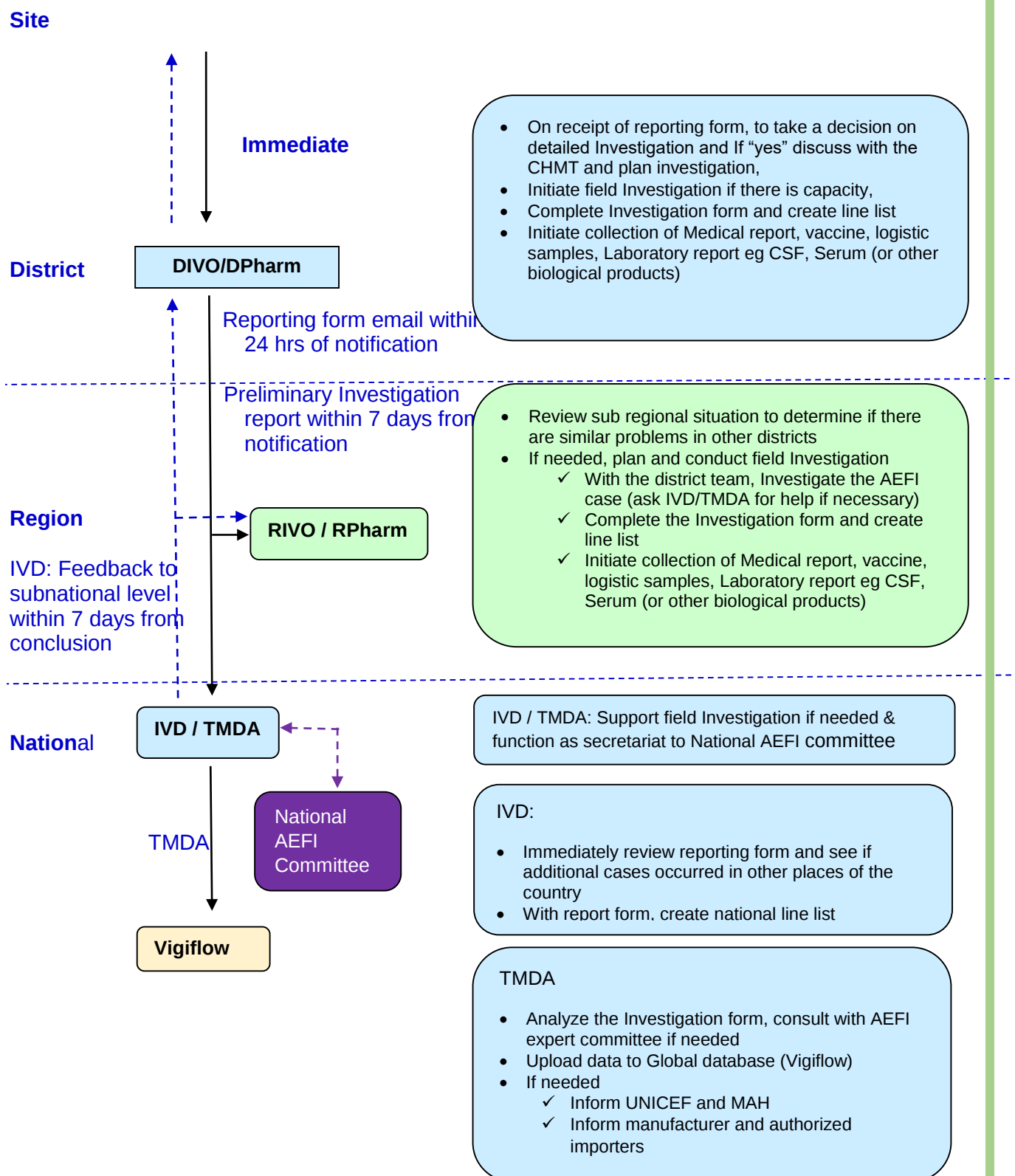


Figure 4: Tanzania AEFI Reporting – Routing, Timeline and Actions

1. Vaccine recipients and healthcare providers

Vaccine recipients and healthcare providers at immunization facilities are most likely to recognize or detect AEFIs when they first occur. The AEFI case that is notified to any healthcare provider should be reported to the District Immunization and Vaccine Officer (DIVO)/District Pharmacist using the standard reporting form through the Electronic or telephonic reporting.

The following AEFI should be investigated:

- i. Serious AEFI,
- ii. Clusters,
- iii. AEFI causing community concern, those that are unexpected, and
- iv. Any AEFI that are known but occur with unexpected frequency.

2. District and Regional levels

- i. Health service providers will report AEFI to health facility in charge, who will then report immediately to the focal person at Council level (DIVO/District Pharmacist). The Focal person will ultimately report to the regional pharmacovigilance Centre and Regional Immunization and Vaccine Officer (RIVO)/Regional Pharmacist who will also report to the National IVD section and Vaccination Pillar.
- ii. Should discuss with the Council Health Management Team (CHMT) and plan a detailed field investigation for any severe/serious AEFI (death, hospitalization, significant disability, life threatening, or congenital anomaly/ birth defect) or a part of a group of events above expected rate/ severity, or a suspected signal.
- iii. Initiating an investigation, e-mail the reporting form to the regional and national levels.

- iv. Visit the patient locality and initiate the detailed investigation along with appropriate members of the local health care team.
- v. Contact RIVO and IVD/TMDA if assistance is required for investigation from the regional or national level.

3. National level

- i. National investigations should be led by a team from the national AEFI committee, supported by the IVD and the TMDA. National AEFI committee is embedded within the National Pharmacovigilance Committee.
- ii. The National AEFI Committee plays a key role in supporting the immunization program for AEFI investigation and causality assessment.
- iii. They provide recommendations to the Tanzania National Immunization Technical Advisory Group (NITAG) and the MoHCDGEC on vaccines based on their causality assessment findings.
- iv. TMDA and IVD Programme coordinate and provide technical/logistical support to the National AEFI Committee meetings. Therefore, the surveillance for COVID-19 vaccines will follow the same structure.

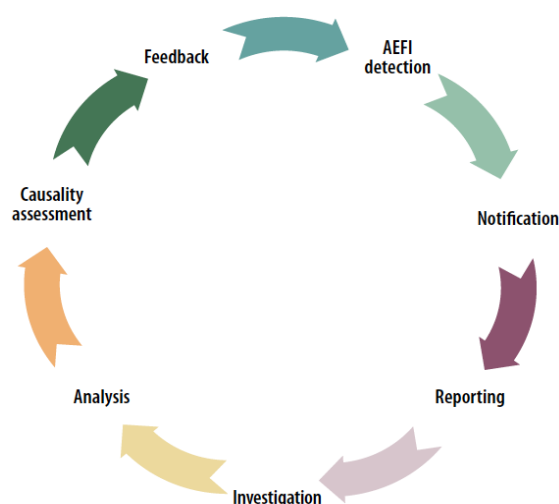


Fig 5. AEFI surveillance cycle.

10.5 Event based surveillance – EBS

EBS will facilitate the detection of COVID-19 Vaccine related adverse events reported from the community through media monitoring. EBS focal persons should follow the EBS existing reporting mechanisms.

10.6 COVAX No-fault compensation program

COVID 19 vaccination will be voluntary and the Government or manufacturer will not be liable for any AEFI that will occur following COVID 19 vaccination. No compensation will be provided

Annex 4: Key vaccine safety definitions and their implications in the COVID-19 context

11.0 WASTE MANAGEMENT AND DISPOSAL

11.1 Safe Disposal of Injection materials

All used syringes and needles must be disposed off immediately after being used throughout the immunization session by putting them into safety boxes provided at all vaccination posts. These boxes reduce the risk posed by contaminated needles and syringes to both the health workers and the general public. Vaccinators are required to put all used needles and syringes in safety boxes immediately after dilution and administering vaccine to a child.



To avoid an occupational hazard, safety boxes should not be over-filled. When the safety boxes are nearly full (approximately 3/4), close the lid and safely store the box in a safe place until it can be properly disposed of, so as to prevent infecting vaccinators, other health workers and the community. It is estimated that, one safety box can hold 100 syringes and needles. Used syringes should not be transferred from container to container, and must not be left in a public area of the post or health facility. Do not transfer filled safety boxes from one place to the other if you expect any damage to the containers to allow spill or uncontrolled drop of used sharps.



Remember

- The safety boxes should be properly assembled according to instructions printed on the sides of the boxes.
- The open safety boxes with used syringes and needles are **DANGEROUS**

11.2 Handling and disposal of Safety boxes

Used syringes and needles at immunization posts will be discarded in the safety boxes provided for that purpose. At the end of each implementation day, safety boxes will be disposed of as follows: for immunization posts located at a distance of less than 5 kilometers from incinerators, the filled safety boxes should be collected for incineration and those more than 5 kilometers from incinerators should be collected and burnt in a

1 meter deep pit at the vaccination posts. Health facility in charge and supervisors will oversee the ultimate disposal by burn and bury by either the pit method.

Pit for Burning used vaccines syringes and needles

- i. Choose an unused area for the burning site, as far from buildings as possible. The area should be well cleared.
- ii. Dig a pit with at least 1.5 meter-wide and 2 meters deep.
- iii. Place the filled safety boxes in the pit. Mix paper, leaves or other flammable materials among the boxes to help them burn.
- iv. Warn people to stay away and avoid smoke, fumes, and ash from the fire.
- v. Burn until all boxes are destroyed.
- vi. Use the pit on subsequent implementation days, covering completely each layer of burned waste with a thin layer of soil till the last day.

11.3 Immunization wastes disposal at posts in urban areas

Explore availability of appropriate waste disposal such as incinerators in urban areas or designate suitable disposal locations for burn and bury pits. Supervisors will also oversee the ultimate disposal of sharps.

11.4 Disposal of Other Immunization Wastes

Any other immunization wastes should **NOT** be put into safety boxes. Instead, other wastes should be disposed of in a bin and burned regularly along with the safety boxes.

12.0 MONITORING AND EVALUATION

Targeted supportive will be conducted by national level, RHMT and CHMT at vaccination sites periodically to monitor the vaccination progress, and mitigate any challenges. Health care workers should contact their immunization focal person in respective district and region at any time whenever they experience an obstacle.

A standardized checklist for supportive supervision will be used by all supervisors to assess the provision of the vaccination services.

13.0 ANNEXES.

13.1 Annex 1: Consent Form

THE UNITED REPUBLIC OF TANZANIA



MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

CONSENT FORM FOR COVID-19 VACCINATION.

Region:

District:

Health Facility:

Date:

I.....aged years, residing at
..... Ward..... District.....

Region, have been informed by the healthcare worker on the COVID-19 vaccine safety, efficacy and potential adverse events.

I am willing to receive the COVID-19 vaccination, and I will not hold the Government of United Republic of Tanzania accountable for any adverse events that may happen after being vaccinated.

Signature of the client:

Name and Signature of Healthcare worker:

Date:

13.2 Annex 2 (a): COVID-19 Tally sheet with HCW

COVID-19 Vaccination Daily Tally Sheet No :

Country:		Province/State/Region:		District:		Name of health facility:			
Date (DD-MM-YY) ____/____/____	Unit/Section/Site _____	Site: Fixed ☐ Reach ☐ Mobile ☐							
COVID-19 Vaccine first dose (Vaccine name)	Health Care workers	Less than 60 years (Not Older adult)				60 years and above (Older adult)			
		At least one health condition		No Existing health condition		At least one health condition		No Existing health condition	
		Male	Female	Male	Female	Male	Female	Male	Female
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13.3 Annex 2 (b): COVID-19 Tally sheet without HCW

COVID-19 Vaccination Daily Tally Sheet No :																
Country: _____				Province/State/Region: _____				District: _____				Name of health facility: _____				
Date (DD-MM-YY) ____/____/____ Unit/Section/Site _____ Site: ☐ Fixed ☐ Mobile ☐																
COVID-19 Vaccine first dose (Vaccine name)	Less than 60 years (Not Older adult)								60 years and above (Older adult)							
	At least one health condition				No Existing health condition				At least one health condition				No Existing health condition			
	Male		Female		Male		Female		Male		Female		Male		Female	
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Total		Total		Total		Total		Total		Total		Total		Total		
COVID-19 Vaccine second dose (Vaccine name)	14 15 16 17 18 19 20 21 22 23		14 15 16 17 18 19 20 21 22 23		14 15 16 17 18 19 20 21 22 23		14 15 16 17 18 19 20 21 22 23		14 15 16 17 18 19 20 21 22 23		14 15 16 17 18 19 20 21 22 23		14 15 16 17 18 19 20 21 22 23		14 15 16 17 18 19 20 21 22 23	
	24 25 26 27 28 29 30 31 32 33		24 25 26 27 28 29 30 31 32 33		24 25 26 27 28 29 30 31 32 33		24 25 26 27 28 29 30 31 32 33		24 25 26 27 28 29 30 31 32 33		24 25 26 27 28 29 30 31 32 33		24 25 26 27 28 29 30 31 32 33		24 25 26 27 28 29 30 31 32 33	
	34 35 36 37 38 39 40 41 52 43		34 35 36 37 38 39 40 41 52 43		34 35 36 37 38 39 40 41 52 43		34 35 36 37 38 39 40 41 52 43		34 35 36 37 38 39 40 41 52 43		34 35 36 37 38 39 40 41 52 43		34 35 36 37 38 39 40 41 52 43		34 35 36 37 38 39 40 41 52 43	
	44 45 46 47 48 49 51 52 53 54		44 45 46 47 48 49 51 52 53 54		44 45 46 47 48 49 51 52 53 54		44 45 46 47 48 49 51 52 53 54		44 45 46 47 48 49 51 52 53 54		44 45 46 47 48 49 51 52 53 54		44 45 46 47 48 49 51 52 53 54		44 45 46 47 48 49 51 52 53 54	
	55 56 57 58 59 60 61 62 63 64		55 56 57 58 59 60 61 62 63 64		55 56 57 58 59 60 61 62 63 64		55 56 57 58 59 60 61 62 63 64		55 56 57 58 59 60 61 62 63 64		55 56 57 58 59 60 61 62 63 64		55 56 57 58 59 60 61 62 63 64		55 56 57 58 59 60 61 62 63 64	
	65 66 67 68 69 70 71 72 73 74		65 66 67 68 69 70 71 72 73 74		65 66 67 68 69 70 71 72 73 74		65 66 67 68 69 70 71 72 73 74		65 66 67 68 69 70 71 72 73 74		65 66 67 68 69 70 71 72 73 74		65 66 67 68 69 70 71 72 73 74		65 66 67 68 69 70 71 72 73 74	
	75 76 77 78 79 80 81 82 83 84		75 76 77 78 79 80 81 82 83 84		75 76 77 78 79 80 81 82 83 84		75 76 77 78 79 80 81 82 83 84		75 76 77 78 79 80 81 82 83 84		75 76 77 78 79 80 81 82 83 84		75 76 77 78 79 80 81 82 83 84		75 76 77 78 79 80 81 82 83 84	
	85 86 87 88 89 90 91 92 93 94		85 86 87 88 89 90 91 92 93 94		85 86 87 88 89 90 91 92 93 94		85 86 87 88 89 90 91 92 93 94		85 86 87 88 89 90 91 92 93 94		85 86 87 88 89 90 91 92 93 94		85 86 87 88 89 90 91 92 93 94		85 86 87 88 89 90 91 92 93 94	
	Total		Total		Total		Total		Total		Total		Total		Total	

Number of vaccine doses received _____
 Number of vaccine doses used: _____
 Number of vaccine doses remaining: _____

Number of AEFIs: Minor _____ Severe _____

Name, signature of responsible and Stamp

Comments: _____

Note: To be used when HCW vaccination is completed

13.4 Annex 3: COVID-19 client Vaccination Card

TANZANIA COVID-19 Vaccination Card			
<i>This an individual record that shows your history of the vaccines given. Please keep this card safe and produce to the health worker whenever you are seeking the vaccination/health services</i>			
Unique Identification number (from the vaccination register):			
First Name(s): Surname: Date of birth (DD-MM-YY): ____/____/____ Age:..... Gender: Occupation:			
Physical Address:			
☐ History of Allergy (Y/N): Yes No Existing condition (Y/N): Yes No	☐	☐ ☐	
Items	Responses	Signature and Stamp:	Date of next visit (DD/MM/YY)

Date of 1 st dose (DD/MM/YY)	____/____/____		
Name of vaccine			
Batch number/Lot number			____/____/____
Expiry date (DD/MM/YY)	____/____/____		
Vaccination Center Name			
Date of 2 nd dose (DD/MM/YY)	____/____/____		
Name of vaccine			
Batch number/Lot number			____/____/____
Expiry date (DD/MM/YY)	____/____/____		
Vaccination Center Name			
Remarks:			

13.5 Annex 4: Key vaccine safety definitions and their implications in the COVID-19 context

Issue	Definition	Implications in COVID-19 context
Adverse event following immunization	i. Any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. ii. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease	iii. The same definition will continue to be used to identify and report all AEFI following COVID-19 vaccines iv. Investigate relevant cases and come up with a valid diagnosis before proceeding with causality assessment
Vaccine product-related reaction	i. An AEFI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product.	ii. The identification of rare (occurring in 0.01% to less than 0.1% of immunized individuals) and very rare (occurring in <0.01% of individuals) adverse events is insufficient at the time of COVID-19 vaccine licensing and more information will be needed for which AEFI surveillance has to be strengthened
Vaccine quality defect-related reaction	i. 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	ii. For new vaccines platforms, the knowledge of potential Vaccine quality defects might be insufficient at the time of COVID-19 vaccine licensing and more information will be needed for

	administration device as provided by the manufacturer.	which AEFI and AESI surveillance must be strengthened. iii. The rapid scaling up of vaccine production poses additional potential risks and identification of the exact substance causing the event is needed
Immunization error-related reaction	An AEFI that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable.	i. It is anticipated that COVID-19 vaccines will be administered on a massive scale in a short time interval with minimum training and field preparation and larger number of immunization error-related reactions are anticipated. ii. Staff who are not familiar with immunization may be asked to perform immunization duties. iii. Multiple vaccines with different specifications for storage, administration, dose etc. may in be in use in a country simultaneously
Immunization anxiety-related reaction	An AEFI arising from anxiety about the immunization	iv. A larger number of Immunization anxiety-related reactions are anticipated due to numerous factors including older age groups, the different vaccinating environments, the novelty of the vaccines and their administration modalities

Coincidental event	An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety	v. Because of potential comorbidities in vaccinees, it will be challenging to differentiate true coincidental events from COVID-19 vaccine product related reactions or drug reactions or interactions. vi. Coincidental events can occur in healthy individuals without comorbidities especially where a higher frequency is expected based on age, gender, geographic location or ethnic background. vii. Knowing the population-based incidence (background rates) of pre-specified adverse events of special interest (AESI) helps to anticipate and respond to such events.
A serious AEFI	A serious adverse event results in death, hospitalization or prolongation of an existing hospitalization, persistent or significant disability or incapacity, congenital anomaly/birth defect or could be life-threatening.	viii. Information on serious rare and very rare adverse events following COVID-19 vaccines is lacking currently.
Cluster	A cluster occurs when two or more AEFIs related in time, place and/or vaccine* occur together.	ix. When vaccines are administered on massive scale, it is important for immunization programs to anticipate and prepare for clusters of AEFI as the chances for immunization errors and

		Immunization anxiety-related reactions are much higher than that of routine immunization. Coincidental events can also occur as clusters
Signal	A signal is information that arises from one or multiple sources(including observations and experiments) which suggests a new potentially causal association, or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verification action	x. Signal detection, verification and response is a key activity that has to be specially addressed in the COVID-19 context. Signals can best be identified by pooling of data from multiple sources and analysing if the pooled data points to the occurrence of a new event that could causally related to the vaccine.

13.6 Annex 5 (a): Health facility Daily Report

COVID-19 Vaccination Daily Report

Country:

Region:

District:

Name of health
facility:

Date (DD-MM-YY) ____/____/____ Unit/Section/Site

COVID-19 Vaccine first dose (Vaccine name)	Less than 45 years (Not Older adult)				45 years and above (Older adult)				Total
	At least one health condition		No Existing health condition		At least one health condition		No Existing health condition		
		Male	Female	Male	Female	Male	Female	Male	Female
	Health Care workers								
	Others								
	Total Cov-1								

COVID-19 Second dose (Vaccine name)	Health Care workers									
	Others									
	Total Cov-1									

Number of vaccine doses available

Number of AEFIs: Minor _____
Severe _____

Name,
signature
of
responsible
and Stamp

Number of vaccine doses Received _____

Number of vaccine doses used:

Number of vaccine doses remaining: _____

Comments: _____

13.7 Annex 5 (b): Health facility Monthly Report

COVID-19 Vaccination Monthly Report

Country: _____ Region: _____ District: _____ Name of health facility: _____ Month: _____

Date (DD-MM-YY) ____/____/____ Unit/Section/Site _____

COVID-19 Vaccine first dose (Vaccine name)	Less than 45 years (Not Older adult)				45 years and above (Older adult)				Total
	At least one health condition			No Existing health condition		At least one health condition		No Existing health condition	
		Male	Female	Male	Female	Male	Female	Male	Female
	Health Care workers								
	Others								
	Total Cov-1								

COVID-19 Second dose (Vaccine name)	Health Care workers									
	Others									
	Total Cov-1									

Number of vaccine doses
available _____

Number of AEFIs: Minor _____
Severe _____

Number of vaccine doses Received _____

Number of vaccine doses
used: _____

Number of vaccine doses remaining: _____

Comments: _____

Name,
signature
of
responsib
le and
Stamp

13.8 Annex 6: District Daily/Monthly Report

COVID-19 Vaccination District Daily/Monthly Report

Country:

Region:

District:

Daily/Monthly

Date (DD-MM-YY)

____/____/____

COVID-19 Vaccine first dose (Vaccine name)	Less than 45 years (Not Older adult)					45 years and above (Older adult)				Total
	At least one health condition			No Existing health condition		At least one health condition		No Existing health condition		
		Male	Female	Male	Female	Male	Female	Male	Female	
	Health Care workers									
	Others									
	Total Cov-1									

COVID-19 Second dose (Vaccine name)	Health Care workers									
	Others									
	Total Cov-2									

Number of AEFIs: Minor _____

Severe _____

Number of vaccine doses available :

Number of vaccine doses received : _____

Number of vaccine doses used :

Number of vaccine doses remaining:

Comments: _____

Name, signature of
responsible and
Stamp

13.9 Annex 7: COVID-19 Vaccination National periodic report

COVID-19 Vaccination National periodic report

Country: Region: District Month: Starting Date of vaccination (DD-MM-YY)

Date (DD-MM-YY)
/ /

a) Current month

COVID-19 Vaccine first dose (Vaccine name)	Less than 45 years (Not Older adults)					45 years and above (Older adults)				Total
	At least one health condition			No Existing health condition		At least one health condition		No Existing health condition		
		Male	Female	Male	Female	Male	Female	Male	Female	
	Health Care workers									

	Others									
	Total Cov-1									
COVID-19 Second dose (Vaccine name)	Health Care workers									
	Others									
	Total Cov-2									

b) Cumulative

	Less than 45 years (Not Older adult)	45 years and above (Older adult)	Total
--	--------------------------------------	----------------------------------	-------

	At least one health condition			No Existing health condition		At least one health condition		No Existing health condition		
		Male	Female	Male	Female	Male	Female	Male	Female	
COVID-19 Vaccine first dose (Vaccine name)	Health Care workers									
	Others									
	Total Cov-1									
COVID-19 Second dose (Vaccine name)	Health Care workers									
	Others									
	Total Cov-2									

Vaccine Management

Number of vaccine doses available at beginning of the month: _____

Number of vaccine doses available received during the month: _____

Number of vaccine doses used during the month: _____

Number of vaccine doses remaining at the end of the month: _____

AEFI monitoring

	Minor	Severe	Total
Last month			
Cumulative			

Comments: _____

Total COVID-19 Vaccine received in the country since the beginning

Source of vaccine	Name of vaccine and Quantity			
	Vac1:	Vac2:	Vac3:	Vac4:
COVAX				
AVATT (African Union)				
Bilateral agreement				
Total				

Name, signature of responsible and Stamp