The Philippine National Deployment and Vaccination Plan for COVID-19 Vaccines

Interim Plan

January 2021

Foreword

The COVID-19 pandemic has indubitably been be a great challenge to every Filipino in the past year. While this unprecedented situation has caused major changes in the everyday life of our citizens, we have proven well our ability to forge forward in the face of this crisis. In the past year, our strategy has focused on ensuring the minimum public health standards through the BIDA Solusyon campaign to mitigate the spread of the virus and protect the most vulnerable in the absence of a cure for the virus.

The hard work of scientific and medical professionals all over the world allowed us to enter the new year with not just brand new insights, but renewed confidence and vigor to fight this pandemic. The breakthroughs in the development of a vaccine for COVID-19 is an effective way of protecting our communities by reducing the possibility of severe cases. Now, countries all over the world are launching their respective vaccination programs to turn the tides of the pandemic, with the Philippines among the ranks of countries to have given the green light for the largest vaccination campaign to date.

Through the National Vaccine Deployment Plan, the Philippine government brings together all national agencies, local government counterparts, as well as partners in the private sector and civil society. By approaching the vaccination program in a whole-of-system, whole-of-government, whole-of-society approach, we can ensure the successes of the national vaccine deployment program in delivering safe, effective, and accessible vaccines for all Filipinos.

As our history, experience, and science has proven in the past decades, vaccines save lives. An effective and national vaccination program, in tandem with the continued observance of the minimum public health standards, will pave the way for the recovery of our beloved country and bring us one step closer to our vision of a Healthy Pilipinas.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health
Chair, Inter-Agency Task Force for the Management of Emerging Infectious Diseases

Foreword

In the past year, we have faced the most challenging of times in our country's and in the world's history with the COVID-19 pandemic drastically affecting our lives. Globally, there are more than 90 million confirmed cases and 2 million deaths. Of this number half a million Filipinos have contracted the virus while nearly ten thousand have died. The pandemic has disrupted the economy, causing a nine percent contraction in the first half of 2020 and increased unemployment rate to 17.7 percent. While we are resuming economic activities and continuously adapting to the "New Normal", the risk of us or our loved ones getting infected and the uncertainty as to how or when the pandemic will end remains.

One of the most important developments in our fight against the pandemic is the development of COVID-19 vaccines at an unprecedented speed. While there is no cure and none of the vaccines that are being developed have been proven to prevent transmission, the vaccines still serve very important purposes. These are that of preventing severe disease thereby reducing deaths caused by severe effects of the virus and preventing symptoms from occurring thereby reducing transmission.

The Philippine situation must also be understood in light of the following major challenges in the national deployment and vaccination program. First, there is a very limited global supply of vaccines where every country in the world is seeking to gain access to vaccines and where 80% of available supply has already been taken by the richest countries. Knowing there is a limited supply, our policy is to build a portfolio of safe and effective vaccines and working with the private sector and our local government units because gaining access to more vaccine manufacturers and more partners enables us to secure more supply for our countrymen. Second, is that the effects of the vaccine have not been fully observed in some population groups.

Combatting the COVID-19 pandemic requires a Whole-of-Nation Approach. To ensure efforts are synchronized and integrated, there must be strong leadership and governance starting from the President, the Inter-Agency Task Force, the National Task Force, with the DOH and the DILG playing crucial roles in exercising command and control with the cooperation and strong participation of supportive academic societies, engaged government agencies and the private sector, highly committed LGUs and LCEs, adequately informed communities and well-prepared health systems.

While the vaccine is among the solutions, it is not the only solution to end the pandemic. Thus, it is critical for everyone's health, safety and well-being to still adhere to minimum public health standards, make smart choices based on correct information, practice safe behavior and for the health sector to conduct effective surveillance, contact tracing and have adequate capacity to manage the sick. The Department of Health, through the Task Group COVID-19 Immunization Program, has diligently worked on this comprehensive plan for vaccine deployment and vaccination in collaboration with other national government agencies under the COVID-19 Vaccine Cluster. This document will help unify the efforts of all stakeholders to effectively implement the National Deployment and Vaccination Plan for COVID-19 Vaccines and inform the general population on the plans of the government. We hope the combined efforts of all stakeholders will enable us to implement a sustainable immunization program essential to start economic recovery and restore normalcy in the lives of the Filipino people.

SECRETARY CARLITO G. GALVEZ, JR.
Chief Implementer and Vaccine Czar
National Task Force Against COVID 19

Acknowledgement

The Philippine National Deployment and Vaccination Plan for COVID-19 Vaccines (NDVP) was developed by the Philippine Government under the leadership of President Rodrigo Roa Duterte, and under the guidance of Health Secretary Franscisco T. Duque III and COVID-19 Vaccine Cluster Chair, Secretary Carlito G. Galvez Jr.

All government agencies under the COVID-19 Vaccine Cluster have contributed in the development of this plan: Office of the President (OP), Office of the Chief Presidential Legal Counsel (OCPLC), Department of Health (DOH), Department of Science and Technology (DOST), Food and Drug Administration (FDA), Research Institute for Tropical Medicine (RITM), Department of Trade and Industry (DTI), Department of Foreign Affairs (DFA), National Development Company (NDC), Department of Finance (DOF), Department of Budget and Management (DBM), Department of Interior and Local Government (DILG), Department of Social Welfare and Development (DSWD), Department of Education (DepEd), Department of National Defense (DND), Department of Information and Communications Technology (DICT), Department of Transportation (DOTr), Department of Justice (DOJ), Department of Labor and Employment (DOLE), Armed Forces of the Philippines (AFP), Office of Civil Defense (OCD), Philippine National Police (PNP), Bureau of Corrections (BuCor), Bureau of Jail Management and Penology (BJMP), and Task Group Resource Management and Logistics (TGRML) under the National Task Force Against COVID-19.

The Task Group COVID-19 Immunization Program, under the guidance of Undersecretary Myrna C. Cabotaje and Director Napoleon Arevalo, consolidated and ensured the completion of this plan. Further, special thanks to the following for doing the technical writing, editing and proofreading: Dr. Marianne B. Calnarv, Dr. Rhodora S. Cruz, Ms. Christine Joy Candari, Dr. Kezia Lorraine Rosario, Dr. Shaymae Ufano, Mr. Jay Dulay, Dr. Sarah Lazaga, Mr. Venjie Benito and Ms. Rowena J. Capistrano.

The contributions and insights of everyone are truly appreciated.

List of Acronyms

AEFI	Adverse Event Following Immunization
AESI	Adverse Event of Special Interest
AFP	Armed Forces of the Philippines
API	Application Program Interface
BHERTs	Barangay Health Emergency Response Teams
BJMP	Bureau of Jail Management and Penology
BuCor	Bureau of Corrections
CEIR	COVID-19 Electronic Immunization Registry
CHD	Center for Health Development
CHO	City Health Office
CIOMS	Council for International Organizations of Medical Sciences
COVID-19	Coronavirus Disease 2019
CPG	Clinical Practice Guidelines
CPR	Certificate Product of Registration
CSO	Civil Society Organization
DBM	Department of Budget and Management
DENR	Department of Environment and Natural Resources
DepEd	Department of Education
DFA	Department of Foreign Affairs
DICT	Department of Information and Communications Technology
DILG	Department of Interior and Local Government
DND	Department of National Defense
DOF	Department of Finance
DOH	Department of Health
DOJ	Department of Justice
DOLE	Department of Labor and Employment
DOST	Department of Science and Technology
DOTr	Department of Transportation
DPA	Data Privacy Act
DPCB	Disease Prevention and Control Bureau
DSWD	Department of Social Welfare and Development
DTI	Department of Trade and Industry

EB	Epidemiology Bureau
EO	Executive Order
ESU	Epidemiology and Surveillance Unit
EUA	Emergency Use Authorization
EXECOM	Executive Committee
FDA	Food and Drug Administration
GAA	General Appropriations Act
GAVI	Global Alliance for Vaccines and Immunization
GFI	Government Financial Institutions
GOCC	Government-owned and Controlled Corporation
H1N1	Influenza A virus subtype H1N1
HCWM	Health Care Waste Management
HEMB	Health Emergency Management Bureau
HIS	Health Information System
HPDPB	Health Policy Development and Planning Bureau
HTAC	Health Technology Assessment Council
HUC	Highly Urbanized Cities
IATF-EID	Inter-Agency Task Force on Emerging Infectious Diseases
ICC	Independent Component Cities
ICT	Information and Communication Technology
IHR	International Health Regulation
IPC	Infection Prevention Control
JV	Joint Venture
KMITS	Knowledge Management and Information Technology Service
LCE	Local Chief Executive
LGU	Local Government Unit
MERS-CoV	Middle East Respiratory Syndrome Coronavirus
MOH-BARMM	Ministry of Health-Bangsamoro Autonomous Region of Muslim Mindanao
MR-OPV SIA	Measles-Rubella Oral Polio Vaccine Supplemental Immunization Activity
NAEFIC	National Adverse Events Following Immunization Committee
NAP	National Action Plan
NART	National AEFI Response Team
NCDA	National Council on Disability Affairs
NDA	Non-Disclosure Agreement
NDC	National Development Company
NDVP	National Deployment and Vaccination Plan

NEDA	National Economic Development Authority
NIP	National Immunization Program
NITAG	National Immunization Technical Advisory Group
NPC	National Privacy Commission
NRA	National Regulatory Authority
NTC	National Telecommunications Commission
NTF	National Task Force
OCD	Office of Civil Defense
OCPLC	Office of the Chief Presidential Legal Counsel
ODA	Official Development Assistance
OHCS	One Hospital Command System
OP	Office of the President
PCG	Philippine Coast Guard
PCHRD	Philippine Council for Health Research and Development
PCOO	Presidential Communications Operations Office
PDL	Persons Deprived of Liberty
PDOHO	Provincial DOH Office
PHEIC	Public Health Emergency of International Concern
PHO	Provincial Health Office
PIA	Philippine Information Agency
PIC	Personal Information Controllers
PIDSR	Philippine Integrated Disease Surveillance and Response
PIP	Personal Information Processors
PNP	Philippine National Police
PPE	Personal Protective Equipment
PWD	Persons with Disability
RHU	Rural Health Unit
RITM	Research Institute of Tropical Medicine
RMP	Risk Management Plan
rVSV-ZEBOV	Recombinant Vesicular Stomatitis Virus-Zaire Ebola Virus
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SAGE	Strategic Advisory Group of Experts
SCB	Safety Collector Boxes
SOP	Standard Operating Procedure
STG	Sub-Task Group
TG	Task Group

TGRML	Task Group Resource Management and Logistics
UNICEF	United Nations Children's Fund
VAL	Vaccination Administration Location
VEP	Vaccine Expert Panel
VIMS	Vaccine Information Management System
VIRAT	Vaccine Introduction Readiness Assessment Tool
VOC	Vaccination Operation Center
WHO	World Health Organization

Table of Contents

Executive Summary

This document describes the National Deployment and Vaccination Plan for COVID-19 vaccines. It is comprised of an Introduction, Special Chapters, and the Main Chapters for the seven phases of the plan, namely: Scientific Evaluation and Selection, Access and Acquisition, Procurement and Financing, Shipment and Storage, Distribution and Deployment, Implementation of Nationwide Vaccination, and Assessment, Monitoring, and Evaluation.

The Introduction provides the rationale, guiding principles, and process for development of the Plan. The Special Chapters includes discussion on the governance structure of the deployment and vaccination program, the risk communication and community engagement, and the vaccination registry and data management of vaccination information.

The first chapter in the Main Chapters section is the Scientific Evaluation and Selection which defines the criteria to be used in evaluating the COVID-19 vaccines and the prioritization mechanism for the vaccines that will be initially considered for evaluation.

The second chapter is the Diplomatic Negotiation and Engagement which describes the process of engagement of the government with foreign entities as to the vaccine development, evaluation, and selection that are to be considered for procurement and clinical trials in accordance with the national regulatory processes.

The third chapter is on Procurement and Financing which discusses the three phases of the vaccine procurement process, the resources and funding requirements for the vaccination program and the measures placed in ensuring that the government funds are allocated and provided to entities with vaccines that are proven safe and with efficacy.

The fourth chapter is the Shipment and Storage which provides the technical details on the adequate supply chain system for the COVID-19 vaccination program which includes the proposed distribution process flow and distribution scenarios based on the vaccine specifications, the cold chain management, and details on the ancillary immunization supplies.

The fifth chapter is on Distribution and Deployment and discusses the principles that will guide the distribution and deployment of COVID-19 vaccines, its corresponding strategies and the identification of the segments of the population that are considered eligible for vaccination.

The sixth chapter provides a discussion on the Implementation of a Nationwide Vaccination. This section provides a detailed explanation on the three phase approach, namely the i) Pre-implementation Phase, ii) Implementation Phase, and iii) Post-Implementation Phase of the national government in operationalizing the COVID-19 vaccination program.

The final chapter is on Assessment, Evaluation and Monitoring which discusses the post-implementation phase events where it describes in details the vaccines safety monitoring, the management of adverse events following immunization, the protocols for safety surveillance and responses, and the mechanism for appropriate reporting, monitoring and evaluation of the COVID-19 vaccination program.

Overall, this plan has been developed with input from experts of various government agencies wherein central to its crafting is the objective of providing the operational guidance in the implementation of the COVID-19 vaccine deployment and vaccination program in the Philippines.

Introduction

Background

On 30 January 2020, the World Health Organization (WHO) declared Coronavirus Disease 2019 (COVID-19) as a Public Health Emergency of International Concern (PHEIC). On the same date, the Philippines, an archipelagic country in Southeast Asia with a population of 109,581,078 (based on the 2020 Philippine Statistics Authority census), had its first laboratory-confirmed case of COVID-19. COVID-19 is a disease caused by a novel coronavirus first reported from Wuhan, China last 31 December 2019, and was later named as the Severe Acute Respiratory Syndrome-Coronavirus 2 (SARS-CoV-2). On 7 March 2020, the Department of Health (DOH) announced the country's first reported local transmission when a 60-year-old male, without any travel history outside the Philippines was confirmed to be positive for SARS-CoV-2. On 11 March 2020, the WHO characterized COVID-19 as a pandemic.

Since then, the Philippines has been responding to mitigate the impact of COVID-19 pandemic and has been implementing numerous interventions with varying levels and degrees of success. These interventions are anchored on the National Action Plan Against COVID-19 (NAP), the national strategic plan for COVID-19 pandemic response, and utilized the Prevent-Detect-Isolate/Quarantine-Treat-Reintegrate (PDITR) strategy. For NAP Phase I (March-June 2020), the National Government focused on preventing and containing the COVID-19 pandemic while mitigating its socioeconomic impact. For NAP Phase II (July-September 2020), the National Government focused on socioeconomic recovery. Lastly, for NAP Phase III (October 2020-March 2021), the National Government focused on managing the health risk while gradually transitioning to full socioeconomic recovery, and inclusion of vaccines as part of the COVID-19 interventions.

Vaccines have saved millions of lives in the past. Countries around the world have implemented numerous immunization programs against more than 20 life-threatening diseases, such as measles, poliomyelitis, hepatitis B, influenza, and many others. These vaccination efforts prevented almost 2-3 million deaths every year and allowed people to live longer and healthier lives. Also, through vaccination, eradication and near elimination of diseases have been made possible, such as in the case of smallpox and poliomyelitis.

In the past, vaccines have also been utilized as an integral part of epidemic (pandemic) response to infectious diseases. Examples are the 2009 Influenza pandemic vaccines against the novel influenza A (H1N1) virus and the Recombinant Vesicular Stomatitis virus–Zaire Ebola virus (rVSV-ZEBOV) vaccine against Ebola in 2014 to 2016. Such vaccines have prevented succeeding outbreaks and further disease spread, and have aided in saving thousands of lives. An exemplar of the benefit of vaccines in halting disease outbreaks and breaking the chain of transmission was in August 2018

when the Democratic Republic of Congo (DRC) declared the Kivu Ebola epidemic as 53 individuals were infected and 29 deaths were reported, 300,000 individuals were vaccinated immediately thereafter. This endeavor resulted in halting the outbreak within the region, and due to continuous efforts via *the ring vaccination strategy*, the reported number of deaths among those who were infected and infected cases of tertiary contacts (contacts of contacts) were significantly reduced.

Thus, with the COVID-19 pandemic, the Philippines is exploring all means to access COVID-19 vaccines and prepare the country for the implementation of a COVID-19 deployment and vaccination program once a safe, effective and good quality vaccine is readily available.

Rationale for the National Deployment and Vaccination Plan

The Philippine National Deployment and Vaccination Plan for COVID-19 Vaccines was drafted for the purpose of providing operational guidance in the implementation of the COVID-19 vaccine deployment and vaccination program.

The drafting of the plan involved the participation of various government agencies to ensure alignment of policies and plans among agencies and integration of the said plans into national governance mechanisms.

In addition, the deployment of COVID-19 vaccines and the implementation of the COVID-19 vaccine program necessitates the participation of all members of the society. Thus, a whole-of-society approach is being implemented where all members of the society and government are encouraged to participate and take action to achieve collective goals and objectives. In this regard, while the government leads in the deployment of vaccines and implementation of a vaccination program, the private sector and other organizations are engaged to collaborate and work closely with the government to ensure a unified and coordinated vaccination campaign is conducted.

Target Audience

The target audience for the Philippine National Deployment and Vaccination Plan for COVID-19 vaccines include but are not limited to:

- Policy makers
- Planners
- Program and project implementers
- Development partners
- Health service providers
- Partners in public and private sector
- Civil Society Organizations

- Health consumers and the general public.

Dissemination of the Plan

Providing this Plan to the different audiences in a meaningful way that will engage the audience and enable action will require that there are different versions and formats of this plan. The visual below summarizes the proposed dissemination of the plan.

Users	Needs	Dissemination
● Government at all levels ● Development partners ● International agencies ● Private Sector ● Academic and Research Institutions ● General Public	● Taking stock ● Any changes / updates in the plan ● Follow-up ● Planning and Projections ● Sector analysis ● Buy-in	**Contents (what)** ● Tables ● Graphs and maps ● Analysis ● Policy briefs and briefers ● Powerpoint presentations **Media (How)** ● hard copy of the plan ● Soft copy of the plan ● media (TV, newspapers) ● workshops and seminars ● government's knowledge management website.

Implementers at all levels should bear in mind the *science, scale, skills, speed and systems* needed for proper, effective and seamless execution of this plan.

Guiding Principles

The development of the Philippine National Deployment and Vaccination Plan for COVID-19 vaccines is guided by the following principles:

A. National Ownership

The Philippine Government recognizes the huge national endeavor that the country needs to undertake to ensure equal access to vaccines and to implement quality vaccination services; the complexity of the vaccine deployment and vaccination activities; and the necessity to protect national interests while ensuring that rigorous scientific review has been undertaken prior to deployment and considering population safety. Thus, the national government shall be the primary responsible entity to ensure good governance in the implementation of vaccination services and provision of quality and effective immunization

services for all.

B. Shared Responsibility

The COVID-19 vaccine deployment and vaccination program is an endeavor necessitating the participation of all members of the society where each member has a vital responsibility to uphold and role to play. The Filipino Citizen, the communities, the national government and the private sector have intertwined responsibilities in which when rightfully upholded can positively dictate the success of the COVID-19 vaccination efforts of the country.

A whole-of-society approach shall be applied where all members of the society and government are encouraged to participate and take action to achieve collective goals and objectives. In this regard, while the government leads in the deployment of vaccines and implementation of a vaccination program, the private sector and other organizations are encouraged to collaborate and work closely with the government to ensure a unified and coordinated vaccination campaign is conducted.

C. Integration

With the COVID-19 pandemic, vaccination against COVID-19 is provided to Filipino citizens as an intervention and as an integral part of the national government's pandemic response. However, the COVID-19 vaccination services shall be fully integrated into the country's health systems and eventually to the regular immunization services.

D. Innovation

There has been a tremendous abundance of innovations and breakthroughs in the development of COVID-19 vaccines. Developers and regulatory experts have collaborated early on to help speed up vaccine development by ensuring that standards of safety and efficacy are integrated in the process of development. In this regard, the Philippine government recognizes the vitality of adapting newer knowledge and scientific evidence gathered through research and innovation on COVID-19 vaccine and immunization to ensure effective implementation of COVID-19 immunization services.

The allocation and prioritization of COVID-19 immunization shall be anchored to the following principles:

A. Human well-being: where health, social and economic security, human rights and civil liberties of all citizens and individuals are protected and promoted.

B. Equal respect: where all human beings are treated equally and their interests are considered with equal moral consideration.

C. National equity: where equity in vaccine access is assured nationally and those with greater burden of COVID-19 pandemic.

D. **Reciprocity:** where individuals and groups who bore a greater burden in the COVID-19 pandemic response and have higher significant risks brought by their responsibilities and roles shall be given greater priority.
E. **Legitimacy:** where decisions are made through transparent processes based on shared values and scientific evidence.

Process for Developing the Plan

The development process for this Plan was participatory and involved various stakeholders led by the COVID-19 Vaccine Cluster and its Task Group (TG) and Sub-Task Group (STG) members. These TGs and STGs were composed of various Departments and Agencies as outlined in the section of Governance. The TGs and STGs under the COVID-19 Vaccine Cluster developed briefs to guide the implementation of the vaccine. Key Informant Interviews were also conducted to understand various perspectives in addition to various rapid assessments. A short-term technical assistance staff was hired to collate the briefs/guides developed by each of the TGs and STGs. A series of meetings were held to review and enrich the plan. The final draft of the plan was presented to the DOH Executive Committee, COVID-19 Vaccine Cluster of the National Task Force for endorsement. This is a living plan and will be updated as more information becomes available or as recommendations are provided by WHO and Unicef.

Lay-out of the Plan

This Plan is set out in two sections: Special Chapters and Main Chapters.
The Special Chapters details cross-cutting interventions which covers:

- Governance
- Risk Communication and Community Engagement
- Registry and Data Management.

The Main Chapters cover the 7 stages of the Vaccine Roadmap:

- Scientific Evaluation and Selection of the Vaccine
- Access and Acquisition
- Procurement and Financing
- Shipment and Storage
- Distribution and Deployment
- Implementation of Nationwide Vaccination
- Assessment, Evaluation, and Monitoring

Special Chapter

Governance

COVID-19 vaccine deployment and vaccination program is a combined national, regional, and local responsibility that requires close collaboration between public health, external agencies, and community partners. It is imperative that national and local agencies, public and private sectors, and other planning partners clearly understand each other's roles and responsibilities in the COVID-19 vaccination program. Therefore, a comprehensive and extensive organizational structure is critical in the planning and execution of COVID-19 vaccine plans and policies; and essential for establishing a robust system of leadership, accountable and transparent decision-making structure and process to protect national interests. A wide array of expertise shall be represented among team members; thus, a multi-sectoral organizational structure capable of making transparent and robust decision-making and organizational processes is organized.

Using the guidance provided by the World Health Organization's Vaccine Introduction Readiness Assessment Tool (VIRAT), a multi-sectoral national organizational structure for the COVID-19 vaccine is established, institutionalized, and integrated with existing organizational structures and coordination mechanisms for COVID-19 response. The VIRAT recommends creating the following: a National Coordinating Committee, Technical Working Groups and Sub-Technical Working Groups; and establishment and institutionalization of the National Immunization Technical Advisory Group (NITAG) and National Adverse Events Following Immunization Committee (NAEFIC), both are independent/external advisory bodies.

Therefore, the Philippine Government established the COVID-19 Vaccine Cluster Organizational Structure. The COVID-19 Vaccine Cluster shall serve as an unified command, control, coordination, communication, and cooperation mechanism that ensures the procurement, deployment of COVID-19 vaccine and the vaccination of identified eligible populations *(see Figure 1).*

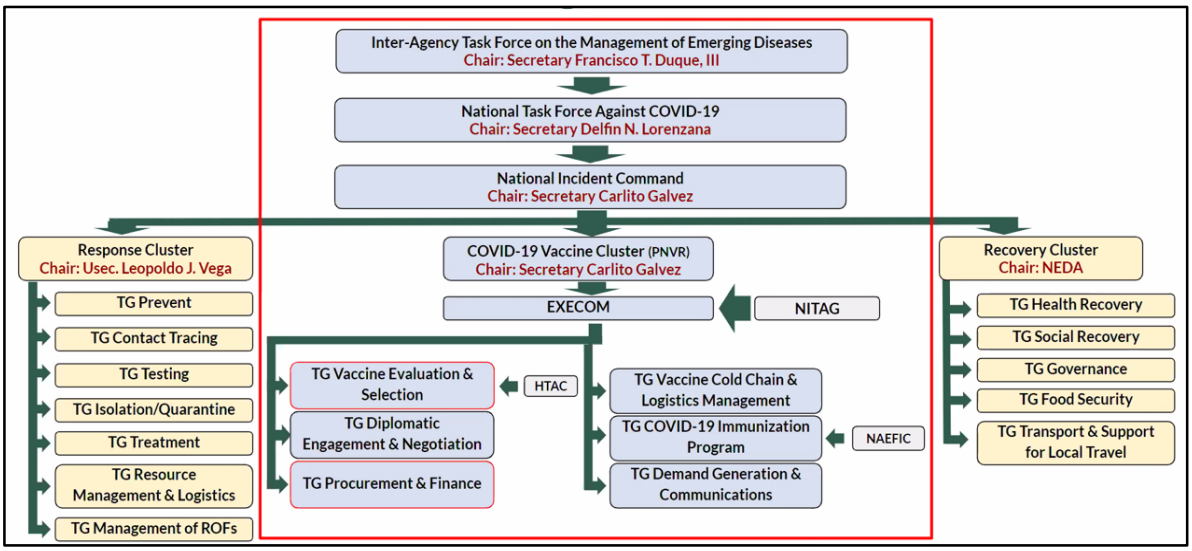


Figure 1. COVID-19 Vaccine Cluster organizational structure.

Specifically, utilizing existing organizational structures and coordination mechanisms established for the COVID-19 pandemic response, the organizational structure and line of command for COVID-19 vaccines is as follows:

1. The **Inter-Agency Task Force on Emerging Infectious Diseases** (**IATF-EID**, or merely the **IATF**) is a task force created through Executive Order No. 168 s. 2014 by the Philippine President to respond to affairs concerning emerging infectious diseases in the country. For COVID-19 vaccines, the IATF-EID shall serve as the National Coordinating Committee.

2. For the COVID-19 pandemic response, President Rodrigo Roa Duterte established the **National Task Force (NTF) Against COVID-19** to oversee the operations of the national response. Detailing the strategic framework of the pandemic response, the National Task Force drafted the National Action Plan Against COVID-19 (NAP) to guide the operations of the pandemic response anchoring on the principle that the response should be national-government-enabled, local government unit (LGU)-led, and people-centered.

3. Under the NTF Against COVID-19, there are three clusters namely, the Response Cluster, the Recovery Cluster and the **COVID-19 Vaccine Cluster.** As mentioned above, seeing the need for an organizational structure to support the strategic directions of the national government, the COVID-19 Vaccine Cluster was added based on the guidance stipulated in the NAP Phase III. In line with the directions of the VIRAT, the COVID-19 Vaccine Cluster shall serve as the National Technical Working Group. The COVID-19 Vaccine Cluster is led by Secretary Carlito G. Galvez, Jr., who was designated by President Rodrigo Roa Duterte as the COVID-19 Vaccine Czar.

4. Under the COVID-19 Cluster are six **Task Groups**, and based on the direction of the VIRAT, shall serve as the Sub-Technical Working Groups. Each TGs is represented by the

designated lead in the COVID-19 Vaccine Cluster Executive Committee. The Committee, in turn, advises and updates the COVID-19 Vaccine Cluster Chair. The six Task Groups are (*see Figure 2)*:

a. Scientific Evaluation and Selection
b. Diplomatic Engagement and Negotiation
c. Procurement and Finance
d. Cold Chain and Logistics Management
e. Immunization Program
f. Demand Generation and Communications.

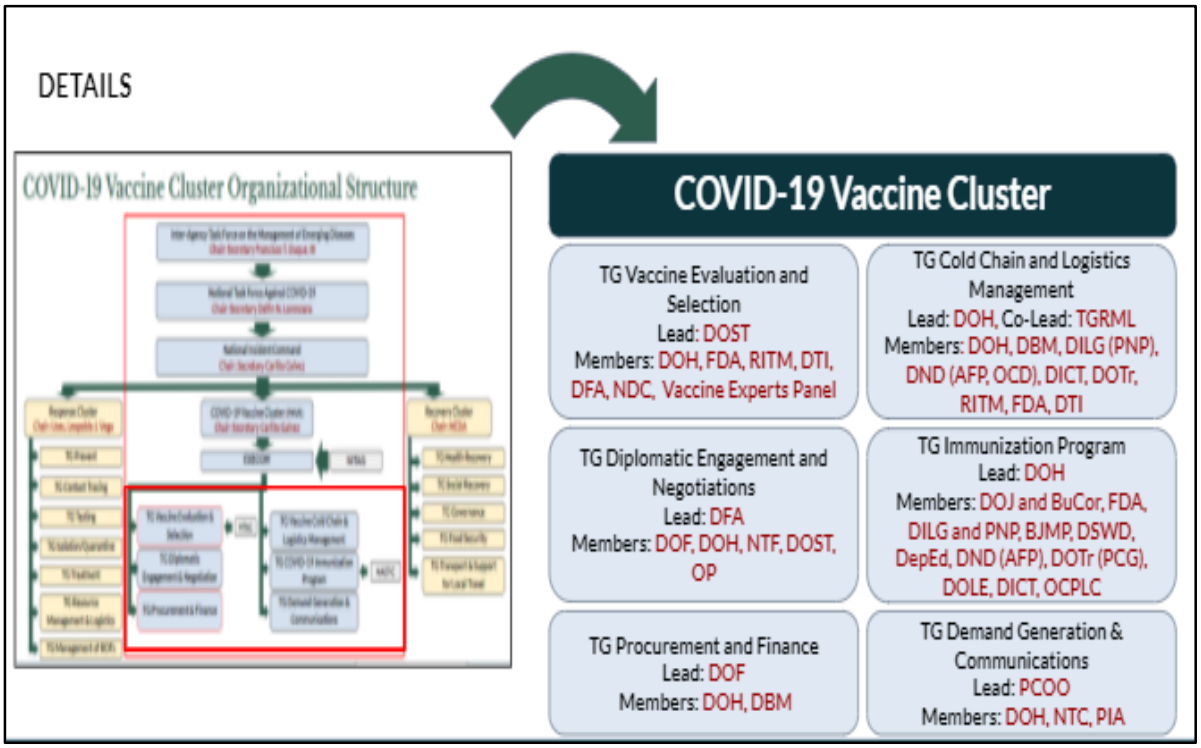


Figure 2. The COVID-19 Vaccine Cluster and its Task Groups.

The Task Groups are composed of various government agencies and participated by diverse experts and professionals:

a. TG Scientific Evaluation and Selection

i. Lead: Department of Science and Technology (DOST)
ii. Members: Department of Health (DOH), Food and Drug Administration (FDA), Research Institute for Tropical Medicine (RITM), Department of Trade and Industry (DTI), Department of Foreign Affairs (DFA), National Development Company (NDC), and the Vaccine Expert Panel (VEP)
iii. Roles and Responsibilities:
    1. Provide oversight on the evaluation of applications and conduct of COVID-19 vaccine clinical trials in the country.

2. Evaluate results of COVID-19 vaccine clinical trials as part of the inputs on the criteria for COVID-19 vaccine selection.
3. Develop criteria and provide recommendations of the evaluation and selection of COVID-19 vaccines that will be considered for procurement.
4. Continue engagement with bilateral partners for clinical trials interested in pursuing local manufacturing and technology transfer.

b. TG Diplomatic Engagement and Negotiation

i. Lead: Department of Foreign Affairs (DFA)
ii. Members: Department of Finance (DOF), DOH, National Task Force, DOST, Office of the President (OP)
iii. Roles and Responsibilities:
1. Initiate diplomatic engagements with other governments, international bodies, international non-government organizations, international financial institutions, and international cooperation agencies.
2. Provide feedback and updates to the other respective TGs pertaining to vaccines in the global market.
3. Coordinate and collaborate with TG Procurement and Finance in identifying viable global market vaccine manufacturers and entities.
4. Negotiate agreements for the provision of technical and financial assistance.

c. TG Procurement and Finance

i. Lead: DOF
ii. Members: Department of Budget and Management (DBM), DOH
iii. Roles and Responsibilities:
1. Facilitate procurement through various mechanisms allowed under existing laws, rules and regulations through bilateral, multilateral and other financial modalities (e.g. COVAX Facility and etc.).
2. Activate price negotiation board subject to HTA's cost-effective price, if applicable.
3. Coordinate with legislators, as may be necessary on budget and co-payment ceilings.
4. Explore local vaccine production and supply, if applicable.

d. TG Cold Chain and Logistics Management

i. Lead: DOH, Co-Lead: Task Group Resource Management and Logistics (TGRML) under the Response Cluster

ii. Members: DBM; Department of Interior and Local Government (DILG), specifically, the Philippine National Police (PNP); Department of National Defense (DND), specifically the Armed Forces of the Philippines (AFP) and the Office of Civil Defense (OCD), Department of Information and Communications Technology (DICT), Department of Transportation (DOTr), RITM, FDA, and DTI

iii. Roles and Responsibilities:

1. Map the potential port(s) of entry, points of storage (stores), and fallback facilities in the country with their respective cold chain and transportation/distribution capacity for vaccines and ancillary products and assess dry storage and cold chain capacity at all levels.
2. Facilitate acceptance and inventory of vaccines and logistics.
3. Facilitate and ensure storage, distribution and delivery of vaccines and logistics to target areas.
4. Monitor cold chain practices and ensure that vaccines are handled and disposed correctly and properly.
5. Develop a distribution plan down to the local level; adapt needs of vaccines, syringes and safety boxes to planning of stages or phases according to vaccine availability.
6. Schedule transportation of vaccines and other supplies at all levels.
7. Implement monitoring systems for vaccine distribution and conduct inventories using logistics information software integrated into existing systems and technology development (barcodes, electronic tracking, etc.).
8. Define indicators to evaluate the supply chain from the international up to the service delivery points.

e. TG COVID-19 Immunization Program

i. Lead: DOH

ii. Members: DILG, DND, Office of the Chief Presidential Legal Counsel (OCPLC), Bureau of Corrections (BuCor), Philippine Coast Guard (PCG), Department of Social Welfare and Development (DSWD), Department of Justice (DOJ), Department of Education (DepEd), AFP, PNP, BJMP, DICT, FDA, Department of Labor and Employment (DOLE)

iii. Roles and Responsibilities:

1. Plan and craft policies, guidelines and standard operating procedures related to the COVID-19 vaccine deployment and program implementation.

2. Estimate potential numbers of target populations that will be prioritized for access to vaccines stratified by target group and geographic location
3. Identify potential COVID-19 vaccine delivery strategies
4. Create a data information system for all vaccine recipients
5. Provide capacity building and trainings to implementers
6. Develop or adapt existing and implement AEFI/Post-marketing surveillance and monitoring framework
7. Ensure or craft guidelines, procedures and tools for planning and conducting vaccine pharmacovigilance activities

f. TG Demand Generation and Communications

i. Lead: Presidential Communications Operations Office (PCOO)

ii. Members: DOH, National Telecommunications Commission (NTC), Philippine Information Agency (PIA), DILG

iii. Roles and Responsibilities:

1. Design a demand and risk communication plan.
2. Implement social mobilization and community engagement activities.
3. Ensure social preparation of target population groups and geographical areas prior to vaccination.

5. Under the TG COVID-19 Immunization Program, are **four Sub-Task Groups (STGs)**, namely: STG Planning, Policy & Technical Support, STG Program Implementation, STG Registry, Data Management and Monitoring & Evaluation, and STG Safety Surveillance & Response. The STGs are composed of (*see Figure 3)*:

a. STG Planning, Policy & Technical Support

i. Lead: DOH [Disease Prevention and Control Bureau (DPCB)]

ii. Members: DOH [Epidemiology Bureau (EB), and Health Policy Development and Planning Bureau (HPDPB)], OCPLC, DepEd, DILG

b. STG Program Implementation

i. Lead: DOH (DPCB)

ii. Members: DOH [Health Emergency Management Bureau (HEMB) and Health Human Resource Development Bureau (HHRDB)], DILG (BFP, PNP, BJMP), DSWD, DepEd, DND (AFP), DOJ (BuCor), DOTr (PCG)

c. STG Registry, Data Management & M&E

i. Lead: DOH (EB)

ii. Members: DOH [Knowledge Management and Information Technology Service (KMITS) and DPCB], DICT, DWSD, DepEd

d. STG Safety Surveillance & Response

i. Lead: FDA

ii. Members: DOH [EB, Field Implementation and Coordination Team (FICT), DPCB, HEMB]

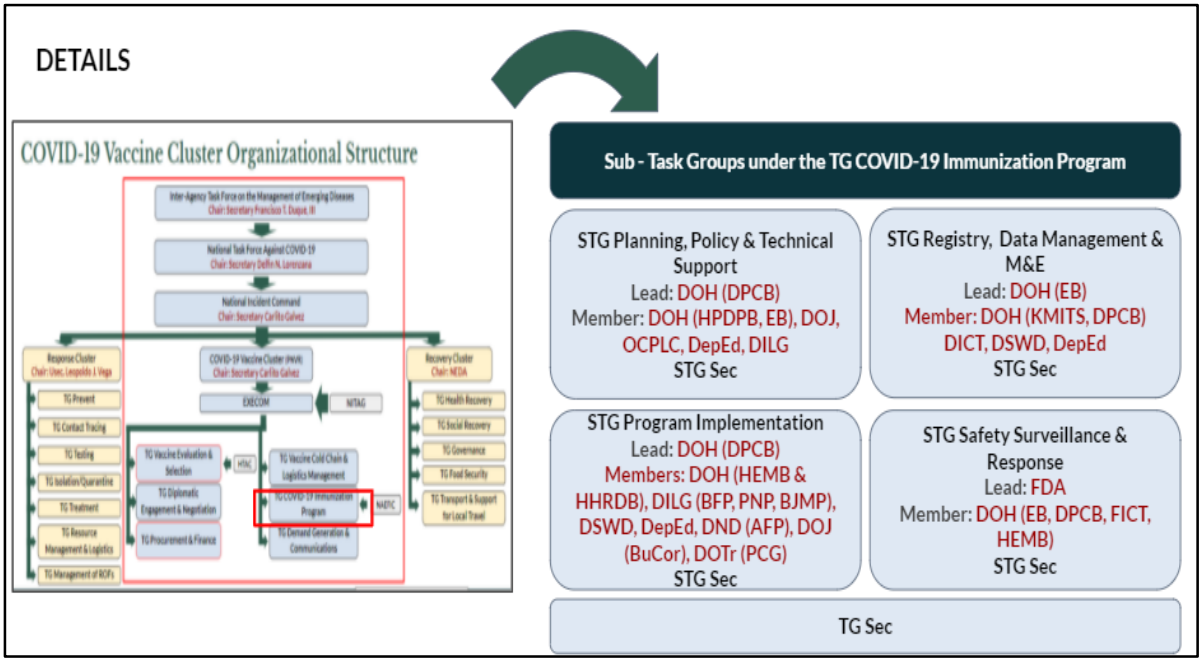


Figure 3. Sub-Task Groups under the TG COVID-19 Immunization Program.

6. The COVID-19 Vaccine Cluster is supported by several independent bodies. These are:

a. The **National Immunization Technical Advisory Group (NITAG) for COVID-19 Vaccines** is a multidisciplinary group of national experts responsible for providing independent, evidence-informed advice to policymakers and program managers on immunization and vaccine policy issues. The Philippine NITAG was organized and created through a Department Personnel Order as issued by the Secretary of Health of the Republic of the Philippines. The NITAG shall serve as an independent body that provides recommendations to the DOH and COVID-19 Vaccine Cluster, ensuring transparency, credibility, and technical soundness to the decision-making process and contributes to building public confidence COVID-19 vaccination program.

b. The **National Adverse Event Following Immunization Committee (NAEFIC),** comprises representatives from different medical societies and vaccine experts. It reviews, analyzes, and comes up with causality assessment as the basis for the Food and Drug Authority (FDA) action and appropriate DOH bureaus/offices on Adverse Events Following Immunization (AEFI) and Adverse Events of Special Interest (AESI).

c. The **Health Technology Assessment Council (HTAC)**, whose mandate is to undertake technology appraisals by determining their clinical and economic values in the Philippine healthcare system, with the aim to improve overall health outcomes and ensure fairness, equity and sustainability of coverage for all Filipino citizens.

Coordination

A coordination mechanism shall be set in place to ensure sufficient communication and information are shared between Task Groups, Sub-Task Groups, and independent bodies such as the NITAG, NAEFIC and HTAC, and the Vaccine Expert Panel.

The Vaccine Expert Panel shall provide regular updates to the COVID-19 Vaccine Cluster Head, HTAC, NITAG, and NAEFIC.

Complementation

The national organizational structure, the COVID-19 Vaccine Cluster, is complemented with the activation of an Incident Command System (ICS), which is supported by an operations center, duly named as the COVID-19 Vaccine Operations Center. The VOC shall be established and operationalized at all levels, as follows:

1. National COVID-19 Vaccination Operations Center
2. Regional COVID-19 Vaccination Operations Centers
3. Local COVID-19 Vaccination Operations Centers

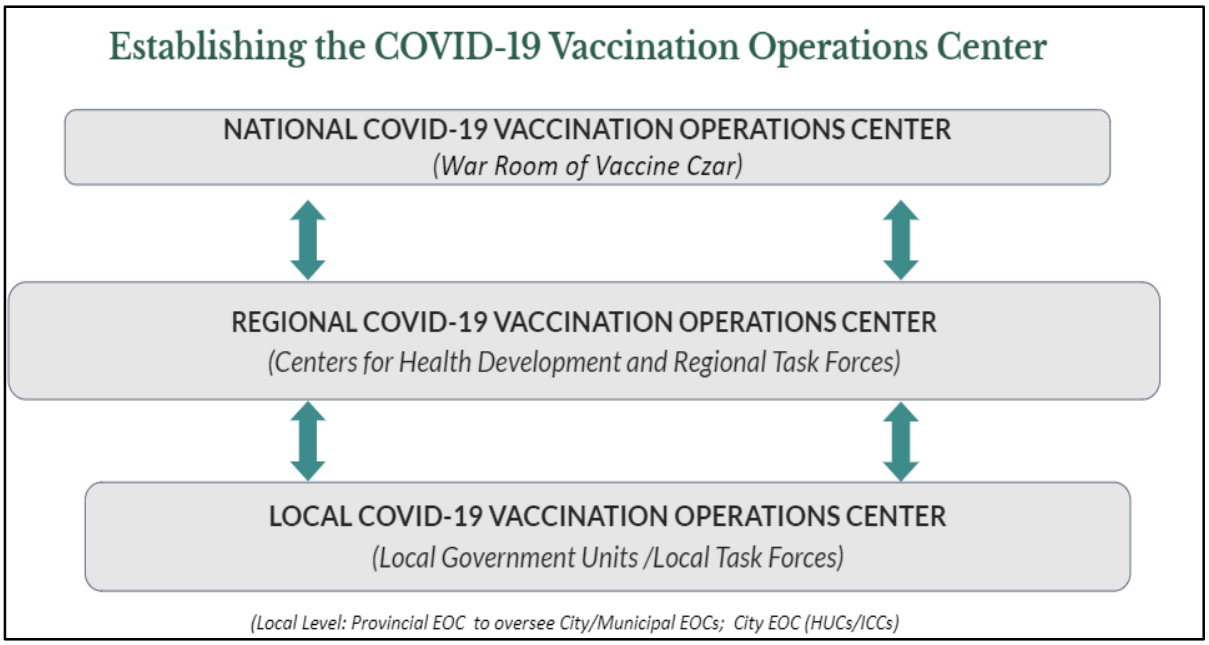


Figure 4. The COVID-19 Vaccination Operations Centers at all levels.

The National COVID-19 Vaccination Operations Center shall be headed by the COVID-19 Vaccine Cluster Chair, The Regional COVID-19 Vaccination Operations Center shall be led by the Centers for Health Development with the participation of other government agencies and the Regional Task Forces Against COVID-19. And lastly, the Local COVID-19 Vaccination Operations Center shall be led by the Local Government Units. The Provincial Vaccination Operations Center shall oversee the Municipal and City Vaccination Operations Center (component cities). To avoid overlapping of functions and oversight, the COVID-19 Vaccination Operations Centers shall be distinctly separated from the EOCs of the COVID-19 Response Clusters which are headed by the Regional/Local Task Forces.

The COVID-19 Vaccination Operations Center shall compose of various teams, namely:

1. **Planning, Campaign Management and Technical Team [DOH, DILG, DSWD, DepEd, AFP (their counterparts in the regional and local levels)]**

   Roles and Responsibilities:

   a. National VOC:

   i. Develop and release guidelines, policies, bulletins and advisories relevant to the vaccination campaign.
   ii. Set-up the National Vaccination Operations Center (NVOC).
   iii. Conduct orientations/training to program managers, stakeholders, implementers and monitors.
   iv. Monitor the implementation of the campaign.
   v. Review preparedness plans of the Regional VOCs and provide guidance/recommendations to Regional VOCs.

   b. Regional VOC:

   vi. Develop and release bulletins and advisories relevant to the vaccination campaign.
   vii. Set-up the Regional VOCs within their respective areas; and advocate for the establishment of the Local VOCs.
   viii. Roll-out the conduct orientations/training to program managers, stakeholders, implementers and monitors.
   ix. Conduct orientations/training to program managers, stakeholders, implementers and monitors.
   x. Monitor the implementation of the campaign.
   xi. Review preparedness plans and provide guidance / recommendations to implementers.
   xii. Analyze and report data to the National VOC.

c. Local VOC:

xiii. Develop and release bulletins and advisories relevant to the vaccination campaign.
xiv. Set-up the Local VOCs within their respective areas.
xv. Roll-out the conduct orientations and capacity building to program managers, stakeholders, implementers and monitors.
xvi. Monitor the implementation of the campaign.
xvii. Review preparedness plans of barangays and provide guidance/recommendations to implementers.
xviii. Analyze and report data to the Regional VOC.

2. Finance, Cold Chain and Logistics Team [OCD, DOH, AFP; (their counterparts in the regional and local levels)]

Roles and Responsibilities:

a. National VOC:

i. Conduct inspection and ensure the quality of logistics to be delivered.
ii. Ensure timely delivery of vaccines, syringes, personal protective equipment (PPEs) and other logistics to Centers for Health Development (CHDs) and Ministry of Health - BARMM, and those that are delivered directly to implementing units.
iii. Closely coordinate with CHDs to ensure availability of vaccines, vaccine carriers for cold chain management, and other supplies.
iv. Manage inventory of vaccines, its storage and distribution.
v. Coordinate with regional offices and LGUs on the latest inventory of logistics, supplies and its actual utilization.
vi. Facilitate the budget for the campaign's operations.
vii. Prepare sub-allotment upon receipt of the approved sub-allotment guidelines and ensure downloading of budget to regions prior to the campaign.

b. Regional VOC:

viii. Conduct inspection and ensure the quality of logistics to be delivered.
ix. Deliver vaccines, syringes, PPEs, and other logistics to Local Government Units, and or if required to implementing units.
x. Closely coordinate with CHDs to ensure availability of vaccines, vaccine carriers for cold chain management, and other supplies.
xi. Manage inventory of vaccines, its storage and distribution.
xii. Coordinate with LGUs and implementing units on the latest inventory of logistics, supplies and its actual utilization.

xiii. Facilitate the budget for the campaign's operations.

c. Local VOC:

xiv. Conduct inspection and ensure the quality of logistics to be delivered.

xv. Ensure timely delivery of vaccines, syringes, personal protective equipment (PPEs) and other logistics from national or regional delivery hubs.

xvi. Deliver vaccines, syringes, PPEs, and other logistics to implementing units.

xvii. Closely coordinate with CHDs to ensure availability of vaccines, vaccine carriers for cold chain management, and other supplies.

xviii. Manage inventory of vaccines, its storage and distribution.

xix. Coordinate with implementing units on the latest inventory of logistics, supplies and its actual utilization.

xx. Facilitate the budget for the campaign's operations.

3. Coordination Team [OCD, DOH, DILG; (their counterparts in the regional and local levels)]

Roles and Responsibilities:

a. National VOC:

i. Coordinate and collaborate with other government agencies, response partners and stakeholders.

ii. Coordinate immediate concerns to appropriate DOH and NGA offices and bureaus.

iii. Assist the Finance and Logistics Team for concerns related to delivery and distribution of logistics and supplies.

iv. Oversee and provide human resource support to the National EOC.

b. Regional VOC:

i. Coordinate and collaborate with other government agencies, partners and stakeholders at the regional level.

ii. Coordinate immediate concerns of LVOCs to the RVOCs. Coordinate with regional government agencies and partners to provide assistance and response, and address concerns raised.

iii. Assist the RVOC Finance, Cold Chain and Logistics Team for concerns related to delivery and distribution of logistics and supplies.

iv. Oversee and provide human resource support to the RVOC.

c. Local VOC:

i. Coordinate and collaborate with barangays, health facilities, partners and stakeholders.

ii. Coordinate immediate concerns of implementing units to the LVOCs. Coordinate with partners to provide assistance and response, and address

concerns raised.

iii. Assist the LVOC Finance, Cold Chain and Logistics Team for concerns related to delivery and distribution of logistics and supplies.

iv. Oversee and provide human resource support to the LVOC.

4. **Vaccine Safety, Surveillance and Response Team [DOH, FDA, DILG; (their counterparts in the regional and local levels)]**

Roles and Responsibilities

a. National/Regional VOC:

i. Oversee the design and implementation of the AEFI/AESI surveillance system.

ii. National to assist regions in the conduct of AEFI/AESI case investigation and comprehensive data analysis.

iii. Generate National AEFI/AESI Surveillance Report and provide information to N/R VOC.

iv. Provide technical assistance or training to develop/enhance capacity of regional/local AEFI/AESI surveillance.

v. Facilitate the convening of the National/Regional AEFI Committee meetings for causality assessment.

vi. Coordinate AEFI/AESI surveillance activities with all VOC levels.

vii. Maintain a database of all reported AEFIs/AESIs.

viii. Provide regular updates on COVID-19 vaccine surveillance to the N/R VOC.

b. Local VOC:

i. Implement AEFI/AESI surveillance activities.

ii. Lead in the conduct of AEFI/AESI case investigation and comprehensive data analysis.

iii. Generate AEFI/AESI Surveillance report and provide information to Local VOC, then submit to RVOC.

iv. Provide technical assistance or training to develop/enhance capacity of regional/local AEFI/AESI surveillance.

v. Provide regular updates on COVID-19 vaccine surveillance to the N/R VOC.

5. **Communications, Advocacy and Partnership Team [PCOO, PIA, DOH (their counterparts in the regional and local levels)]**

   Roles and Responsibilities

   a. *National/Regional VOC:*

      i. Develop a communication and community engagement plan, advocacy/information materials, and/or other relevant communication documents/materials.
      ii. Capacitate Health Education and Promotion Officers, social mobilizers and communicators.
      iii. Issue press releases relevant to the COVID-19 vaccination campaign.
      iv. Document COVID-19 vaccination campaign activities.
      v. Monitor the implementation of communications and community engagement activities in the LGUs.
      vi. Provide feedback or report communications and community engagement issues and concerns to NVOC.

   b. *Local VOC:*

      i. Advocate to and conduct partnership meetings with partners and stakeholders such as but not limited to the Local Chief Executives, LGU officials, medical societies, civil societies, religious sector, private physicians and other stakeholders.
      ii. Distribute advocacy/information materials, and/or other relevant communication documents/materials.
      iii. Document COVID-19 vaccination campaign activities.
      iv. Monitor the implementation of communications and community engagement activities in the implementing units and communities.
      v. Provide feedback or report communications and community engagement issues and concerns to LVOC.

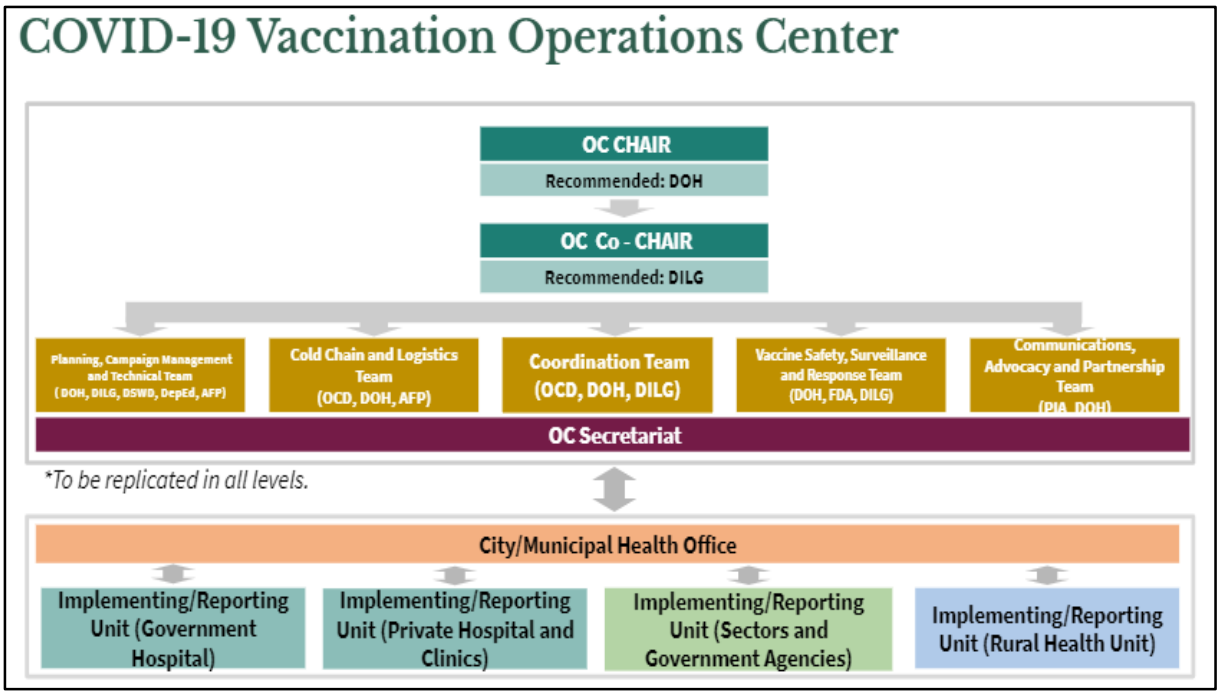


Figure 5. The teams under the COVID-19 Vaccination Operations Center.

The National Government is enjoining all Regional Offices and Local Government Units to establish the Vaccination Operations Center as soon as possible.

The implementing units such as government hospitals (both private and public), private clinics, government agencies, rural health units) shall forward all concerns and reports to the City/Municipal Health Offices. The City/Municipal Health Offices, in turn, are required to report all concerns and updates to the VOC.

All reports and unsettled issues of a VOC shall be raised to the overseeing VOC. The overseeing VOC, on the other hand, shall provide feedback and provide recommendation to the reporting VOC.

Three months prior to the vaccination activity, the VOCs are required to conduct regular meetings and to submit readiness assessments on a regular basis to the overseeing VOC. During the campaign period (as determined by DOH), all VOCs are required to operate for 24 hours in a week, and to submit daily bulletin detailing coverage, refusals and deferrals, and AEFIs and AESIs monitored. The reporting mechanism will be expounded on Chapter 7. After the campaign period, all VOCs are required to conduct a program implementation review and submit the final coverage report.

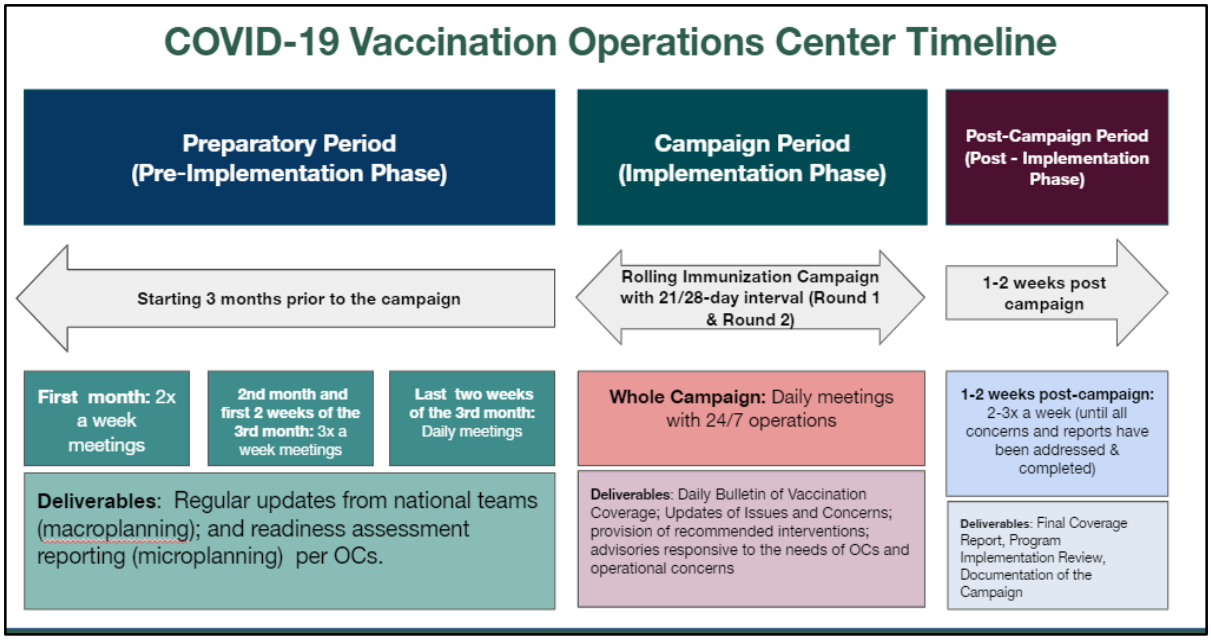


Figure 6. COVID-19 Vaccination Operations Center timeline.

Special Chapter

Risk Communication and Community Engagement

When a vaccine is introduced, it is necessary to guarantee that the population will receive the necessary information about its characteristics and benefits to boost confidence and generate demand. Demand Generation is a communication and engagement process to enable, inform, motivate and empower specific groups to access a health service and claim their right to do so[1]. Strategies to achieve this include advocacy, ongoing community engagement and trust-building, active hesitancy prevention, regular national assessment of vaccine concerns, and crisis response planning.

Table 1. Strategies and their definition.

Term	Definition
Advocacy	Building coalitions and communicating evidence to influence decision-makers, stakeholders and relevant audiences to change law, policies and administrative practices
Social Mobilization	Uniting partners at national and community levels through dialogue, coalition building and group activities to create an enabling environment for positive health behaviors.
Social Change Communication	Enabling interpersonal communication and community dialogue to allow groups of individuals to engage in a participatory process to define their needs, demand their rights and transform their social system.
Behavior Change Communication	Implementing interpersonal communication and mass/social media campaigns to change individual knowledge, attitudes, motivation, self-efficacy and behavior.
Capacity building and motivation	Training of program managers, health workers, community health workers and civil society organizations (CSOs) to enable them to implement and manage Demand Generation activities and effectively link vaccination services to communities.

Strategic communications and public messaging will be critical to ensure maximum acceptance of vaccines, requiring a saturation of messaging across the national and local media platforms. This communication and messaging will target the different audience groups like opinion makers and social communicators who can influence the uptake, health care providers in both public and private sectors, and the vaccine's primary beneficiaries. Partnerships with the media are essential to ensure their support in promoting these messages. The information campaign led by the PCOO, through

[1] Definition was adopted from the WHO-UNICEF guide on Positioning Demand Generation in National EPI Planning and Implementation Processes

the PIA, will include key messages on vaccine safety and efficacy and target key populations and communities addressing vaccine hesitancy[2]. The campaign will be developed using human-centered design, extensive public and stakeholder engagement, and research on message development and delivery. The different agencies of the TG Demand Generation and Communications will work collaboratively to ensure that consistent and accurate information is at the foundation of the communications effort. The communication plan will also help inform the Filipino people about the national strategy of delivering the COVID-19 vaccine faster while still safeguarding the national standards for safety and effectiveness as with any other vaccine.

Identifying the right messages to promote vaccine confidence, countering misinformation, and targeting outreach to vulnerable and at-risk populations will be necessary to achieve high coverage. The members of the national task group will build on its existing relationships with key regional and local government offices to effectively implement communication campaigns. The national task group will also be working to develop innovative approaches to improve vaccine uptake among hard-to-reach critical populations.

Initiate demand generation

Ensuring sustainable demand for vaccination is only possible when beneficiaries and communities trust the safety and efficacy of vaccines and the quality and reliability of the vaccination services. They also need to have the necessary information, access, and motivation to complete the recommended vaccination schedule on time.

The COVID-19 vaccination demand promotion strategy embraces contextualized and targeted evidence-informed approaches, including social and behavior change communication, political will and advocacy, health workforce capacity development, social mobilization, and community engagement activities. The strategy provides the why, what, when, and how of COVID-19 vaccination. In support of the key messages on the COVID-19 vaccination, the demand promotion and communication strategy will also leverage an enhanced BIDA Solusyon campaign to emphasize the continued need to practice essential preventive behaviors, to enforce minimum public health standards, to address myths and misinformation, and to empower individuals.

Understand and act on drivers of vaccine acceptance and uptake

Ideally, before preparing any informational material, the population's knowledge and perception of the disease and vaccination should be evaluated so that information and education needs can be determined and appropriate content prepared.

[2] These messages target identified drivers of motivation as per the Increasing Vaccination Model by the WHO-established group, measuring behavioral and social drivers of vaccination (BeSD)

The SAGE working group on vaccine hesitancy classified contributors to vaccine hesitancy into 3 main groups:[3]

- Complacency: Low perceived risk of vaccine-preventable diseases, and vaccination not deemed necessary. Other life/health issues are a higher priority.
- Confidence: Low levels of trust in vaccines, in the delivery system, and in health authorities.
- Convenience: Barriers related to geographic accessibility, availability, affordability, and acceptability of services.

The IEC materials developed will address all three factors. In addition to IEC material for the general public, materials for several different target populations, including physicians, vaccinators, and journalists, will be developed.

An integrated demand approach supporting informed decision among citizens participating in the vaccination program

a. Informed Consent

Obtaining informed consent for immunization is both an ethical and legal requirement in any vaccination program. Consent derives from the principle of autonomy and forms an important part of medical and public-health ethics, as well as international law. The importance of consent is that it facilitates the freedom to make choices that reflect the individual's own values, beliefs and life experiences. The primary principle for informed consent described in the Guide to Professional Conduct, states: "Patients must be given enough information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care. Consent is not valid if the patient has not been given enough information to make a decision." While the context of a public health immunization program differs from both primary and secondary care prescribing, similar principles apply. For consent to be valid, it must be informed, understood and voluntary, and the person consenting must have the capacity to make the decision. Special consideration must be given to consent arrangements for those individuals who may lack capacity to give consent. Informed consent must be preceded by disclosure of accurate, adequate and relevant information in a manner that is comprehensible to the person about the nature, purpose, benefits and risks of vaccination. The benefits of vaccination should address both benefit to the individual and to society such as the potential for individual and herd immunity. Risks, both in terms of known risks e.g. adverse side effects as well as the potential for unknown risks attaching to the vaccine, should be communicated to the vaccine recipient. In the current situation, it will be important to make clear to potential recipients of a COVID-19 vaccine that the duration of immunity conferred is currently

[3] 3C framework is adopted from the report of the SAGE working group on vaccine hesitancy.

unknown and may not be equally effective across all age-groups. The benefits and risks that are disclosed will depend on what is known about them at the time consent is given. Knowledge about the vaccines will continue to advance and it is important that the benefit/ risk ratio be continually reviewed and updated in all information and consent material provided to potential recipients will often change.

b. Building Confidence for the Vaccine

It must be acknowledged that people will have questions about the COVID-19 vaccine. Potential recipients should be given an opportunity to ask questions and to discuss any fears they may have around vaccination. This is particularly pertinent in the context of promoting vaccine confidence. The Philippines is no different to other countries when it comes COVID-19 vaccination planning and the myriad of challenges this presents. As the health system gets ready for the national effort to vaccinate against COVID-19, public health and healthcare and clinical experts, policy makers, and the public will benefit from lessons learned from planning and workshop exercises and examining the experience of previous public health mass vaccination programs. This Plan has considered both the expertise developed and the experience gained by Expert Groups, organizations and agencies across the country and continent from pandemics and outbreaks that have affected the Philippines in the past, including the 2009 H1N1 Pandemic, and have proactively applied these lessons learned to COVID-19 vaccination planning.

c. Provision of Concise and Clear Information

The members of the national TG Demand Generation and Communications, will generate information for patients, consistent with the available authorized product information. For each vaccine, this will be written in plain language including all major dialects and English and will be displayed prominently and be freely available at all vaccination sites. It will also be available online. A copy of the regulatory, approved patient information leaflet will also be made available (paper or electronic means). This will help to ensure that each person receiving a vaccine is giving informed consent to receive a COVID-19 vaccination, and that they (or their parents or guardians) will be provided with consent forms and sufficient information to allow an informed choice to be made. This information will be provided in a way that is fully comprehensible, and will describe the nature, purpose, benefits and risks of the vaccination and any measures to alleviate the symptoms arising from aftereffects (e.g. paracetamol to relieve high temperature). All information surrounding the vaccine development, testing limitations (if any), and administration held by the manufacturer and regulatory authorities must be fairly represented in a balanced and summarized manner. To provide valid consent, potential recipients, who might have a range of literacy and numeracy skills, should understand the core message of the vaccine's purpose, benefits and risks. This includes disclosing that suspected adverse reactions might not be caused by the vaccine and that rare side effects may not have been detected in clinical trials.

d. Providing Up to Date information

All information, education and communication materials (including posters, social media releases, patient information leaflets) will be subject to change as new data emerges, and may include, but will not be limited, to the following relevant information about the COVID-19 vaccines:

- Approval process related to the vaccine's market authorization, including testing and limitations of testing
- Licensing
- Any new component or technology that has not been licensed or used previously
- Post-marketing analysis by the relevant regulatory agencies
- Potential and known side effects and adverse reactions including that described in the regulated package leaflet (issued by EMA)
- How and where to report side effects – a phone number will be included
- How to alleviate possible symptoms arising

Accurate and updated information should be accessible to the target eligible population, with an available central information source (such as a designated telephone service) that can be easily approached for additional concerns/queries. While all information provided will represent the state of knowledge at that time, new information and emerging facts will be documented and promulgated where appropriate and in a timely manner. It is strongly recommended that none of the communication strategies to be undertaken will compare or provide recommendations between vaccine variants (currently available or yet to be approved) in a way that may devalue/denigrate one in favor of the other.

e. Continuous Engagement with the Regulatory Authority

The TG Demand Generation and Risk Communication will continually monitor data from the regulatory authority (FDA) in relation to vaccine safety signals, as well as any data arising from public health monitoring and surveillance activities. As stated elsewhere within this plan, the relevant authorities will be carrying out formal post-monitoring surveillance on the use of the COVID 19 vaccines to identify any emerging issues including significant adverse, purported or coincidental events. The TG Demand Generation and Risk Communication will also ensure that any necessary information arising from this monitoring of the vaccines will be adequately and promptly communicated. Healthcare Professional Communications will be issued by DOH/Dept for Human Resource. Any emerging safety issues will be communicated to DOH, or escalated to National Immunization Program (NIP), as appropriate.

Communication and engagement of the public

Since the start of the COVID-19 pandemic, consistent communication of the public health advice to protect from COVID-19 has played a central role in the Government's response to the pandemic, earning wide public co-operation. Clear and transparent communication on all aspects of COVID-19 vaccines, led by subject matter experts, to build public trust in vaccine safety and efficacy will be a critical element to the success of the Philippines' vaccination program. The approach will build on the successful communication and engagement program delivered throughout the COVID-19 pandemic to date, ensuring the communications response to the vaccine program is integrated into existing COVID-19 communications. The arrival of vaccines will not mean zero COVID-19. Instead, the COVID-19 vaccine will be added to the existing public health toolkit. Aligned to this, Government public health advice will expand to include the availability of a vaccine. As the vaccines roll out across the country, it will remain important that we continue to work with the public health advice which asks us to wash our hands, cough into our elbows, maintain 2m social distance and wear face coverings where appropriate.

a. Communications Strategy

This strategy aims to position COVID-19 vaccines as an additional tool in the public health advice to protect against COVID-19 and encourage universal vaccination. Communication around the program will be informed by the following principles:

- Ongoing understanding of public sentiment regarding vaccine
- Open and transparent communication, to be led by the PCOO's Philippine Information Agency (PIA), and developed by public health and immunization experts
- Clear and consistent communication to encourage vaccine uptake
- Cross Government collaboration reinforcing the public health advice

Communication on COVID-19 public health advice, including the COVID-19 vaccination program, will need to be agile as with our response to the pandemic to date this will involve regular communications and updates via the different government platforms, including but not limited to, the Office of the President, the PCOO, and the DOH. Once the vaccination program has commenced, data on the vaccine uptake will be incorporated into the daily COVID-19 press release, COVID-19 data hub, and current communication channels.

b. An Evidence Informed Approach

Since the early days of the COVID-19 pandemic, the different government agencies have actively listened to the public. Understanding, reacting and responding to public sentiment have been core elements of the COVID-19 campaign. As progress has been made in vaccine development, that work has continued, and has informed every element of this Strategy. Key insights from work to date with the public:

- Many people who doubt the vaccine are in a dilemma: they want the vaccine but are cautious. People are concerned as to the speed of the development of the vaccines and want to be reassured as to their safety and effectiveness.
- Overall, we must own the idea that science is never 100%; no guarantees; no cast iron certitudes.
- We should be forthright and proportionate in what we say. People of different ages have different understanding and expectations about what vaccines will bring in the short to medium term.
- Communication on the vaccine must be led by medics coming from a perspective of expertise, science and health advice.
- Whatever the unknowns are, they need to be stated and owned; only communicate when we have the facts.
- We need language that anyone will understand - so that everyone feels welcomed into the communication.

c. Key Elements

c.1 A Phased Approach

The communications and engagement strategy will have three main phases.

- The **first phase (pre-roll out)** will focus on preparing for the vaccine roll-out - this includes speaking about the safety and regulatory processes that are in place in the Philippines and across the world; engaging with people who have genuine hesitancies around the vaccine; communicating the Government Plan from acquisition to prioritization to distribution; and communicating about the results of the clinical trials when they are available.
- The **second phase (deployment)** will focus on the deployment of the COVID-19 vaccine – this includes national and local communication from key champions (including medical societies, allied healthcare workers, local chief executives, etc) encouraging the public to get the vaccine, informing who will administer it and where, identifying people of trust, opinion leaders to act as ambassadors for the vaccine. Active expert participants in the campaign will come from the DOH and other collaborating agencies, ensuring clear and consistent communications from a trusted source.
- The **third phase (post-deployment)** will focus on strategies for after the COVID-19 vaccine deployment (post-deployment) - this includes continuous monitoring and updates for key stakeholders and the general public, and building a sense of community and responsibility to ensure the sustained protection of communities and continued promotion of preventive behaviors (eg. wearing a mask, social distancing, etc)

c.2 Trusted Voices and Peer to Peer support

Healthcare workers are an important at-risk population group. They are also a recognized and trusted source of information and influence. Nurses, in particular, are trusted sources of information for the public. The national TG Demand Generation and Communications will prepare targeted messaging and briefings for this important stakeholder group. One of the most effective means of increasing uptake of the flu vaccine among healthcare workers (HCW) continues to be peer-to-peer communication and support. The national TG Demand Generation and Communications will identify and inform local champions on the importance of all HCWs receiving the COVID-19 vaccine when it is available to them.

This approach will also be taken with the general public. The Regional and Local VOCs will be supported to work with local print and broadcast media, as well as local stakeholders to inform their communities and support uptake of vaccine in their community. It is recognized that uptake will be influenced by a wide range of influencers, depending on demographics. The role of community leaders, religious leaders, celebrities and other influencers, will be important in conveying the message.

c.3 Audiences and Stakeholders

The COVID-19 vaccine program will touch every person, every healthcare worker, every household, every family in the Philippines. This is a challenge in terms of scale and timing, but it also offers us an enormous open door to build trust and confidence in this vaccination program, because, like COVID-19 itself, the vaccine is something that everyone cares about and has been affected by. There are challenges in the scale of the program, the need for sequencing how the vaccine is offered to people in priority groups, and in providing assurance about safety and effectiveness. Pressures may grow in the coming months in these areas of challenge, but with the benefit of a comprehensive demand generation and communication plan, these challenges can be addressed.

c.4 Initial Key Messages

The vaccine communications and narrative has already begun. The first key messages are already being communicated (for the **pre-roll out phase**) and these include the following themes for the general public:

- Benefits of Vaccine Urgency and Deployment
- Prioritization and Timing
- Rigorous Development, Approval, and Monitoring
- Global Cooperation

These identified themes include the following supporting messages:

- The Philippines will only use a vaccine if it meets the required standards of safety and effectiveness. All the recommended vaccines used in the country are licensed by the EMA (European Medicines Agency), the US Food and Drug Authority as well as our FDA. The vaccines will be subject to ongoing monitoring in the Philippines by the FDA. They are licensed for use only when they have been shown to be both safe and effective.
- Due to the urgency posed by the pandemic, exceptional efforts are ongoing to develop COVID-19 vaccines and make them available as soon as possible. Unprecedented levels of scientific research and collaboration, investment and early and proactive engagement between vaccine developers and regulators has helped speed up development and ensured that quality, safety and effectiveness are not compromised.
- Vaccines are a proven, cost-effective intervention to protect public health; second only to the provision of clean water. Worldwide, they save at least 2-3 million lives each year – and many more from crippling and lifelong illnesses.
- Certain priority groups will be vaccinated first. For example, frontline healthcare workers and people who are most at risk from serious infection if they catch COVID-19. Once these priority groups have been vaccinated, the vaccine will be available to the rest of the population.
- The vaccines will be delivered in stages so it will take time to vaccinate everyone. This means we will need to continue to be careful about our individual actions to stop the spread of COVID-19. For example, social distancing, wearing a face covering and regular hand washing. We cannot afford to drop our guard now.

After the pre-rollout phase, the messages for the next phase (**deployment phase**) will address themes focusing on 1) Patient responsibility and follow-through; and 2) Legitimate sources of vaccines and reliable vaccination posts.

Then for the third and last phase (**post-deployment phase)**, the messages will focus on 1) Continuous monitoring and responsible reporting; and 2) Sense of community.

d. Promoting Vaccine Confidence

The vaccine confidence continuum includes a small minority who refuse all vaccines with conviction, and those who have valid concerns and need more information before deciding to take a vaccine as well as those who have a positive predisposition to vaccination programs. From the October 2020 IDinsight survey commissioned by the DOH Health Promotion Bureau and UNICEF, about half (52%) of the participants responded that they would get vaccines for themselves if available. Effectiveness was the most frequently cited important piece of information necessary for deciding whether to get a vaccine (40%), followed by side effects (18%) and safety risks (17%).

As part of the approach to building confidence, the TG Demand Generation and Communications will strategically address misinformation which may appear on social media and the internet, and direct people to more credible sources of information such as the online platforms/websites of the PCOO-PIA and the DOH. There is precedence for the introduction of novel vaccines in response to significant health risks associated with certain diseases, for example, polio, meningitis and haemophillus influenza B (HiB) vaccines as part of the childhood vaccination programme, and pertussis vaccine in pregnancy.

After the Ebola outbreak of 2014-2016, researchers in Oxford University began preparing plans to create a vaccine for any new emerging diseases that might afflict the world in the shortest possible time. This body of work formed the basis of the Oxford AstraZeneca vaccine development process. The Pfizer/BioNTech Phase 3 Clinical trials involved over 43,000 participants. Normally, clinical trials can be held back due to low volunteer numbers and low disease prevalence – neither of which have been an issue in the case of COVID-19.

While we await regulatory reports from the vaccine trials, government communication will prioritize that proportion of the population that are unsure, addressing their questions and concerns through clear and transparent evidence-based communication via a multitude of channels.

Special Chapter

Registry and Data Management

A robust and comprehensive data management system using information and communications technologies, shall be established and utilized to monitor progress of vaccination activity, including monitoring of vaccine safety and effectiveness. The data management system shall be used to:

1. Measure real-time and equitable uptake and coverage over time by geography and eligible population groups.
2. Monitor implementation of the national vaccination program encompassing population eligibility, supply chain logistics, and other important parameters.
3. Monitor vaccine safety, disease surveillance, and effectiveness.
4. Retrieve personal vaccination records or certification as deemed required.
5. Ensure data collection, consolidation, and analysis compliant with data privacy and security standards.

I. Masterlisting during Pre-Implementation Phase

A nationwide profiling of eligible population shall be conducted prior to the implementation of the vaccination activity and shall be utilized to determine the eligibility of the priority groups receiving the vaccine.

To prepare the country for the COVID-19 vaccination program of the DOH, creation and maintenance of a masterlist of priority sectors is necessary to: (a) provide basis for identification of target eligible groups for vaccination and identification of priority areas for registration of eligible individuals; (b) ensure uniqueness of individuals in the vaccine administration plan; and (c) provide input to operational planning especially for costing and allocation of resources. Masterlisting shall use the phased approach, and be initiated at the LGU level, specifically municipalities and cities, with profiling and screening of eligible target population cohorts will be conducted prior to registration into the electronic immunization registry. An informed consent is required before proceeding to the registration.

The COVID-19 Electronic Immunization Registry (CEIR) shall be the official platform for masterlisting and registration for COVID-19 vaccination. External systems may be used to submit the necessary information following the Interim Minimum Required Data Fields based on DOH standards and policies.

Local Government Units, specifically municipalities and cities, shall lead masterlisting, and monitoring and evaluation within their catchment area, which shall be consolidated by province/ HUC/ ICC.

LGUs shall ensure that data provided in submission platforms are unique through deduplication of linelists across facilities within their catchment. The DOH shall likewise conduct deduplication checks on the final endorsed masterlists.

Consistent with actions necessary for Universal Health Care, LGUs should initiate profiling the health status of their population and generate a masterlist of population with comorbidities and other important information that will be necessary to implement the National Deployment and Vaccination Plan. Health profiling through Electronic Medical Records consistent with DOH standards is recommended.

II. Reporting and Data Management during Vaccination Date and for Adverse Events Following Immunization (AEFI)

Municipalities/CC/HUC/ICC may utilize the CEIR or third party solutions that may link to the CEIR, following set data standards. Reporting processes and data standards during actual vaccine administration and monitoring for adverse events following immunization shall be released in succeeding issuances. Ongoing simulation activities in select hospitals and LGUs shall inform these standards.

In addition, registration of official members of the vaccination workforce (i.e., vaccinators) will be conducted with data being recorded vis-à-vis the official vaccination sites/facilities as recorded in an expanded version of the current National Health Facility Registry.

III. Overall Dashboard: Vaccination Information Management System

Pursuant to IATF Resolution No. 85, section B, item 8, the DICT shall lead and manage the design, development, deployment, monitoring and evaluation of the Vaccine Information Management System (VIMS). The VIMS shall serve as an electronic, confidential, and secure information system that will record all vaccination doses administered by participating providers to people residing within a given geopolitical area. It will be used to assess local vaccination coverage levels or to assist during disease outbreaks, public health emergencies, or vaccine shortage situations to identify individuals in need of vaccination. The VIMS shall be used to ensure vaccine management and accountability, in tracking of vaccine safety issues, and in the evaluation of vaccine effectiveness.

The objectives of the VIMS will be as follows:

1. Provide visibility and control over vaccine stock balances and supplies beyond the central stores (to correct overstocking and understocking);
2. Determine the status of our current cold chain capacity in near real-time;
3. Monitor temperatures in storage equipment to help identify underperforming equipment or causes of (persistent) cold chain breaks
4. Determine vaccine consumption rates on a daily basis for purposes of forecasting and distribution planning;

5. Determine, and potentially anticipate, if stockouts at the local government levels are a problem; and
6. Determine how much vaccine ends up being wasted.

The following shall be the components of the VIMS:

1. Immunization registry
2. Logistics management
3. Stock management
4. Warehouse management
5. Supply chain management
6. Cold chain management

In order to successfully implement the VIMS, it shall follow a clearly defined governance model using key global interoperability standards for a digital smart yellow card and leveraging a trusted architecture to support roll out of the anticipated COVAX, and application to other routine immunization systems.

The following will be the minimum required set of solutions:

1. A governance framework
2. A common enterprise architecture
3. Use of interoperability standards (i.e., HL7 FHIR) with a common taxonomy (i.e., SNOMED)
4. Defined certification specifications for secure issuance of certificates
5. Vetted digital solutions that incorporate all above items

Finally, the VIMS shall have the ability to issue a vaccination event certification, which shall be an electronic form of the hard copy immunization card that the NIP issues to all vaccine recipients.

IV. Adoption of National Health Data Standards for Interoperability

The implementation of Universal Health Care Act recognizes the vital role of information and communications technologies (ICTs) in the adoption of an integrated and comprehensive approach to health development. Under Sections 31 and 36 of the Act, two of the key strategies identified are to strengthen evidence-based sectoral policy and planning, and to improve the country's health information system (HIS).

To tangibly operationalize these strategies requires the use of common data standards to enable seamless and interoperable health services and information flow operating under a functional national health information infrastructure. The Department of Health shall regularly update mandatory national health data standards for interoperability, enabled by establishing a core set of terminologies, definitions, and structures for data and reports processing, sharing and exchange.

V. Ensuring Data Privacy and Security

a. Consent of the Data Subject

Parties tasked to collect personal data should assure and undertake to obtain the consent of the data subject and inform them of the following:

1. The identity of personal information controllers (PICs) and personal information processors (PIPs) that will be given access to the personal data;
2. The purpose of data sharing;
3. The categories of personal data concerned;
4. Intended recipients or categories of recipients of the personal data;
5. Existence of the rights of data subjects, including the right to access and correction, and the right to object. However, the other party shall be informed of any request to access or correct personal information which is the subject matter of this sharing agreement; and
6. Other information that would sufficiently notify the data subject of the nature and extent of data sharing and the manner of processing.

b. Procedures of Use or Process of Personal Data

Sharing and processing of personal data should be via a secure encrypted link, with a middleware that shall have full control over such online access. Actual transfer of shared personal data or a copy thereof from one party to another like in the form of emails or physical submission of printed copies from one party to another may be done provided that processing and sharing must adhere to the data privacy principles laid down in Republic Act No. 10173 (Data Privacy Act of 2012 [DPA]), its Implementing Rules and Regulations, and other issuances of the National Privacy Commission (NPC).

Recipients of the personal data shall likewise use appropriate safeguards to protect the personal data from misuse and unauthorized access or disclosure, including maintaining adequate physical controls and password protections for any server or system on which the personal data is stored, ensuring that personal data is not stored on any mobile device (for example, a laptop or smartphone) or transmitted electronically unless encrypted (using encryption standard prescribed by the National Privacy Commission), and taking any other measures reasonably necessary to prevent any use or disclosure of the personal data other than as allowed under this Agreement.

All identified personnel that have been authorized to receive, access and process shared personal data shall sign a Non-Disclosure Agreement (NDA), specifically for the purpose of the national COVID vaccination program.

Chapter 1: Vaccine Selection and Evaluation

There are 235 COVID-19 candidate vaccines under development as of 5 January 2021 based on the WHO Draft landscape of COVID-19 candidate vaccines. Of these, 63 are under clinical development with 15 candidates in Phase 3 clinical trials and 6 candidates in Phase 2/3 clinical trials. To guide the choices on which vaccines will be considered for negotiation and procurement, the VEP developed criteria for the technical evaluation of the candidate vaccines.

The VEP mandates are defined in the Philippine Council Health Research and Development (PCHRD) Special Order No. 20-073 Series of 2020:

1. To identify and evaluate possible vaccine candidates from the local and international partners of the DOST.
2. To identify local partners or institutions for the conduct of preclinical and clinical trials of the vaccine candidates in the country.
3. To provide recommendations and action plans on the engagement of partners, preclinical and clinical trials' requirements of the FDA Philippines, DOH and WHO.
4. To evaluate project proposals on vaccine development seeking financial assistance from PCHRD or DOST.
5. The mandate was expanded to evaluate applications for Emergency Use Authorization (EUA).

Table 2. Criteria developed by the Vaccine Expert Panel for technical evaluation of COVID-19 Vaccines.

Criteria	Weight
1. Track record of company in developing and/or manufacturing other vaccines	10%
2. Technology platform (reliability and stability related to storage requirement)	10%
3. Safety based on Phase 1 and 2 clinical trials	20%
4. Immunogenicity (potential efficacy based on Phase 2 clinical trials)	20%
5. Potential efficacy and safety based on published Phase 3 interim result and/or with Emergency Use Authorization	30%
6. Vaccine implementation (i.e dosing schedule)	10%
TOTAL	100%

The above-mentioned criteria adapt the WHO Criteria for COVID-19 Vaccine Prioritization and WHO Target Product Profiles for COVID-19 Vaccines with additional criteria and considerations suited for local needs. The two (2) guiding documents describe the preferred and minimally acceptable profiles for human vaccines for long term protection of persons at high ongoing risk of COVID-19 such as healthcare workers and for reactive use in outbreak settings with rapid onset of immunity.

Considering that the Vaccine Roadmap will span three years with a target to start the vaccination of eligible priority population by 2021, a prioritization mechanism was adopted by the Task Group on Vaccine Evaluation and Selection to shortlist which vaccines will be initially considered for evaluation:

1. Candidate vaccine is in advanced stage of clinical development, preferably in Phase III clinical trial;
2. Vaccine developer is from a country with bilateral S&T partnership with the Philippines;
3. Vaccine developers expressed interest to conduct clinical trials in the Philippines and/or engage in local manufacturing and/or technology transfer in the medium term.

Following the above-mentioned prioritization mechanism, the following vaccines were short-listed, scored and weighted using the criteria developed by the Vaccine Expert Panel:

Table 3. COVID-19 vaccines shortlisted for VEP evaluation.

Vaccine Developer	Technology Platform
Sinovac	Inactivated
Sinopharma	
Bharat Biotech	
Anhui Zhifei	Subunit
Novavax	
Clover	
Janssen	Viral-vectored
Gamaleya	
AstraZeneca	
Pfizer	mRNA
Moderna	

Based on the overall scores, a ranking across platforms and ranking within platforms was endorsed by the VEP to the Task Group on Vaccine Evaluation and Selection. This takes into account the consideration that a vaccine per technology platform may need to be selected as it is expected that there will be differences in vaccine characteristics depending on the type of technology platform used, and a particular platform may be better suited to specific sectors or groups based on the results of clinical trials.

The evaluation is subject to updating as more scientific data and evidence becomes available. Further, as more candidate vaccines are expected to advance in late-stage clinical development, the vaccines for consideration may be updated as there are still populations targeted for vaccination in 2022 and 2023.

The list of vaccine platforms, as ranked by the Task Group on Vaccine Evaluation and Selection will advise the negotiations by the Vaccine Czar through the Task Group on Diplomatic Engagement and Negotiation. Once an Agreement is reached, an Official Purchase Agreement will be affected either thru bilateral or multilateral negotiations. To ensure safety and efficacy, it is to be clearly understood that ONLY vaccines which are granted Emergency Use Authorization (EUA) or Certificate of Product Registration (CPR) by the Philippine FDA will be purchased by the government.

In the subsequent years of the Vaccine Roadmap implementation, as global supplies become stable, and broad-base knowledge of vaccine efficacy and safety is established, the Department of Health will develop a "Clinical Practice Guidelines (CPG) on the Use of Different Vaccines for Specific Population Groups" in collaboration with professional societies and relevant stakeholders. The vaccine selection will be based on this CPG, which will be further reviewed by the NITAG and the Health Technology Assessment Council. The ultimate recommendation will be sought from HTAC by the Department of Health before it procures from a portfolio of FDA-registered COVID-19 vaccines, subject to the provisions of Republic Act 9184 or the Philippine Procurement Reform Act.

Chapter 2: Diplomatic Negotiation and Engagement

The Department of Foreign Affairs (DFA) oversees engagement with foreign governments, pharmaceutical companies, and other relevant entities on vaccine development and evaluation and selection of vaccines to be considered for procurement and clinical trials, with the view of assuring that Filipinos will have access to COVID-19 vaccines.

The country apart from bilateral negotiations is also pursuing the multilateral track through the COVID-19 Vaccines Global Access (COVAX) Facility that would ensure the country's access to COVID-19 vaccines for 20 million Filipinos.

Regulatory Preparedness

The COVID-19 vaccines may be accessed through: (1) conduct of clinical trial, and (2) emergency use authorization (EUA) and eventually, market authorization. The Food and Drug Administration (FDA), as the National Regulatory Authority (NRA), has the mandate on both as provided under Republic Act No. 3720, or the "Food, Drug and Cosmetic Act," as amended by Executive Order No. 175, s. 1987, and Republic Act No. 9711, or the "Food and Drug Administration Act of 2009".

A. Conduct of COVID-19 Vaccine Clinical Trials

Prior to the pandemic, the conduct of clinical trials in the country is regulated following FDA Administrative Order No. 2020-0010, otherwise known as the "Regulations of the Conduct of Clinical Trials for Investigational Products".

In light of the COVID-19 pandemic, the Inter-Agency Task Force for the Management of Emerging Infectious Diseases (IATF-EID) created the Sub-Technical Working Group on Vaccine Development through its Resolution No. 39 dated May 22, 2020 to coordinate matters pertaining to clinical trials of COVID-19 vaccine candidates. The Sub-TWG is chaired by the Department of Science and Technology, co-chaired by the Department of Health, and with the FDA, Research Institute of Tropical Medicine, Department of Foreign Affairs, Department of Trade and Industry - Board of Investments, and the National Development Company as member agencies.

The IATF-EID further supplemented the earlier resolution with its Resolution No. 65, s. of 2020, which requires that all applications for COVID-19 vaccine clinical trials should first be submitted to the Vaccine Expert Panel (VEP) for technical review, to designated Ethics Board/s (ERB/s) for ethical review, and once approved by the VEP and ERB/s, submitted to the Food

and Drug Administration for regulatory review and final approval. The Vaccine Expert Panel (VEP) was created by the DOST to provide technical expertise on the evaluation of candidate COVID-19 vaccine applications and to provide recommendations to the Task Group on Vaccine Evaluation and Selection (then the sub-Technical Working Group on Vaccine Development) on S&T activities on COVID-19 vaccine development. The regulatory process of the FDA and the policies of the IATF-EID has been harmonized and streamlined under FDA Circular No. 2020-029. The same Circular further expedites the evaluation for COVID-19 vaccine clinical trials application to a maximum of 40 working days, provided all requirements are complete.

The functions of the Task Group, with the technical assistance from the VEP, has expanded from providing oversight on the evaluation of applications and conduct of COVID-19 vaccine trials in the country, to include as well the evaluation of COVID-19 vaccines that could be considered by DOH in its selection of COVID-19 vaccines for the Philippines.

B. Emergency Use Authorization

In the Philippines, any new drug and vaccine should have an authorization from the FDA based on an application containing full reports of investigations to show whether or not such vaccine is safe, efficacious and of good quality for use based on clinical studies, prior to manufacture, sale, importation, exportation, distribution or transfer thereof.

In light of the COVID-pandemic, the Philippines was declared under State of Public Health Emergency, pursuant to Proclamation Nos. 922 (s. 2020) and 1021 (s.2020). Subsequently, Republic Act No. 11494 or the "Bayanihan to Recover as One Act" was enacted authorizing the President to suppress the COVID-19 pandemic through the procurement of drugs and vaccines.

Considering that there is no registered drug and vaccine yet for COVID-19 in the Philippines, the President of the Republic of the Philippines issued Executive Order (EO) No. 121 entitled "Granting Authority to the Director General of the Food and Drug Administration to Issue Emergency Use Authorization (EUA) for COVID-19 Drugs and Vaccines, Prescribing Conditions therefore and for other Purposes." The said issuance gave authority to the Director General of the FDA to issue an EUA, and establish the conditions under which said authorization may be issued.

FDA Circular No. 2020-036 provides the process for the issuance of the EUA aimed to sustain and strengthen the county's preparedness and response for the COVID-19 public health emergency. The principles of regulatory reliance and recognition are adopted to accelerate the evaluation and approval process for EUA to ensure immediate access to drug products and vaccines for COVID-19. The said circular defines that the EUA shall only be issued and remain valid when all of the following circumstances are present:

a. Based on the totality of evidence available, including data from adequate and well-known controlled trials, it is reasonable to believe that the drug or vaccine may be effective to prevent, diagnose, or treat COVID-19;
b. The known and potential benefits of the drug or vaccine, when used to diagnose, prevent, treat COVID-19, outweigh the known and potential risks of the drug or vaccine, if any; and
c. There is no adequate, approved and available alternative to the product for diagnosing, preventing or treating COVID-19.

The last condition is deemed present when there exists no registered drug or vaccine in the country for diagnosing, preventing or treating COVID-19. FDA Circular No. 2020-036 likewise provides other conditions for authorization on the distribution requirements, reporting requirements, and safety and monitoring requirements.

Vaccines Access

Based on this guidance, a three-year vaccination roadmap was developed, where, in each year from 2021 to 2023, an identified eligible population will be given the vaccine. The vaccines will be sourced from the COVAX Facility and from bilateral/multilateral sources [e.g. AstraZeneca, Sinovac, Pfizer, Novavax, Johnson & Johnson, Gamaleya, Moderna, Sinopharm, CansinoBio (in no particular order)].

The COVAX Facility, the vaccine pillar of the Access to COVID-19 Tools (ACT) Accelerator, is a global risk-sharing mechanism for pooled procurement and equitable distribution of COVID-19 vaccines. The said facility will make investments across a broad portfolio of promising vaccine candidates to make sure at-risk investment in manufacturing happens now. This means, by pooling purchasing power from all countries that participate, the facility will have rapid access to doses of safe and effective vaccines as soon as they receive regulatory approval. Guided by an allocation framework being developed by WHO, the COVAX Facility will then equitably distribute these doses to help protect the most at-risk groups in all participating countries. The COVAX Advance Marketing Commitment (AMC), together with GAVI Alliance, will provide assistance and support for the participation of 92 lower-middle and low-income economies, which includes the Philippines.

The selection of vaccines is based on the type of vaccine platform, track record of manufacturer for developing or manufacturing vaccines for other diseases, safety based on Phase I and II clinical trial results, potential immunogenicity based on Phase II clinical trials results, potential safety and efficacy for those with interim Phase III clinical trial results, vaccine implementation (i.e. dosing schedule), vaccine stability, and supply chain considerations. These criteria are weighted, and the type of vaccines are subsequently ranked, and endorsed by the VEP to the Task Group on Vaccine Evaluation and Selection.

Table 4 below shows the yearly eligible population from 2021 to 2023, its proportion to the national population.

Table 4. Target population for COVID-19 vaccination, its proportion to the national population.

Year	2021		2022		2023	
Vaccine Access	**Eligible Population**		**Eligible Population**		**Eligible Population**	
	Number	**Proportion to national population**	**Number**	**Proportion to national population**	**Number**	**Proportion to national population**
PHL Population	**110M**		**112M**		**114M**	
Total Eligible Population	**70M**	**63%**	**42M** **70M** **112M**	**37%** **63%** **100%**	**2M** **112M** **114M**	**2%** **98%** **100%**

Note: National Population Figures used: 2021 - 110,198,654; 2022 – 111,572,254; 2023 – 112,892,781. National Population Figures were based on Population Projections by the Philippine Statistics Authority. Assumptions: By 2022, 16 years old and below can be vaccinated already and this sums to 42M Filipinos. By 2022, the total population of 15 years old and above is 77 M. Those previously vaccinated shall be given booster dose the following years. By 2023, newborns shall be vaccinated.

The COVAX facility will supply 20% of the total population of the country for free, while the other bilateral/multilateral sources will be the source of vaccines to cover the rest of the eligible population from 2021 to 2023.

Chapter 3: Procurement and Financing

The TG Procurement and Finance divides the process for procurement of vaccines into three phases. The first phase involves preliminary meetings with said manufacturers and the signing of a reciprocal Non-Disclosure Agreement (NDA). The NDA is put in place to protect the rights of both the National Government and the manufacturer to their respective confidential information and allow for smooth and transparent negotiations. Through the NDA, both parties agree on the type of confidential information that may be disclosed to each other, the specific purpose for such disclosure, exceptions to the right to confidentiality, as well as the rights of the parties and available reliefs in case of breach. High level meetings facilitated by the TG Diplomatic Engagement are likewise held.

During the second phase, the parties engage in formal negotiations, which normally commence with the exchange of the term sheet. The term sheet ideally outlines all the relevant offers and details on the vaccine procurement, including the number of doses to be ordered, the purchase price, the target date of signing of the definitive and binding Supply Agreement, payment and effectivity dates, delivery schedules, and all other rights and obligations of the parties. The term sheet is also reviewed for possible implications under the procurement law as well as other applicable local laws. With the goal of getting the best deal for the government, the TG Procurement and Finance would engage in several rounds of negotiations with the supplier for possible revisions and/or clarifications of the term sheet.

Matters that are resolved during the course of negotiations are documented, and pending matters are likewise recorded for immediate consideration and resolution by the parties. Finally, negotiations culminate in the signing by both parties of a Term Sheet, which although not yet binding, then contains all the accepted offers and conditions for the supply of vaccines.

In the third and final phase, the National Government submits the Term Sheet to the financing banks for clearance, and the parties finalize and sign the supply agreement in the form of either an Advance Market Commitment, Supply Agreement or a Research & Development Investment.

The TG Procurement and Finance ensures that safeguards are well in place in the commercial agreements to guarantee that government funds go to vaccines with proven safety and efficacy. Thus, one of the integral terms negotiated by the team as a condition in the agreements is the registration with the Philippine FDA through the Emergency Use Authorization before delivery, and payment of balance. Among others, once the authorization is in place and in case of successful delivery, the GoP stands ready to pay.

The financing for COVID-19 vaccine is made through the following modalities: (i) Using the General Appropriations Act, (ii) Multilateral Financing, (iii) Bilateral Financing, and (iv) Contractual Joint Venture (JV)/ Private Sector Financing. The first mode is carried out in accordance with Republic Act No. 9184 or the "Government Procurement Reform Act" and Republic Act No. 11494 or the Bayanihan to Recover as One Act (Bayanihan II). This amount will partially cover logistics, distribution and monitoring costs. Procurement of COVID-19 goods, supplies, and resources are exempt from the requirement of competitive bidding under Bayanihan II, which has expired on December 13, 2020. Moreover, advance payment of 15% of the contract price will be allowed in areas where a State of Calamity has been declared. Any advance payment exceeding 15% of the contract price will have to be made under the directive of the President.

For procurement of vaccines and the Government's contribution to the COVAX facility, the GoP will tap financing with its multilateral development partners such as the ADB and the WB. The rules governing procurement through multilateral loans are exempt from R.A. 9184 as this will be an Official Development Assistance (ODA) loan. Nevertheless, the procurement rules of the WB or the ADB, which are consistent with international standards, will apply.

To supplement the financing requirements under multilateral facilities with the ADB and the WB, the government may consider co-financing from bilateral partners, such as China (Eximbank), the UK (UKEF), the US, India, Singapore, and Australia, through tied-aid ODAs. Under this mode, the executive agreement will apply when it comes to the procurement rules (limited source bidding).

Lastly, the funding for the vaccines covering the population that are not covered by the foregoing may be through contractual joint venture (JV) agreements between the private sector, the government, and a vaccine manufacturer/supplier. This may also be the route for procurement of higher cost vaccines. With the private sector proponent initiating the process with its proposal, negotiated procurement may be followed under the Revised NEDA Joint Venture (JV) Guidelines. The procedure for a negotiated JV, and the approvals required depending on the terms of the JV agreement shall be complied with. Ideally, the private sector and GOCC may share in the purchasing process of the vaccine. Generally, no financing cost should be incurred by the Government, however, there may be a need to evaluate the amount of user pay, which can require a subsidy from either the private partner of the Government counterpart.

Resources and Funding

The WHO recommends allocating a budget for COVID-19 vaccination in multiple terms. The short-term budget should consider the initial allocation that covers the first 3% of the national population (health workers) and the next 17% of the population (older people and those with underlying health conditions). The medium-term budget should consider the incremental shipments to cover beyond the initial 20% (the additional priority populations). The 36-month

budgetary horizon is practical as it is compliant with ministry of finance (MoF) medium-term budgetary and expenditure exercises.[4]

In addition to the cost of vaccines, other costs include those of the logistics needed to deploy the vaccines (e.g. injection devices, PPEs), costs of hauling and storage, disposal of waste, program operations, health promotion and communications and surveillance.

To fund the procurement of vaccines, several funding sources will be used. These include multilateral and bilateral agreements, Domestic Government Financial Institutions (GFIs) and bilateral negotiations. To procure the logistics needed for the deployment of vaccines, the 2021 General Appropriations Act (GAA) will be used. Table 5 below shows the different funding sources and prospective amounts of funding.

Table 5. Funding sources for COVID-19 vaccine deployment program and corresponding funding amounts.

Object of Procurement	Source	Amount
Vaccines	Unprogrammed Funds in 2021 GAA (Foreign multilateral and bilateral loans; domestic loans)	₱70 billion
Logistics and other supplies	2021 GAA (DOH)	₱2.5 billion
	Bayanihan II in relation to RA 11520 on Continuing Appropriations	₱10 billion
TOTAL AVAILABLE FUNDS		**₱82.5 billion**

[4] Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines. Geneva: World Health Organization; 2020 (WHO/2019-n-COV/NVDP/2020.1). License: CC BY-NC-SA 3.0 IGO.

Chapter 4: Shipment and Storage

Supply Chain

Successful immunization programs are built on functional, end-to-end supply chain and logistics systems ensuring an effective vaccine storage, handling, and stock management; rigorous temperature control in the cold chain; and maintenance of adequate logistics management information systems. The ultimate goal is to ensure the uninterrupted availability of quality vaccines from manufacturer to service-delivery points, so that opportunities to vaccinate are not missed because vaccines are unavailable. Managing the supply, storage and distribution of potentially multiple COVID-19 vaccines will involve complex logistical operations. In line with other countries, the Philippines will leverage and build on existing vaccination delivery services and structures for the rollout of COVID-19 vaccination plans.

Supply Chain Systems Readiness

To adequately prepare the existing supply chain systems to cope with the additional work required to receive and distribute the COVID-19 vaccines, a rapid assessment of the existing supply chain systems was conducted. The introduction of a new vaccine offers the opportunity to improve the current distribution mechanism.

The assessment identified strengths and gaps in the End-to-End supply chain system including but not limited to storage systems, distribution, real time temperature monitoring and tracking, real-time tracing and reporting of vaccine stocks. The action plan based on the assessment will ensure that:

1. There are coordinated deployment plans and standard operating procedures (SOPs) are developed and communicated to all levels of the supply chain;
2. There are adequately trained, and sufficient quantity of supply chain and health staff;
3. There is sufficient cold chain capacity, including surge capacity, and capacity for ongoing maintenance, necessitating the contracting of private providers;
4. There is an efficient supply chain system and infrastructure, preferably leveraging on existing systems;
5. There is a real time robust data recording and reporting mechanism for vaccines and cold chain equipment;
6. There is robust oversight and data-driven management, including systems for monitoring adherence to cold chain practices; and
7. There are adequate secured resources from both internal and external sources.

End-to-End Supply Chain

While the specific logistics associated with each potential vaccine are not yet fully known, each vaccine will broadly follow a similar supply chain to reach the vaccination locations as outlined in the process below. Additional supply chain and logistics expertise across the wider public sector and the private sector will be leveraged where necessary. The supply chain process will involve the receipt of vaccines in the Philippines from several manufacturers, the storage of these vaccines in a temperature controlled central storage facility, preparation of vaccines for distribution to vaccination locations and the delivery logistics to vaccination locations. Figure X below highlights the five components of the Supply Chain Management.

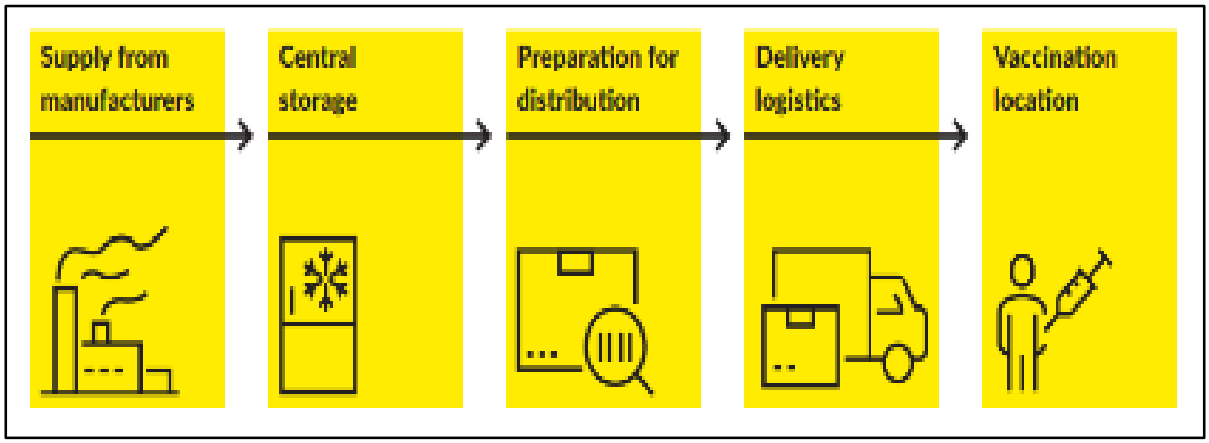


Figure 7. Five components of the Supply Chain Management.

Supply from Manufacturers

The arrangements for supply of potentially approved vaccines from pharmaceutical companies as well as from the GAVI COVAX facility and the timing of delivery to the Philippines are currently under discussion. It is expected that the volume of vaccines delivered will ramp-up through 2021 as production capacity increases. Shipping methods from manufacturing sites will mainly be by air and agreed upon with manufacturers. Supply Chain risks associated with natural disasters and emergencies will be included in contingency planning.

Proposed Distribution Process Flow for COVID-19 Vaccines and Ancillary Immunization

The proposed process flow of the vaccines and other immunization supplies at the national level from the notification of the delivery up to the reverse logistics for the final disposal of the immunization wastes gathered from all the vaccination sites is summarized in the visual below.

The CHDs and the LGUs as well as those that will be identified as recipients of these immunization commodities shall likewise develop their distribution plan appropriate to their situation. This shall be consolidated by the Task Force to come-up with a comprehensive national cold chain and logistics plan for COVID-19 vaccination.

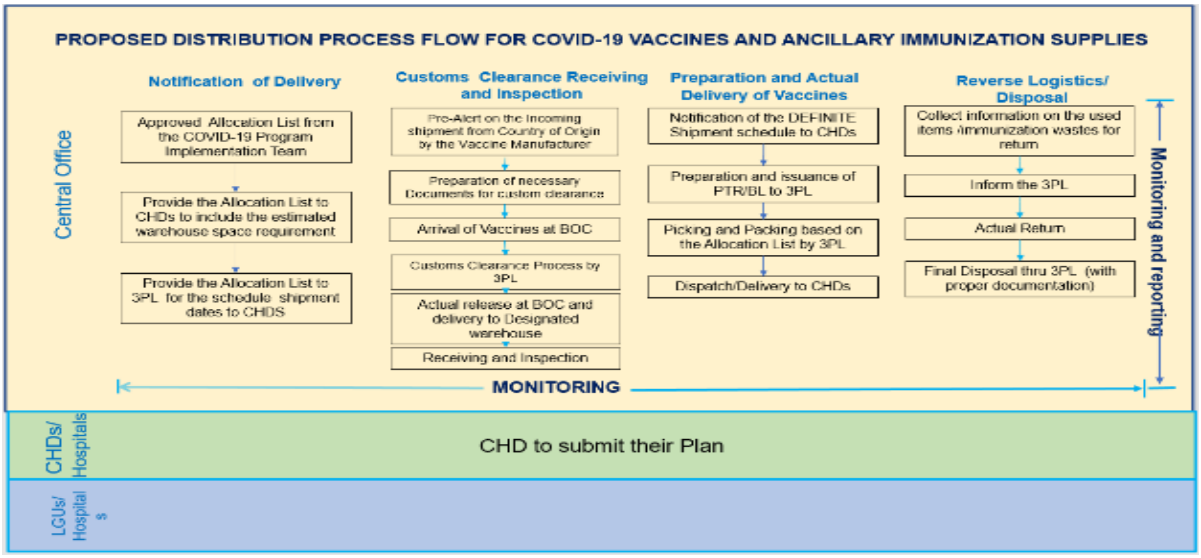


Figure 8. Distribution process flow for COVID-19 vaccines and ancillary immunization supplies.

A detailed process in each category shall be presented. Existing relevant forms required for each process shall be reviewed, revised and adopted specific for this purpose.

Cold Chain Management

COVID-19 vaccines require refrigeration with temperature ranges of +2ºC to +8ºC, -15ºC to -24ºC and to as low as -70ºC to -80ºC; cold chain management, whereby adequate refrigeration levels are maintained from manufacturing, storage and distribution of vaccines, and ensures integrity of vaccine compounds via specialized packaging as well as refrigeration and freezer devices. However, ensuring effective cold chain management for COVID-19 vaccines shall entail particular requirements and constraints around temperature maintenance for transport and storage and administration of the vaccines. With this, supply chain readiness at all the management levels shall be in place to efficiently deploy COVID-19 vaccines to the target population.

STORAGE AND DISTRIBUTION OF COVID-19 VACCINES

Given the Philippine's geographic size and population, storage of the vaccines will be centralized and managed preferably by a single logistics provider, with substantial relevant experience.

As the different types of vaccine require varying temperature storage requirements, (1) ultra-cold (-70°C to -80°C), (2) frozen (-15°C to -25°C), and (3) refrigerated (2°C to 8°C), the identified logistics partner/s have to ensure substantial capacity for each temperature range.

To ensure the correct volume of vaccines are received by each Vaccination Administration Location (VAL) at the right time, a robust, accurate, real-time inventory management system will be in place to assure availability and maintenance of adequate supplies, minimize potential wastage and accurately forecast demand which can be met. The varying storage temperatures and shelf-lives out

of storage of each vaccine type will mean certain vaccine types may be more suited to certain vaccination location types, depending on the volume of vaccinations carried out at the setting and the storage facilities on site. The distribution plan has accounted for this assigning the different vaccines for different locations. Ensuring adequate availability of the vaccine for the second dose will also be considered when managing stock levels.

To cater for the three (3) main temperature categories, namely: (1) +2°C to +8°C, (2) -20°C and (3) -70°C to -80°C, a scenario based planning has been developed. The first two temperature ranges can be handled in the current health structures because vaccines in the National Immunization Program (NIP) has the same temperature requirement. However, the vaccines requiring -70°C to -80°C are new and shall need a special storage package and a complicated distribution mechanism. Thus, the following scenarios has been considered in the vaccine distribution:

> **Scenario 1 & 2:** Distribution shall follow the pathway for the routine vaccines from the national cold storage facilities up the service delivery points, the health centers and hospitals allow the cold chain storage and distribution in NIP pathway of the current vaccines in the National Immunization Program of the DOH. These vaccines require +2°C to +8°C cold storage facilities. Such facilities are in place such as the Research Institute for Tropical Medicine (RITM) as the centralized vaccine hub, regional warehouses and the RHUs and hospitals.
>
> **Scenario 3** requires a cold storage facility of -70°C to -80°C. Currently, none of the government hospitals are capable of such, thus the government will have to procure or outsource/hire a private facility.

These scenarios may also vary based on the services that will be provided by the vaccine manufacturer such as but not limited to direct distribution to the service delivery sites, presence of a distributor in the country.

Within the Philippines, existing infrastructure and established vaccination distribution channels will mean vaccines can be delivered efficiently using air and road distribution channels directly from the central storage facility to the designated cluster hub warehouses. The logistics partner/s will also manage the delivery fleet and outbound logistics / delivery to the principal vaccination locations. All deliveries will be by chilled (+2°C to +8°C) distribution using the selected logistics partner's fleet. The fleet will operate to a very high specification with full GPS monitoring, remote temperature monitoring and redundancy on the cooling systems on the vehicle. The vaccine handling characteristics for other vaccines will be more clearly defined by manufacturers as the regulatory approvals process emerges.

Assessment of Cold Chain Facilities and Dry Storage Capacities

The plan to introduce the vaccine includes the calculation of additional space requirements and cold chain equipment at the national, and local levels, and even in the vaccination rooms. The data on additional storage requirements are based on the dosage form and characteristics of the new vaccine and those currently in use. and transport capacity for the vaccine at each level of the cold chain, determining the need for additional equipment. This evaluation offers an ideal opportunity to update the national cold chain inventory by type of equipment and operating condition. Both public and privately managed cold storage facilities and logistics providers shall be assessed and visited in partnership with the FDA.

Distribution of the Ancillary Immunization Supplies

Ancillary immunization supplies provided by the program shall include auto-disabled (AD) needles and syringes, mixing syringes, safety collector boxes (SCB), PPEs (masks and face shields). The same process as above shall be followed. The plan is all these items shall be delivered earlier than the vaccines.

Chapter 5: Vaccine Distribution and Deployment

Determining the Vaccine Recipients

Vaccination against SARS-CoV-2 offers the possibility of significantly reducing severe morbidity and mortality and transmission when deployed alongside minimum public health standards and improved clinical management of symptoms. However, even if safe and effective COVID-19 vaccines (most of which are still under various stages of development) will officially be authorized for emergency use and eventually licensed by the FDA, these vaccines will not be immediately available in amounts sufficient to vaccinate a large portion of the adult Filipino population. The country's COVID-19 vaccine deployment and vaccination program are largely dependent on the global supply of vaccines available for the Philippines and the country's ability to access them and on the application of foreign manufacturers for EUA and Certificates of Product Registration (CPR).

Equitable allocation of the COVID-19 vaccine is premised on current available evidence on COVID-19 and its transmission, susceptibility to the disease, and risks of severe disease or death. The current public health and clinical policies, recommendations need to be flexible and should be updated as evidence emerges and realities change.

The identification of eligible populations was identified based on the WHO Strategic Advisory Group of Experts on Immunization (SAGE) Values Framework for the Allocation and Prioritization of COVID-19 Vaccination. In addition, the recommendations of the NITAG of COVID-19 Vaccines shall guide the identification and finalization of the eligible population, taking into consideration the national context, the epidemiologic settings and the COVID-19 vaccine characteristics and supply.

The SAGE Values Framework provides the overarching goal and six core principles that should guide the distribution of COVID-19 vaccines, of which, five (except global equity) were adopted by the country. Thus, the identification of eligible population is guided by the following principles:

Table 6. Guiding principles adapted from the WHO SAGE Values Framework.

Principles	
Public Good	The COVID-19 vaccines shall be a main prevention commodity, and shall be made available to all members of the society as public good, without prejudice to practice of public health measures.

Human well-being	Where health, social and economic, security, human rights and civil liberties of all citizens and individuals are protected and promoted.
Reciprocity	Where individuals and groups who have greater burden in the COVID-19 pandemic response and have higher significant risks brought by their responsibilities and roles shall be given greater priority.
Equal respect	Where all human beings are treated equally and their interests are considered with equal moral consideration.
National equity	Where equity in vaccine access is assured nationally and those with greater burden of COVID-19 pandemic.
Legitimacy	Where decisions are made through transparent processes based on shared values and scientific evidence.

The primary goal in identifying the eligible population and vaccination is to directly reduce morbidity and mortality and maintain most critical essential services. The secondary goal is to control transmission and minimize disruption of social economic and security functions. And lastly, the tertiary goal is to resume the country's essential activities to near normal. These goals guided the selection of priority eligible groups. The selection of priority eligible group A fulfills the primary goal, priority eligible group B addresses the secondary goal, and lastly, the priority eligible group C addresses the tertiary goal.

Guided by these principles, the National Government drafted a decision matrix as stipulated in DOH Administrative Order No. 2021-0005 entitled "National Strategic Policy Framework for COVID-19 Vaccine Deployment and Immunization".

Table 7. The Decision Matrix in determining priority eligible population groups.

Principles	Objectives	Population Groups
Human well-being	• Reduce deaths and disease burden • Protect those in the health services and essential services	• Health workers • Older adults (senior citizens with or without comorbidities) • Persons with comorbidities • Personnel in government agencies providing essential services (DSWD, DepEd, DILG, BJMP & Bureau of Correction, PNP, AFP, PCG, BFP, CAFGU) • Government workers, teachers and students, essential workforce (agriculture, tourism, transportation, food industry, tourism, manufacturing, construction, among others) • All workforce
Principles	**Objectives**	**Population Groups**
Reciprocity	• Protect those who bear significant additional	• Health workers (all) • Essential workers outside the health sector, those with

	risks and burdens of COVID-19 to safeguard the welfare of others	high-risk of exposure, such as contact tracers, social workers providing social services, among others
Equal respect	• Treat the interest of all individuals and groups with equal consideration as allocation and priority setting • Vaccinate all citizens	• All citizens based on the availability of vaccines
National equity	• Ensure that vaccine prioritization takes into account vulnerabilities, risks and needs groups because of underlying societal, geographic or biomedical factors	• People living in poverty (indigent population) • Disadvantaged groups (PWD, PDLs, among others) • Low-income workers • Hard-to-reach areas • Overseas Filipino Workers

Thus, the Philippine National Government identified the following priority eligible population:

Table 8. The Priority Eligible Population.

Priorities	Population Group	Definition of Terms
Priority Eligible Group A*		
1	Frontline Health Workers	All health workers from the PRIVATE and PUBLIC sector currently on ACTIVE practice/service, whether they are permanent, contractual, job-order and/or outsourced employees or staff:
	a) Public and private health facilities [hospitals, medical centers, laboratories, infirmaries, Treatment Rehabilitation Centers (TRCs) and Temporary Treatment and Monitoring Facilities (TTMFs)]	• All those are working in medical centers, hospitals, clinics, laboratories, Temporary Treatment and Monitoring Facilities (TTMFs), and Treatment Rehabilitation Centers (TRCs). If the vaccine supply is limited, priority shall be given to hospitals and medical centers directly catering to COVID-19 patients, including suspects, probable and confirmed COVID-19 cases. • Specifically, all those who are assigned in the triage areas, out-patient departments, emergency rooms, wards, intensive care units, operating rooms, delivery rooms, laboratory, radiologic and pathology areas, rehabilitation units, among others. • Medical and allied health students who are serving as

		clerks or interns in hospitals ● Those who are assigned as part of the disinfection or decontamination teams, medical social workers, admin personnel, and security guards of the above-mentioned facilities.
	b) Public health workers (all RHU/CHO personnel, PHO, PDOHO, CHD and CO) and LGU contact tracers	All workers in the public health sector: ● ALL employees in the public primary care facilities (Rural Health Units, City Health Offices (whether LGU-hired or DOH-hired/deployed) ● ALL health workers employed/deployed/detailed in Provincial Health Offices, Center for Health Development and Department of Health Central Offices, including Food and Drug Administration and Bureau of Quarantine ● ALL health workers employed/deployed/detailed in DOH-attached agencies such as Philippine Health Insurance Corporation, Philippine National AIDS Council, Philippine Institute of Traditional Alternative Health Care, Dangerous Drugs Board, and National Nutrition Council ● LGU-deployed/designated/hired contact tracers [those with appropriate documents stating deployment/designation of government employees as contact tracers either through an Executive Order (EO), resolution and/or ordinance] ● Note: If the vaccine supply is limited, among workers in public health, priority shall be given to those who are providing direct health services.
	c) Barangay Health Workers including Barangay Health Emergency Response Teams (BHERTs)	● ALL Barangay Health Workers in active service ● ALL active members of the BHERTs (based on appropriate documents stating designation either through an LGU EO, resolution and/or ordinance)
	d) Other NGAs (DSWD, DepEd, DILG, BJMP and Bureau of Correction)	● DSWD, and its regional and local counterparts ○ All employees manning close-setting facilities and long-term care facilities, e.g. orphanage, home for the aged, women's crisis centers. ○ Social workers providing social amelioration, and social services in the communities ● DepEd ○ Health and nutrition personnel ● DILG

		○ Those hired by DILG as contact tracers (active service) ● BJMP (under DILG) ○ All employees and health workers assigned in direct contact with Persons Deprived of Liberty (PDLs) such as jail officers, wardens, and/or guards ● BuCor (under DOJ) ○ All employees and health workers assigned in direct contact with Persons Deprived of Liberty (PDLs) such as jail officers, wardens, and/or guards
2	Indigent Senior Citizens	ALL indigent senior citizens registered and as determined by DSWD
3	Remaining Senior Citizens	ALL senior citizens (not categorized as indigent) registered and as determined by DWSD
4	Remaining Indigent Population	ALL indigent population as determined by DSWD
5	Uniformed Personnel	All enlisted uniformed personnel in active services under the: ● Armed Forces of the Philippines ● Philippine National Police ● Philippine Coast Guard ● Bureau of Fire Protection ● Citizen Armed Force Geographical Unit ● BuCor (remaining personnel) ● BJMP (remaining personnel)
Priority Eligible Group B**		
6	Teachers and school workers	ALL teachers and school workers, whether permanent, job-order, contractual or out-sourced in all educational levels, from primary, secondary, tertiary, and vocational educational institutions, both private and public
7	All government workers (national and local government)	ALL government workers, whether permanent, job-order, contractual or out-sourced, in national government agencies, government-owned and controlled corporations (GOCCs), government financial institutions (GFIs), local government units, among others.
8	Essential workers	• All workers providing basic services during this time of pandemic and essential to the growth of the economy as

		determined by DTI and DOLE ● These workers may come from the following sectors: agriculture, forestry and fisheries; transportation; construction; food industries; manufacturing of essential goods; tourism; essential retail; water-refilling stations; laundry services; logistics service providers; delivery and courier services; water supply and sanitation services; telecommunication services; energy and power companies; gasoline stations, among others
9	Socio-demographic groups at significant higher risk other than senior citizens and indigent populations [e.g. Persons Deprived of Liberty (PDLs), Persons with Disabilities (PWDs), Indigenous Peoples, Filipinos living in high-density areas) Eligible Students	● All Persons Deprived of Liberty as determined by BJMP and BuCor ● All Persons with Disability as determined by DSWD, and National Council for Disability Affairs (NCDA) and LGUs ● All Indigenous Peoples as determined by the National Commission on Indigenous Peoples (NCIP). This may include: the Lumads of Mindanao, the Peoples of the Cordillera, and scattered tribal peoples of the hinterlands of Central and Southern Luzon, Visayas, Mindoro and Palawan ● All Filipinos living in high-density areas as determined by the LGUs (as documented in the LGU's Comprehensive Land Use Plan) such as in slums and temporary shelters, among others; including those who are homeless and living in temporary shelters and homes ● All students in primary, secondary and tertiary and vocational educational institutions. However, vaccination of students below 18 y.o. will depend on the recommendations of WHO and NITAG, with the concurrence of the COVID-19 Vaccine Cluster.
10	Overseas Filipino Workers (OFWs)	Filipino migrant workers who reside in another country for a limited period of employment that were not yet vaccinated
11	Other remaining workforce	All remaining Filipino workforce as determined by the DOLE, DTI and CSC
Priority Eligible Group C**		
12	Remaining Filipino Citizens	All Filipino Citizens that were not mentioned in priority A and B

** Persons with co-morbidities are being taken into consideration as part of Priority Eligible Group A depending on the latest development and scientific evidence. This is being discussed by the NITAG.*
***The Priority Eligible Group B and C may change as these categories will still undergo review of the NITAG and final approval of the COVID-19 Vaccine Cluster and the IATF.*

Vaccine Deployment Strategies

The deployment of vaccines will be in a phased approach depending on the delivery (timing, available doses, logistical requirements) of vaccines to the country. It will be executed based on a sectoral approach - that is, all frontline healthcare workers will be vaccinated first before proceeding to the next priority group. The number of individuals to be vaccinated in a round will depend on the total number of vaccines delivered, in which computation of the 2nd dose is already considered.

Since the delivery of vaccines to the country is in tranches, the deployment of vaccines in specific geographical areas shall be based on the burden of COVID-19 cases. In the identification of geographical areas, the NITAG set the indicators in determining the areas with high burden of COVID-19 cases. The indicators are as follows:

1. Number of Active Cases in recent four weeks
2. Attack rate per 100,000 in recent four weeks

Active cases refer to the total confirmed cases less those recovered and fatalities. These active cases as such are assumed to be still infectious and currently isolated. For the purpose of this ranking, we computed the attack rate using the total newly reported cases in the recent 4 weeks divided by the region's projected population and a multiplier of 100,000 population.

The determination of priority geographical areas will be per region. Likewise, the NITAG will review the burden of COVID-19 cases in the country every month and will recalibrate the priority areas accordingly.

Table 9. Priority Regions based on burden of COVID-19 cases as of January 2021.

Region	Total Cases As of Jan 8	Total Active Cases as of Jan 6	Rank (Active Cases)	Number of Cases Recent 4 Weeks (Dec 6 - Jan 2)	Attack Rate (Recent 4 Weeks)	Rank (Attack Rate)	Average Rank (Burden of Disease)	Overall Rank (Burden of Disease)	Population Density	Rank (Population Density)
NCR	27,104	7,181	1	10,978	80	2	**1.5**	**1**	22,301.54	**1**
Region IV-A	23,134	3,626	2	6,407	40	5	**3.5**	**2,3,4**	968.71	**2**
Region XI	88,405	1,804	4	3,093	58	3	**3.5**	**2,3,4**	258.94	**8**
CAR	212,876	976	6	2,289	127	1	**3.5**	**2,3,4**	91.22	**17**
Region VIII	8,567	1,314	5	2,544	54	4	**4.5**	**5**	204.11	**12**

Region III	2,885	2,144	3	3,771	31	8	**5.5**	**6**	562.12	**3**
Region II	12,157	701	8	1,425	39	6	**7**	**7**	184.57	**13**
Region VI	5,472	751	7	1,684	21	10	**8.5**	**8**	380.15	**6**
Region X	6,131	834	9	1,241	25	9	**9**	**9,10**	245.24	**9**
CARAGA	5,605	573	11	951	35	7	**9**	**9,10**	92.99	**16**
Region I	4,822	569	12	940	18	11	**11.5**	**11**	406.57	**5**
Region VII	2,853	646	10	952	12	14	**12**	**12**	513.77	**4**
Region XII	32,575	499	13	800	16	12	**12.5**	**13**	215.92	**11**
Region IX	13,810	342	14	606	16	13	**13.5**	**14**	228.21	**10**
Region V	5,194	309	15	525	9	16	**15.5**	**15,16**	338.62	**7**
Region IV-B	8,967	185	16	365	11	15	**15.5**	**15,16**	107.24	**15**
BARMM	6,010	126	17	194	5	17	**17**	**17**	114.14	**14**

As shown in Figure 8, in parallel with the preparations of the National Government in accessing COVID-19 vaccines and in reviewing applications of vaccine manufacturers for EUA, the National Government is also preparing for the COVID-19 vaccine deployment and implementation of the vaccination program. As the National Government will roll-out policies and plans, several activities in coordination with the Local Government Units will be conducted, such as simulation activities, such as table activities and drills, to test local plans and implementation of policies in the local level. The rest of the activities stipulated in Figure 8 will be discuss in Chapter 6.

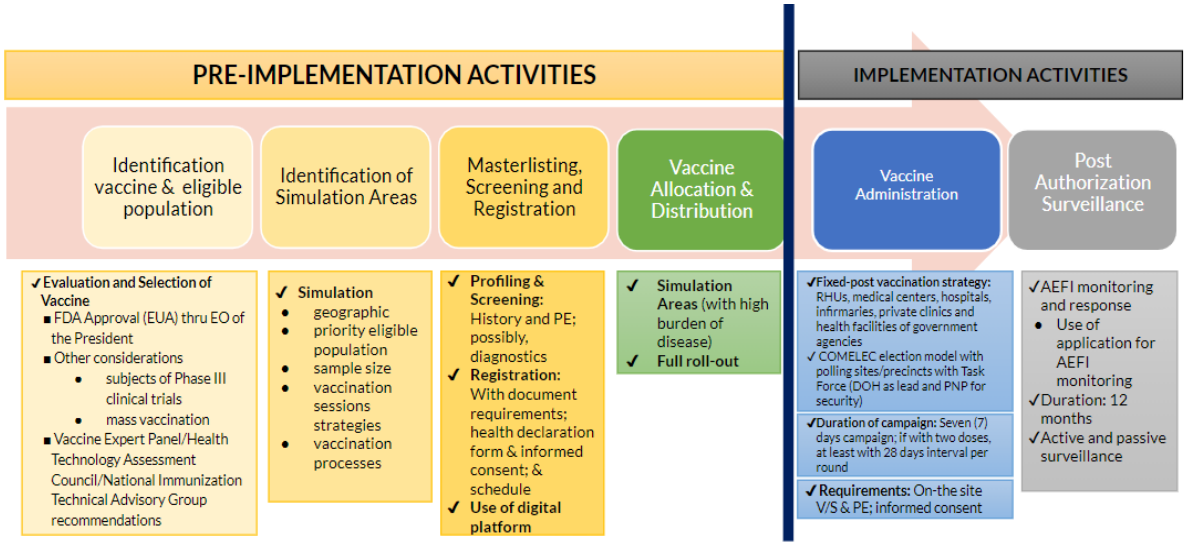


Figure 9. Vaccine Deployment and Service Delivery Activities.

Vaccine Distribution Strategies

The manner of the distribution of vaccines will depend on the storage requirements specific to each vaccine. DOH will provide a Department Memorandum detailing the operational guidelines, including the vaccine storage and cold chain requirements, delivery and deployment mechanisms for each specific vaccine.

For vaccines requiring +2°C to +8°C storage, the vaccines will be delivered from the supplier to the RITM, which will serve as the government Centralized Vaccine Hub. From RITM, the vaccines will be passed on to the regional warehouses/hubs. The Centers for Health Development, in coordination with logistics partners and other government agencies, shall deliver the vaccines to Local Government Units. The LGUs will then allocate vaccines to implementing units such as medical centers, hospitals, infirmaries, RHUs and CHOs, and private clinics, where the vaccine will be administered to the eligible recipient. The distribution process for vaccines requiring -20°C storage will utilize the same process used for vaccines requiring +2°C to +8°C storage.

In addition, for vaccines requiring -70°C to -80°C storage, the vaccines will be delivered from the supplier to a private centralized vaccine hub. And through a private distributor, the vaccines will be delivered to hospitals and medical centers with cold chain capacity to store the vaccines. Or the vaccines can temporarily be stored in rented private warehouses before they are delivered to hospitals and medical centers. Plans and arrangements will be carefully made for the vaccines to be distributed to implementing units and the administration of the vaccine to the eligible recipient.

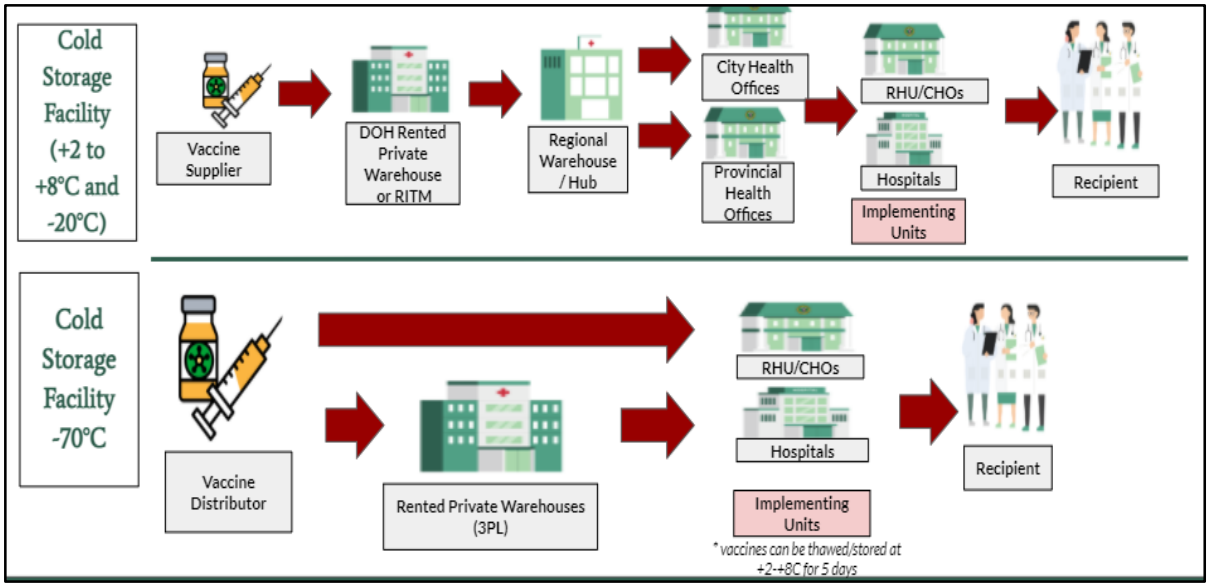


Figure 10. Distribution of vaccines according to storage facility requirements.

Chapter 6: Implementation of a Nationwide Vaccination

The implementation of a nationwide COVID-19 vaccination program shall be in a phased approach taking into consideration the quantity of vaccines delivered to the country, the cold chain requirements, and burden of COVID-19 cases in geographical areas. Therefore, there shall be several rounds of COVID-19 vaccination campaign conducted within the year.

The Local Government Units, as mandated in Republic Act 7160, otherwise known as the "Local Government Code of 1991", shall take the lead in the implementation of the COVID-19 vaccination program in accordance with the policies and guidelines set by the COVID-19 Vaccine Cluster and DOH. Thus, participating agencies and the private sector are enjoined to closely coordinate with the LGUs in which their health facilities are located.

On the other hand, the National Government and its regional counterparts, shall provide strategic direction, and technical and logistical assistance; cascade policies and guidelines; and capacitate implementers, among others.

Specifically, for each deployment of a specific type and quantity of COVID-19 vaccine, the DOH shall provide a Department Memorandum detailing the specific operational guidelines applicable for the specific vaccine.

Further, all vaccination activities, whether the COVID-19 vaccines to be administered have been procured by the National Government, the private sector or the LGU, shall be closely coordinated with DOH and shall follow DOH policies and guidelines. No vaccination activity shall be conducted without the guidance and the knowledge of DOH.

The implementation of a nationwide COVID-19 vaccination program is divided into three phases, namely: 1) the pre-implementation phase, where preparations for the actual vaccination activity are carried out, 2) the implementation phase or the actual vaccine administration schedule, 3) the post-implementation phase, where all activities and reports to conclude a certain round are completed.

Pre-implementation Phase

In the pre-implementation phase, the following activities enumerated are to be undertaken by LGUs, specifically municipalities and cities:

1. Establishment of a VOC (see Special Chapter: Governance)
2. Masterlisting of Eligible Populations, Vaccination Workforce, Implementing Units and Vaccination Sites/Posts

3. Microplanning
4. Mapping of Vaccination Sites and Vaccination Workforce
5. Vaccines, Logistics and Cold Chain Inventory and Management
6. Capacity Building and Training
7. Advocacy, Community Engagement and Social Preparation (see Special Chapter: Risk Communications and Community Engagement)
8. Preparation of Vaccination Sites/Posts
9. Monitoring and Supervision (see Chapter 7: Assessment, Monitoring and Evaluation)

In this section, numbers 2-6 and 8 shall be extensively discussed while other numbers are explained intensively in other chapters of this Plan.

I. Masterlisting, Microplanning and Mapping (3Ms)

The 3Ms, namely, masterlisting of eligible population, vaccination workforce and implementing units and vaccination posts/sites; microplanning; and mapping of vaccination workforce and vaccination posts/sites are critical in the implementation of the COVID-19 vaccination program. In the succeeding section, each of the Ms will be discussed in detail.

1. Masterlisting of eligible population, vaccination workforce and implementing units and vaccination posts/sites

To prepare the country for the COVID-19 vaccination program, creation and maintenance of a masterlist of priority sectors is necessary to: (a) provide basis for identification of target eligible groups for vaccination and identification of priority areas for registration of eligible individuals; (b) ensure uniqueness of individuals in the vaccine administration plan; and (c) provide input to operational planning especially for costing and allocation of resources.

Masterlisting is the linelisting and registration of the population prior to vaccination. This could be done through an online or offline platform developed by the DICT, and DOH's KMITS and EB. From the masterlist, eligible population for specific vaccines will be culled out and accessed by appropriate regions or LGU for registration, scheduling, mapping-out on appropriate vaccination sites and advisory.

a. Phased Submission of LGU Masterlists

Masterlisting shall use the phased approach, as follows:

Table 10. Phases of masterlisting.

Group A	Phase 1: Workers in Frontline Health Services Phase 2: All Senior Citizens (Indicate if indigent) Phase 3: Indigent Population Phase 4: Uniformed Personnels (UPs)
Group B	Phase 5: Other Frontline Workers and Special Populations
Group C	Phase 6: Remaining Population

Targets for Masterlisting are as follows:

1. Submission of total numbers and masterlist of demographics for Group A sectors by **January 31, 2021**.
    a. Minimum demographic fields include complete name, birthdate, sex, address, profession/position, and unique identifier.
    b. Unique identifiers may include QR code, PhilHealth number, or Category ID such as PRC ID for healthcare workers.
2. Completion of patient profile including health status and consent for Group A sectors, especially Phase 1: Workers in Frontline Health Services, by **February 15, 2021.**
3. Completion of full masterlist for Group A and Group B sectors by **March 31, 2021.**
4. Completion of full masterlist of Group C by **June 30, 2021.**

Masterlisting efforts shall be initiated at the LGU level, with profiling and screening of eligible target population cohorts will be conducted prior to registration into the electronic immunization registry. Prioritization for workers in health facilities shall be according to selected health facilities, public or private, such as COVID-19-designated hospitals, those with relatively higher number of admissions past two months, all LGU hospitals; and risk-based categories for healthcare workers that may be determined.

b. Interim Minimum Data Standards for the COVID-19 Electronic Immunization Registry (CEIR)

The COVID-19 Electronic Immunization Registry (CEIR) shall be the official platform for masterlisting and registration for COVID-19 vaccination. External systems may be used to submit the necessary information following the Interim Minimum Required Data Fields as indicated below.

Table 11. Interim minimum required data fields for masterlisting.

Data Set	Definition	Type	Format
1. Category	Category of the Target Eligible Population 01 – Health Care Worker 02 – Senior Citizen 03 – Indigent 04 – Uniformed Personnel 05 – Essential Worker 06 – Other	String	Dropdown
2. CategoryID	ID number depending on the category type For 01 – PRC number 02 – OSCA number 03 – Facility ID number 04 – PWD ID 05 – Other ID	String	Freetext
3. PhilHealth ID	PhilHealth ID	Integer	Freetext, 12 digits only
4. Last name	Surname/Last Name	String	Freetext
First name	First Name/Given name	String	Freetext
Middle Name	Middle Name	String	Freetext
Suffix	Suffix	String	Dropdown
5. Contact_no	Contact Number (Mobile Number or Landline)	Integer	Freetext, 12 digits only
6. Full_address	Unit/ Building/ House Number, Street Name, Purok, Zone	String	Freetext
Province	Name of province	String	PSGC, Dropdown
MunCity	Name of city or municipality	String	PSGC, Dropdown
Barangay	Name of barangay	String	PSGC, Dropdown
7. Sex	Sex 01 – Female 02 – Male 03 – Not to disclose	String	Dropdown

8. Birth date	Date of birth (mm/dd/yyyy)	Date	Date picker
9. Civil status	Civil Status 01 – Single 02 – Married 03 – Widow/Widower 04 – Separated/Annulled 05 – Living with Partner	String	Dropdown
10. Employed	Employment Status 01 – Government Employed 02 – Private Employed 03 – Self-employed 04 - Private practitioner 05 – Others	String	Dropdown
11. Profession	01 – Dental Hygienist 02 – Dental Technologist 03 – Dentist 04 – Medical Technologist 05 – Midwife 06 – Nurse 07 – Nutritionist-Dietician 08 – Occupational Therapist 09 – Optometrist 10 – Pharmacist 11 – Physical Therapist 12 – Physician 13 – Radiologic Technologist 14 – Respiratory Therapist 15 – X-ray Technologist 16 – Barangay Health Worker 17 – Maintenance Staff 18 – Administrative Staff 19 – Other Workers in Frontline Health Services *Categories for other subgroups to be included in succeeding versions; LGU may create sub categories not listed here		
Direct_covid	Providing direct COVID care? 01 – Yes 02 – None	Boolean	Dropdown
12. Employer_name	Name of employer	String	NHFR or freetext

Employer_LGU	Province/ HUC/ ICC of employer	String	PSGC, Dropdown
Employer_address	Full address of employer	String	Freetext
Employer_contact_no.	Contact number of employer	Integer	Freetext,12 digits only
13. Preg_status	If female, pregnancy status 01- Pregnant 02- Not Pregnant	Boolean	Dropdown, conditional (if female only)
14. W_allergy	With Allergy 01 – Yes 02 – None	Boolean	Dropdown
Allergy	Name of Allergy 01 – Drug 02 – Food 03 – Insect 04 – Latex 05 – Mold 06 – Pet 07 – Pollen	String	Freetext, conditional (if with allergy only)
15. W_comorbidities	With Comorbidities 01 – Yes 02 – None	Boolean	Dropdown
Co- morbidity	Name of Comorbidity 01 – Hypertension 02 – Heart disease 03 – Kidney disease 04 – Diabetes mellitus 05 – Bronchial Asthma 06 – Immunodeficiency state 07 – Cancer 08 – Others	String	Dropdown
16. covid_history	Patient diagnosed with COVID-19 01 – Yes 02 – No	Boolean	Dropdown
covid_date	Date of first positive result / specimen collection (mm/yyyy)	Date	Date picker

covid_classification	Classification of infection 01 – Asymptomatic 02 – Mild 03 – Moderate 04 – Severe 05 – Critical	String	Dropdown
17. Consent	Provided electronic informed consent for data collection? 01 – Yes 02 – No 03 – Unknown	String	Dropdown
18. Consent_vacc	Provided initial consent for vaccination? 01 – Yes 02 – No 03 – Unknown	String	Dropdown

c. Prescribed Processes for Masterlisting Intended Vaccinees

1. Local Government Units shall lead masterlisting efforts within their catchment area and consolidate by municipality/CC/HUC/ICC.
2. All institutions (ex: health facilities) shall submit the masterslists to the municipality/CC/HUC/ICC, through any of the following methods:
   a. COVID-19 Electronic Immunization Registry (CEIR);
   b. Information system of the LGU linked to the CEIR through an application program interface (API);
   c. Dataset consistent with prescribed formats for bulk uploading through the CEIR; or
   d. Dataset consistent with prescribed formats for bulk uploading through the assistance of DOH CHDs.

   CEIR platform may be accessed through http://ceir.doh.gov.ph. Training videos and submission templates may be retrieved from http://bit.ly/CEIRdocuments. Regional templates with PSGC codes are also available in said link. For help desk and support please contact covid19ceir@doh.gov.ph.
3. Masterlist data may be submitted and consolidated in phases, to include the following fields:
   a. Patient List - 1, 4, 7, 8, 10, 12
   b. Full Patient Demographics - 1, 2, 4, 5, 6, 7, 8, 9, 10, 11, 12
   c. Full Patient Health Profile - 3, 13, 14, 15, 16, 17, 18
4. LGUs shall ensure that there will be no duplication in masterlists across facilities within their catchment. The DOH shall likewise conduct deduplication checks on the final endorsed masterlists.

a. Masterlisting for Phase 1: Workers in Frontline Health Facilities shall be done based on the location of their health facility of assignment.
b. For the eligible population with multiple affiliations (ex: health care worker in multiple hospitals), they shall choose only one health facility as their intended site for vaccination.

5. Masterlisting of UPs and essential personnel shall be based on their command. Masterlisting of the general population shall be based on the LGU where the vaccinee is residing in.
6. The province/HUC/ICC health office shall provide a status report and updated consolidation masterlist to their respective CHD every Friday.
7. After completion of masterlisting in a health facility, the Chief of Hospital or Head of Facility shall submit physically signed endorsement of all workers in the facility for phase 1 vaccination to the respective local government unit copy-furnish the CHD. The endorsement should indicate those who have and consented and who have not.
8. CHDs shall compile and store all signed and attested masterlists of all LGUs and health facilities, and scan copies saved according to the following format: Region-Health facility name, i.e., NCR-SAN LAZARO HOSPITAL. The document shall be saved in Portable Document Format (PDF) and be uploaded to the bit.ly link provided for their respective region.
9. Consistent with actions necessary for Universal Health Care, LGUs are instructed to initiate profiling the health status of their population now and generate a masterlist of population with comorbidities and other important information that will be necessary to implement the National Deployment and Vaccination Plan. Health profiling through Electronic Medical Records consistent with DOH standards is recommended.
10. Complete masterist including patient list, full demographics, and full health profile is required prior to actual vaccine administration. Phased submissions shall guide local and national planning of the vaccine deployment plan.

d. Masterlisting the Vaccination Workforce

LGUs shall develop masterlists of the vaccination workforce by Municipality/CC/HUC/ICC using the following minimum data fields:

Table 12. Minimum data fields required for the masterlisting of the vaccination workforce.

Data Set	Definition	Type	Format
heathfacility_name	Name of health facility	String	NHFR or freetext
healthfaiclity_LGU	Province/ HUC/ ICC of employer	String	PSGC, Dropdown
Last name	Surname/Last Name	String	Freetext

First name	First Name/Given name	String	Freetext
Middle name	Middle Name	String	Freetext
Suffix	Suffix	String	Dropdown
Position	Position or designation of the	String	Freetext
Team	Team category 01 - Vaccination Team 02 - AEFI/ AESI Composite Team	String	Dropdown
Role	Role in the vaccination team 01 - Screening and Assessment 02 - Health educator 03 - Vaccinator 04 - Documentor/ Recorder 05 - AEFI Monitoring 06 - Others	String	Dropdown

Local governments and CHDs shall determine the vaccination workforce and vaccination site/post, compliant to standards set in the National Deployment and Vaccination Plan. Initial list of these sites shall be submitted to the CHD by **January 31, 2021**.

2. Microplanning

Microplanning is a "bottom-up" planning process carried out to determine local needs and gaps and to ensure smooth and satisfactory vaccine implementation. This is one of the key activities to ensure the planning of the vaccination campaign lays out all operational aspects of the activity at the municipal/city and barangay levels. It is the translation of the national and regional macroplan to the local situation. Microplanning is one of the tools that health workers use and endorsed by the NIP to ensure that immunization services reach every community.

The microplanning activity has been tailored fit for COVID-19 vaccines taking into consideration diverse vaccine portfolios and the complexities of COVID-19 vaccine development.

The following are the objectives of microplanning:

1. To ensure that campaign objectives are reached and immunization strategies are well implemented at the service delivery points (health facilities and LGUs).
2. To ensure that adequate resources are mobilized and in place with expected results to be accomplished on time.
3. To anticipate the challenges and maximize use of limited resources in an efficient manner in the context of the COVID-19 pandemic.

The microplanning shall be done by the LGUs, specifically by municipalities and cities, and shall commence at once after masterlist and/or training has been obtained by the LGU.

It is paramount that microplans get validated at each level as data are collected. This calls for effective supervision of the development of each microplan. Therefore, microplans are submitted in the following order: for municipalities and component cities, to the Provincial Health Offices (PHO) copy furnished Provincial DOH Offices (PDOHO), then the PHO to the CHDs; and for HUCs and ICCs, directly to the CHDs.

Once microplans from C/MHO level reach the province, they get aggregated and the provincial coordinators add province-specific costs (supervision, meetings, transport) are incorporated, before forwarding the plan up to the regional and national level. The microplan must be updated as frequently as possible.

A readiness assessment tool shall be used to assess and monitor the implementation of the plan. This can also be https://tinyurl.com/covidvaccineRA or see Annex A. Also, a microplanning template in excel form is accessible in this link: https://tinyurl.com/microplanningc19.

Here are the critical steps in microplanning:

Critical Step 1: Determine the number of eligible population for COVID-19 vaccination in your area.

The number of eligible population can be culled out in the CEIR and shall be readily accessible to LGUs. The DOH shall provide specific guidelines on who among the priority population shall be vaccinated on a certain period of time depending on the vaccine supply and certain geographical area.

a. Utilize data gathered during the masterlisting and profiling in determining the number of eligible population for COVID-19 vaccination.
b. Once the type of vaccine to be deployed in your area is determined, work closely with the DOH CO and CHD in determining the final eligible population based on the inclusion and exclusion criteria as provided in the DOH guidelines.
c. Ensure that data in the CEIR are complete. And triangulate the accuracy of the profiling data with existing data available in the LGU.
d. Determine the eligible population per municipality/city.
e. Then, disaggregate the eligible population by barangay and/or implementing unit.

Here is a sample form in determining the eligible population in the area:

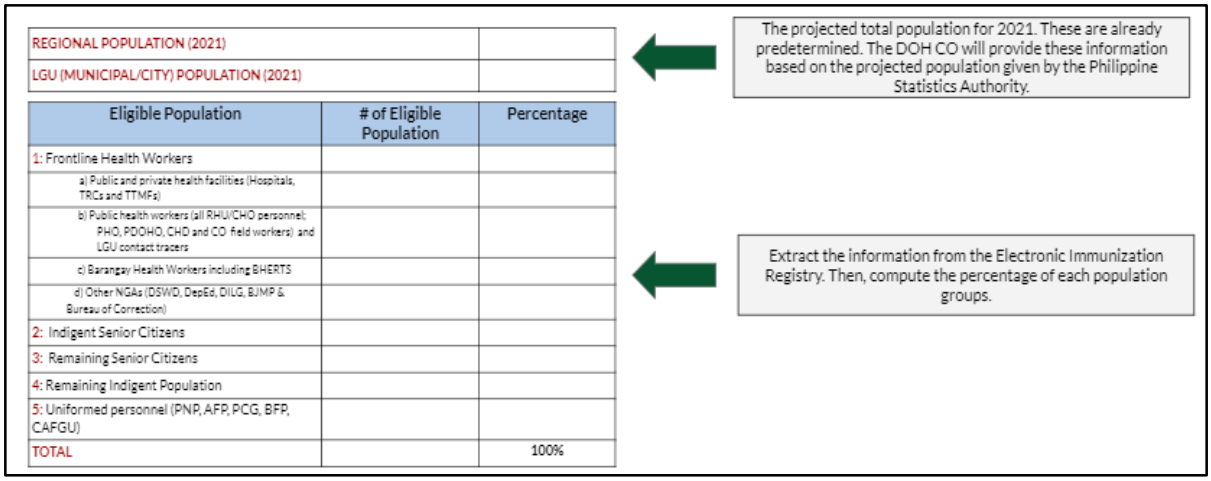


Figure 11. Sample form in determining the eligible population.

Table 13. Disaggregated eligible population by barangay / health facility.

Eligible Population	Barangay /HF 1	Barangay /HF 2	Barangay/ HF 3	Barangay/ HF 4	TOTAL
1: Frontline Health Workers					
a) Public and private health facilities (Hospitals, TRCs and TTMFs)					
b) Public health workers (all RHU/CHO personnel; PHO, PDOHO, CHD and CO field workers) and LGU contact tracers					
c) Barangay Health Workers including BHERTS					
d) Other NGAs (DSWD, DepEd, DILG, BJMP & Bureau of Correction)					
2: Indigent Senior Citizens					
3: Remaining Senior Citizens					
4: Remaining Indigent Population					
5: Uniformed personnel (PNP, AFP, PCG, BFP, CAFGU)					
TOTAL					**100%**

Criteria Step 2: Identify the implementing units in your area, and the number of vaccination sites/posts, and plot in your operational spot map.

a. For COVID-19 vaccination, the fixed-post vaccination strategy shall be used (discussed extensively in the succeeding section of this chapter). Implementing Units are defined as establishments authorized to conduct the vaccination activity. On the other hand, vaccination sites/posts are areas within the implementing units where the vaccination administration proper is conducted. The following shall be utilized as implementing units:
   i. Medical centers, hospitals and infirmaries (private and public)
   ii. Rural Health Units
   iii. Health facilities of other government agencies (e.g. AFP hospitals and facilities,

BJMP/BuCor health facilities, and DepEd clinics)

iv. Private clinics

b. The implementing units may have several vaccination sites/posts within its vicinity, e.g. a medical center can have several vaccination sites/posts within its vicinity.

c. Identify the implementing units as categorized on the table below and quantify the vaccination sites/posts per implementing unit. If possible, determine how many vaccination teams and AEFI/AESI composite teams can be accommodated in a vaccination post/site.

d. Plot in an operational spot map.

Table 14. List of Implementing Units and Vaccination Sites/Posts.

Implementing Units		# of Vaccination Sites/Posts
● Hospitals (government)	a.	
	b.	
● Hospitals (private)	a.	
	b.	
● Rural Health Units	a.	
	b.	
● Health Facilities of other agencies	a.	
	b.	
● Private Clinics	a.	
	b.	
TOTAL		

Here are several points in making an operational spot map:

a. LGUs may utilize this link to map out facilities (except for private clinics) in their area: https://nhfr.doh.gov.ph/rfacilities2list.php. The LGUs need to closely work with the private sector in mapping out private clinics.

b. In addition to mapping of implementing units and vaccination sites/posts, the map may include the following:

i. Roads/tracks (to determine distance of communities of eligible population to implementing units).

ii. geographical landmarks and features (to determine geographical barriers)

iii. Areas with migrant workers, urban poor, ethnic minorities, new rural settlements and groups in movement or unrest.

Critical Step 3. Identify the number of supervisors, vaccination teams, AEFI/AESI composite teams and other personnel needed and available for the vaccination activity.

The guidelines on the composition of the vaccination workforce are detailed in the succeeding section of this chapter.

a. Utilizing the information on the number of eligible population to be vaccinated in a round, compute the required vaccination workforce, taking into consideration the duration of the vaccination activity round. e.g. 50,000 (eligible population) ÷ 100 (numbers of vaccinees to be vaccinated in a day) ÷ 14 (duration of the vaccination campaign) = 36 teams.
b. After determining the teams, determine the number of personnel required per team.
c. Coordinate closely with the health facilities and engage the health professionals and enjoin them to participate in the vaccination activity (see Table X below).

Table 15. List of vaccination workforce, teams and personnel.

COMPOSITION		# of Teams / Individuals Required
Vaccination Team		
2	For Screening and Assessment:	
1	As Health Educator:	
1	As Vaccinator:	
2	As Documenter/Recorder:	
AEFI/AESI Team		
1	As Monitor/Responder:	
1	As Surveillance Personnel:	
Supervisor:		

Critical Step 4: Assign vaccinees and teams to an implementing unit / vaccination post/site.

a. Determine the eligible population to be vaccinated in the implementing unit / vaccination post/site.
    i. Assign frontline health workers and uniformed personnel to health facilities where they are employed/deployed.
    ii. For frontline workers or uniformed personnel employed/deployed in an agency without any health facility, assign them to RHUs and CHOs.
    iii. For senior citizens and indigent population, assign them to the health facility nearest to their residence.
b. Allocate vaccination workforce based on the number of eligible population assigned to the implementing unit / vaccination site/post.
    i. In close coordination with health facilities, the LGU may reallocate vaccination

workforce of health facilities to vaccination posts with a high number of eligible population assigned.

Table 16. Recommended vaccinees under the Eligible Priority Group A that particular implementing units can cater.

Operational Guidelines
● The following may be catered by **Medical Center / Hospital / Infirmary (both private and public):** ○ Frontline Health Workers, as defined in the DOH guidelines, in medical centers/hospitals/infirmaries, Treatment Rehabilitation Centers (TRCs), Temporary Treatment and Monitoring Facilities (TTMFs) ○ Senior Citizens ○ Indigent Population ○ Vaccination Team
● The following may be catered by **Rural Health Units:** ○ Frontline Health Workers employed/deployed/assigned in the public health sector, as defined in the DOH guidelines; Barangay Health Workers and Barangay Health Emergency Response Teams, employees manning close-setting facilities and long-term care facilities, e.g. orphanage, home for the aged, women's crisis centers, among others; and social workers providing social amelioration and social services in the communities; and LGU-hired/deployed/designated or DILG-hired contact tracers; Senior Citizens ○ Indigent Population ○ Uniformed personnel from the Philippine National Police, Bureau of Fire Protection, Philippine Coast Guard ○ Vaccination Team
● The following may be catered by **Private Clinics:** ○ Frontline Health Workers, as defined in the DOH guidelines, working in private clinics ○ Senior Citizens ○ Indigent Population ○ Vaccination Team
● The following may be catered by **Health Facilities of Government Agencies:** ○ Frontline Health Workers employed/deployed/designated/assigned in health facilities managed by the Department of Education, Armed Forces of the Philippines, Bureau of Jail Management and Penology, Bureau of Corrections; frontline workers, as defined in the DOH guidelines, employed/deployed/designated/assigned in BJMP and BuCor ○ Uniformed personnel from the AFP, CAFGU ○ Vaccination Team

Table 17. Sample for the assignment of vaccinees and vaccination workforce to vaccination posts/sites.

Bara-ngay	Vaccination Post	Eligible Population assigned to vaccination posts	No. of Vaccination Teams required	No. of Available Vaccination Teams	Gap	No. of Composite Teams required	No. of Available Composite Teams	Gap	No. of Supervisors required	No. of available supervisors	Gap
B1	RHU 1	5,467	8	4	4	8	6	2	3	2	1
	Private Clinic 1	600	1	1	0	1	1	0	1	1	0

B2	Hospital 1										
	DepEd Clinic 1										

Critical Step 5: Estimate the vaccine requirement and ancillary supplies needed

a. Develop a budgeted cold and logistics plan
b. Determine the logistics required for the implementing units and vaccination posts. The following are the minimum required.

Table 18. Vaccines and logistics required.

Logistics	Formula
Vaccines	● Still to be determined: Eligible population ÷ __ (___doses per via) x ___ (wastage factor) = Total # of COVID-19 vaccine vials
Diluents	● Still to be determined
AD syringes	● Still to be determined
Mixing syringes	● Still to be determined
AEFI /AESI kits	● At least one AEFI/AESI kit per composite team
Safety Collection Boxes (SCBs)	● Total ADS + Total Mixing syringes)/100 x1.1 (WF) = Safety Box Quantity Requirement
PPEs	● **Face mask**: Total HR x 2 masks/day x 7 days x 2 rounds; **Face Shield:** Total HR x 1 face shield
Alcohols, cottons	● **Alcohol:** 1 bottle of alcohol/HR per day x 7 days x 2 rounds; 2 **cotton balls** per vaccinee x 2 rounds
Vaccine carriers and ice packs	● 1 vaccine carrier per 1 Vaccination Team
Vaccine refrigerators	● Still to be determined
Thermal Gun, BP Apparatus, Stethoscope, Pulse Oximeter	● 2 set per 1 Vaccination Team
Immunization cards	● 1 immunization card per vaccinee
Campaign Forms and Checklists	● 1 set per team/day
Cot beds	● 1 bed per composite team
Ambulance	● 1 ambulance per implementing unit

Critical Step 6: Identify gaps in cold chain capacity

Determine the cold chain capacity and identify gaps. Coordinate closely with the CHDs on the logistics to be provided by the national and regional health offices.

a. **Refrigerators:** make an inventory of refrigerators and freezers specifying model, manufacturer, number, energy source and the net vaccine and coolant-pact storage capacity.
b. **Electrical System:** check electrical system for reliability, accessibility, quality and security.
c. **Vaccine Carriers:** Evaluate number of cold boxes, vaccine carriers and coolant-packs. Conduct an inventory of existing equipment at each implementing unit.
d. **Temperature Monitoring:** Assess the number and condition of thermometer/temperature monitoring devices, temperature monitoring sheets.

Critical Step 7: Ensure timely delivery of vaccines and ancillary logistics

a. Develop a delivery and distribution plan for vaccines and ancillary logistics.
b. Coordinate with CHD on the delivery of vaccines and ancillary logistics that the National Government will provide.
c. Consider in the delivery and distribution plan the timeline for the LGUs to deliver vaccines and ancillary logistics to implementing units.
d. Coordinate with the CHD or CO on the direct delivery of certain vaccines to implementing units.

Table 19. Sample Delivery Plan.

	Quantity	Date of Delivery
Vaccines		
Diluents		
AD syringes		
Mixing syringes		
AEFI Kits		
Safety Collection Boxes		
Face Masks		
Face Shield		
Alcohol		
Cotton		
Campaign Forms and Checklists		

Others		

Table 20. Sample Distribution Plan.

Vaccination Post/Site	# Vaccines	# AD Syringes	# Mixing Syringes	# Diluents	# AEFI Kits	# Safety Collection Boxes	# Face Masks	# Face Shields	# Alcohols	# Cottons	Others
Hospital 1											
Hospital 2											
RHU 1											
RHU 2											

Critical Step 8: Prepare a Daily Vaccination Session Plan (daily itinerary)

a. Plot the activities or assignment of each implementing unit / vaccination post on a daily basis. Include in the plan:
   i. Number of teams required daily
   ii. Expected number of vaccinees to be vaccinated per day
   iii. Transportation mechanism for the vaccinees and the teams, ensuring physical distancing is considered in computing the transportation sitting capacity required
   iv. Resources needed for the vaccination post, and its quantity.

Table 21. Sample daily vaccination session plan.

Date of Immunization Schedule	Vaccination Posts	Assigned Vaccination Teams and Composite Teams	Eligible population	Daily Target to be Vaccinated	Transport mechanism for teams	Transport mechanism for vaccinees	Resources needed with quantity
March 15	Hospital 1	Team 1 upto Team 3	Frontline Health Workers	300	3 hired vans	none	vaccines (#) syringes (#) Safety collector boxes (4) Vaccine Carriers (3) Ice Packs (12) and etc
March 18	Hospital 2	Team 6-10	Senior Citizen in the AM Indigent Population in the PM	500	8 vans	10 jeepneys	vaccines (#) syringes (#) Safety collector boxes (6) Vaccine Carriers (5) Ice Packs (20) and etc

Critical Step 9: Develop a communication plan for community advocacy, social mobilization, partnership and engagement

a. Determine the following elements of the Demand Generation and Risk Communication

microplan (see sample plan below):

i. Activities
ii. Indicators
iii. Target
iv. Baseline
v. Timeframe
vi. Responsible person/unit
vii. Budgetary requirements
viii. Funding source

Table 22. Sample demand generation and communication plan.

Activities	Indicators	Target	Baseline	Time frame	Responsible person/unit	Budgetary requirements	Funding Source
BEFORE THE MASS IMMUNIZATION CAMPAIGN							
1. Briefing and feedback with LCEs, city administrator, LGU HEPOs, public information officer, DRRMO, and other key local officials	100% of target key local officials are briefed on the COVID-19 vaccination campaign						
2. Dialogues and/or capacity building with local partners and local leaders							
a. Barangay chairmen, BHWs, BHERTs, and other barangay officials	100% of target barangay chairmen, BHWs, BHERTs and other local officials are oriented and/or capacitated on the COVID-19 vaccination campaign						
b. Community-based leaders and representatives of community-based organizations *(homeowners associations, senior citizens, women's groups, transport groups, youth groups, indigenous peoples)*	80% of target community-based leaders and representatives from community-based organizations oriented and/or capacitated on the COVID-19 vaccination campaign						
c. Representatives of Faith-based groups	80% of target representatives of faith-based groups oriented and/or capacitated on the COVID-19 vaccination campaign						
d. NGOs, CSOs, civic, and other organizations operating in the city	80% of representatives NGOs, CSOs, and other organizations given oriented and/or						

	capacitated on the COVID-19 vaccination campaign						
e. local medical societies and networks	80% of target representatives of local medical societies and networks oriented and/or capacitated on the COVID-19 vaccination campaign						
f. private elementary and high school teachers	80% of target representatives of private elementary and highschool teachers oriented and/or capacitated on the COVID-19 vaccination campaign						
3. Development, production, and/or dissemination/posting of communication materials							
a. Development and/or printing of communication materials	# of communication materials developed						
b. Distribution and posting/installation of streamers, posters, and other communication materials *(consider public markets, transport terminals, ports, health facilities, day care centers, commercial areas)*	# of streamers or posters installed # of flyers distributed						
4. Awareness-raising activities							
a. Announcements via local public address system(s) - *e.g. mobile public address system, community megaphones*	# of announcements made						
b. Awareness-raising activities for eligible population *(group orientation; announcements; barangay assemblies; townhall meetings; online Q&A sessions)*	# of activities conducted						
c. Awareness raising and engagement via the mass media and social media platforms *(e.g. Facebook, Twitter, Instagram, Youtube)*	# of activities conducted						

d. Awareness-raising activities for hard-to-reach or special populations *(e.g. areas with security issues, relocated populations, mobile and transient families, homeless)* - Identifying hard-to-reach or special populations - Conduct of local strategies to reach hard-to-reach or 'special' populations	# of awareness-raising activities for 'special' populations conducted						
e. City-level launching or kick-off activity - Form committee; assign tasks; coordinate with national task group for simultaneous launch - Prepare programme or activity plan, with budget; speeches or talking points - Send invitations; coordinate logistics support - Conduct kick-off activity	# of city-level kick-off activities conducted						
5. Pre-campaign monitoring *(check for visibility of communication materials e.g. streamers; awareness of parents/ caregivers about the campaign; activities conducted by local officials and partners in support of the campaign)*	# of pre-campaign monitoring activities conducted						
a. Documentation of pre-campaign activities *(e.g. video, photo)*	Type of documentation used *(video, audio, photo, narrative)*						
b. Coordination meetings on advocacy and social mobilization	# of coordination meetings conducted						
DURING THE MASS IMMUNIZATION CAMPAIGN							
1. Monitor the progress of immunization activities; check for possible issues including refusals, rumours, misinformation; apply corrective actions, if needed	# of monitoring activities conducted						
2. Continuing social mobilization activities *(add details below; some awareness-raising activities during pre-campaign period may be continued until end of the campaign period and/ or when all children have been immunized)*							
AFTER THE MASS IMMUNIZATION CAMPAIGN							

1. Post-campaign assessment meetings and other activities	# of post-campaign assessment meetings and other related activities conducted						
2. Meetings with local partners to report on campaign accomplishment and to thank them for their support; agreements to maintain/sustain the partnership	# of meetings conducted						
3. Preparation and submission of campaign documentation report(s)	# of reports submitted						

Critical Step 9: Prepare a supervision and monitoring plan and schedule.

a. Ensure that supervisors and monitors are identified. Coordinate with implementing units to identify their vaccination team supervisors and/or implementing unit supervisors (see section on vaccination workforce).
b. Assign them to areas, especially areas needing technical assistance and support. If human resource is scarce, prioritization of areas shall be determined for the deployment of supervisors.
c. Map the areas needing supervisory work.

Table 23. Sample form for supervision and monitoring plan.

Region/Province: _____ LGU: _____
Implementing Unit: _____ Date: _____

Name of Supervisor / Monitor	Team Number and Name of VT Leader	Name of Vaccination Posts and Implementing Units	Mode of Transportation	Start Date	End Date	Contact Number	
						VT Leader	Supervisor
Rosana delos Santos	Team 1 - Carlos Reyes	PGH 3 vaccination posts	Van	March 19	June 19	0917 789 6534	0915 422 5623
Judith Dulay	Team 2 - AJ Cruz	Pasig RHU 1 1 vaccination posts	Van	March 19	June 19	0998 567 2317	0923 673 6423

Critical Step 10: Prepare an AEFI/AESI management, surveillance and response plan

a. Determine how many AEFI/AESI kits are required per vaccination post.
b. Ensure that each composite team has the following emergency equipment:
    - BP apparatus
    - Stethoscope
    - Penlight
    - Cot Bed / Stretcher

c. Identify AEFI/AESI referral facility for each composite team, and identify contact person in the referral facility and his/her contact numbers.
d. Ensure that an emergency transport vehicle is on standby in the vaccination post.

Table 24. Sample from for AEFI preparation.

Vaccination Posts	No. of Composite Team Assigned	No. of AEFI/ AESI Kits	Emergency Equipment Needed	Referral Facility	Contact Person	Contact Details	Assigned Emergency Transport Vehicle
RHU 1	3 Teams (Team 1-3)	3 Kits (with complete items)	Cot Bed / Stretcher: 6 BP: 3 Stet: 3 Pen light: 3	Pasig City General Hospital	Dr. Juan Dela Cruz	0917 569 3455	RHU Ambulance Plate No. TG 3485
Hospital 2							

Critical Step 11: Develop a waste management plan

Details on what to prepare and what to plan are extensively discussed in the last section of this plan. The required management of wastes may vary depending on the type of vaccines. The waste management plan should be extensively laid out based on the recommendation of manufacturers. For a minimum, the following steps must be undertaken:

a. Designate safe temporary storage for immunization wastes generated daily
b. Schedule and designate key responsible persons for waste management, waste transport and waste storage and destruction (if necessary).
c. Identify healthcare waste treatment and final disposal facility

Table 25. Sample form for immunization waste management plan.

Vaccination Post/ Implementing Unit	Disposal Facility	Contact Person and Contact Number	Schedule

3. Mapping of Vaccination Workforce, Implementing Units and Vaccination Sites/Posts

During the pre-implementation phase, it is essential that decision-makers such as the Local Chief Executives (LCEs), planning officers and health officers, among others, are familiar and adept with the guidelines in determining the vaccination workforce, implementing units and vaccination sites/posts.

The Vaccination Workforce

For the COVID-19 vaccination campaign, a diverse set of professionals and personnel, both from the public and private sector, shall be utilized as part of the vaccination workforce.

As more doses of vaccines become available during 2021- 2022, there will be a need to expand the pool of skilled workforce to administer vaccines and to deliver the program. In particular, standalone general practice private clinics and pharmacists can and have successfully delivered very significant numbers of flu vaccines and can offer enhanced capacity for this program subject to agreement. This vaccination program will also require significant increases in the number of administrative and support staff, in this regard there may be opportunities to leverage the broader public service to achieve this.

Thus, to ensure that sufficient workforce is available, the National Government shall engage and include other professionals such as teachers, counsellors, pharmacists, medical and allied health professionals and interns; and the private sector, as part of the vaccination workforce.

These are the minimum set of vaccination workforce needed:

Table 26. Recommended composition of the vaccination and AEFI composite teams, and other personnel needed in the implementing units.

Team/Other Personnel needed	Composition
Vaccination Team (6)	(2) for screening and assessment: Physician/Nurse/Midwife (1) as health educator: Allied Professionals/ Volunteers from partner agencies (e.g. teachers, social workers, medical students, etc) (1) as vaccinator: Physician/Nurse/Midwife of RHU/Pharmacist (certified by PRC) (2) as documentor/recorder and vital signs-taker: Midwife/BHW/Health Staff / Volunteers from partner agencies (e.g. teachers, social workers, medical students, etc)
AEFI Composite Team (2)	(1) to monitor and provide response: Paramedic/Nurse/Midwife (1) to conduct surveillance: Surveillance Officer/ Nurse/Midwife/Pharmacist

Supervisors/Monitors	(1) Vaccination Team Supervisor: preferably a physician, for at least three (3) vaccination teams (1) Implementing Unit Level Supervisor: for the entire implementing unit (1) LGU Level Supervisor: for the entire LGU Internal Monitors and Independent Monitors
Other personnel needed in the implementing units	Cold Chain and Logistics Officer/s Local Officials (barangay captains) Security Personnel (PNP) Drivers Safety Officers (Barangay Tanods, among others)
Other personnel needed in community/health facilities	Social mobilizers: BHWs and hospital staff (HR) Navigators/Transport: BHWs and Local Officials, Health Facility Management

The following are the roles and responsibilities of each team and personnel:

Table 27. Roles and responsibilities of the vaccination workforce.

Teams and Personnel	Roles and Responsibilities
1. Vaccination Team	● Man the vaccination administration area in the vaccination post/site ● Ensure that the vaccination administration procedure has been conducted efficiently and correctly ● Ensure that reports and information are encoded truthfully and submitted timely
a. Personnel assigned as documenter and recorder	● Man the registration area ● Ensure that documents and identification presented by the vaccinee are valid ● Ensure that all information and data are encoded in the data management system ● Assist other team members, especially on vital signs taking ● Submit daily coverage, refusals and deferrals to the C/MHO
b. Personnel assigned as health educator	● Man the health education area ● Ensure that equipment and IEC materials are available during the vaccination post/area ● Provide information to vaccinees, particularly on the benefits of vaccination, the possible adverse reactions, and how to seek help if with adverse reaction, either by answering their queries, or providing them with IEC materials ● Facilitate the signing of the informed consent ● Coordinate with social mobilizers and navigators for those who were deferred and those who refuse on-site.
c. Personnel assigned for screening and assessment	● Man the screening and assessment area ● Conduct physical examination and take the history of present illness (if applicable) and record in the CEIR ● Provide clearance for the vaccinee to be vaccinated. Those deferred for vaccination shall be coordinated with the social mobilization team for follow-up

	and shall be provided with a possible vaccination schedule
d. Personnel assigned as a vaccinator	● Man the vaccine administration area ● Follow the step-by-step procedure of vaccine administration as recommended by the manufacturer and as guided by the immunization protocols ● Completely fill-up the immunization card and encode the needed information to the data management system ● Dispose syringe and vials accordingly
2. AEFI/AESI Composite Team	● Man the post-vaccination area in the vaccination post/site ● Ensure that the vaccinee is monitored and observed for any adverse reaction in the 1st hour after vaccination ● Provide immediate intervention and response for vaccinees experiencing adverse reactions on-site and refer them accordingly and timely
a. Personnel assign to monitor and provide response	● Monitor and observe the vaccine for any adverse reaction in the 1st hour after vaccination ● If the vaccinee has any adverse reactions, provide immediate intervention/treatment ● Refer vaccinee/s with adverse reaction/s to appropriate AEFI/AESI referral health facilities in a timely manner ● Provide the vaccinee with information on what signs and symptoms he/she should watch for at home and where he/she should proceed to for treatment
b. Personnel assign for surveillance	● Monitor and observe the vaccine for any adverse reaction in the 1st hour after vaccination ● If the vaccinee has any adverse reactions, conduct surveillance investigation ● Follow-up the vaccinee/s for any adverse reaction/s at home
Supervisors and Monitors	Supervisors ● Supervise and oversee the vaccination activity ● Address concerns and coordinate accordingly ● Ensure timely submission of reports Monitors ● Monitor and evaluate the quality of vaccination implementation ● Provide feedback to VOCs
a. Vaccination Team Supervisor	● Visit Vaccination Teams at least once a day for supportive supervision using the Supervision Checklist ● Compile vaccination team reports, analyze them and report to higher level ● Review team performance and undertake corrective actions if needed
b. Implementing Unit Level Supervisor	● Visit Vaccination Teams with Team Supervisors, at least once a day for supportive supervision using the Supervision Checklist ● Compile and review vaccination team reports, analyze them and report to higher level ● Review team performance and undertake corrective actions if needed

	● Communicate daily with Coordination team in the VOC
c. LGU Level Supervisor	● Visit implementing units 1-2 weeks prior to the campaign to monitor progress in preparedness. ● Support training and microplanning activities ● Review submitted reports, compile and analyze health center level data
d. Monitors and Independent Monitors	● Visit vaccination sites and complete monitoring forms ● Monitor the vaccination implementation and ensure that it is based on the guidelines set by DOH ● Participate in meetings of the coordination team ● Assist in troubleshooting, as needed

The following are the pertinent operational guidelines on the vaccination workforce:

a. The Local VOCs and City/Municipal Health Officers shall be responsible in mapping and identifying the vaccination workforce and in assigning them to vaccination sites/posts, in coordination with the implementing units.
b. One vaccination team shall be complemented with at least one AEFI/AESI composite team.
c. In minimum, three (3) or more vaccination teams and three (3) or more AEFI/AESI composite teams shall be assigned in a vaccination post/site.
d. Each vaccination team shall have a target of 100 vaccinees per day.
e. A supervisor shall oversee at least 3 vaccination teams and 3 AEFI/AESI composite teams.
f. At least one (1) Safety Officer is designated for every vaccination post. He/She shall ensure that minimum health standards are implemented and observed at all times.
g. The LGUs shall develop a contingency plan to ensure availability of sufficient number of vaccination workforce available considering the following:
    i. Human resource assigned for the COVID-19 pandemic response shall NOT be utilized as part of the vaccination workforce.
    ii. Possibility of COVID-19 infection among the vaccination workforce.
    iii. Services offered in health facilities shall not be hampered because of the vaccination campaign. If so, disruption must be kept to a minimum.
    iv. Possibility of vaccinated health workers experiencing adverse reaction, either mild or severe, after vaccination.

The Implementing Units and Vaccination Sites/Posts

A permanent fixed-post vaccination strategy shall be used in the conduct of the COVDI-19 vaccination campaign. As defined in the National Immunization Program, permanent fixed-posts are posts located at health facilities where there is sufficient capacity and equipment to immediately respond and refer AEFI/AESI cases, and where sufficient health human resources are available.

Therefore, the following shall be utilized as implementing units:

a. Medical centers, hospitals and infirmaries (private and public)
b. Rural Health Units
c. Health facilities of other government agencies (e.g. AFP hospitals and facilities, BJMP/BuCor health facilities, and DepEd clinics)
d. Private clinics

The LGUs shall ensure that all implementing units, including private health facilities, adhere to the protocols required for an implementing unit / vaccination posts/sites. No implementing unit shall be allowed to conduct vaccination activity without compliance to the protocols required of a vaccination post.

4. Human Resource Management and Training

Introduction of a new vaccine requires training activities on components of the National Deployment and Vaccination Plan and compliance with vaccine administration standards. These activities should be geared to personnel at all levels participating in the vaccination program.

The national training plan shall target:

- National and departmental coordinators of areas directly or indirectly related to vaccine introduction (e.g., information system, communication, cold chain, surveillance, etc), who will facilitate the vaccination processes at the district/municipality and local levels.
- Vaccination workforce who will directly or indirectly conduct the vaccination

Training in specific components of the plan should include participation by representatives of the scientific community, social security, and other relevant departments to standardize knowledge regarding the use of the new vaccine.

The COVID-19 Vaccine Deployment and Vaccination Program will be delivered by skilled and trained staff working in a variety of delivery locations. All staff working in the program will receive training relevant to their role in the team and service.

Training programs will be delivered through blended learning: on-line, and when required, in person. In addition to the specialist clinical training required for vaccinator staff, induction and orientation training will be provided for all staff working in implementing units.

Training Curriculum

In keeping with the guidance provided for the introduction of new vaccines, a training package is developed by DOH, together with WHO and Unicef. The training package will include a presentation slide deck and instructional job aids. The training will cover a total of nine (9) main topics including 1) Microplanning, 2) Masterlisting and Data Management, 3) Logistics and Cold Chain Management, 4) Risk Communication and Social Mobilization, 5) Addressing the

Psychological Barriers to COVID-19 Vaccination, 6) Vaccine Administration, 7) Vaccine Safety, Surveillance and Response, and 8) Waste Management and Reverse Logistics and a module on 9) Training Skills and managing virtual training that shall capacitate trainers on the use of technology and virtual platforms not only for training activities but also online/ virtual activities. During the training, a review of the Standard Operating Procedures will be conducted.

Training Execution

Vaccination experts from the WHO, United Nations Children's Fund (UNICEF) and the DOH will provide the initial training and post-training support for the Core of Trainers. The DOH trainers will in turn conduct cluster-based Training of Trainers (TOT) for the 5 identified clusters: North Luzon, South Luzon, Visayas, North Mindanao and South Mindanao who in turn will organize regional training teams. The regional training teams will be responsible for training vaccinators from the local implementing units. These teams will also be responsible for post-training supervision of the vaccinators. Relevant implementing partners will also be leveraged to provide training support where necessary. The table details the roles and responsibilities of the training teams at the different levels of the government.

Table 28: Roles and responsibilities of the training teams.

Level of Training Team	Roles and Responsibilities
WHO, UNICEF and DOH vaccination experts and trainers	• Develop/ Co-Develop the training materials • Conduct the initial ToT for the Core Trainers • Provide post training support to the Core trainers
DOH Cluster trainers	• Identify regional training teams Conduct TOT for the regional training teams • Work with the regional training teams to develop regional training plans • Provide oversight for the cascading of the trainings within each region • Monitor the standards of and the implementation of training for the local implementing units. • Conduct monitoring and evaluation of the training activities
Regional training teams	• Conduct training needs assessment • Develop regional training plan • Conduct trainings for the local implementing units • Conduct post training supportive supervision, observation and mentoring for the local implementing units • Implement quality improvement as needed based on gaps identified during the post training support activities

The following dates of training are:

Table 29. Training schedule.

Dates of Training	Training	Training Participants
December 29-30, 2020	Core of Trainer's Training	Designated DOH Core Trainers from DOH central office Designated trainers from: ● DOH Centers for Health Development Metro Manila ● Medical staff from other national government implementing agencies (DILG (BFP, PNP, BJMP), DSWD, DepEd, DND (AFP), DOJ (BuCor), DOTr (PCG))
January 12-13, 2021	NCR and Luzon Training	Designated trainers from: ● DOH Centers for Health Development ● Selected government and private hospitals ● Provincial Health Officers ● Medical staff from other national government implementing agencies (DILG (BFP, PNP, BJMP), DSWD, DepEd, DND (AFP), DOJ (BuCor), DOTr (PCG))
January 14-15, 2021	Visayas and Mindanao Training	
January 20-21, 2021	BARMM Training	
January 22-31, 2021	Training of Implementing Units	● Provincial and local health units ● Remaining hospitals and other health facilities

Post-training supportive supervision

After training of the trainers, the DOH Core Trainers shall continue to support the trainers through post-training supporting supervision or coaching/mentoring sessions. Since this is a new vaccine and vaccination program, a more hands-on approach shall be implied. A training kit was created which contains the different training materials and updates about the program. The DOH core trainers assigned to 5 Clusters (N. Luzon, S. Luzon, Visayas, N. Mindanao and S. Mindanao) shall assist the trainers in their training activities and will look into the following areas:

1. Use of updated and standard training reference materials.
2. Planning and conduct of training.
3. Capacitating the target number of vaccinators and composite teams.
4. Readily addressing issues and concerns of the trainees
5. Continuous coordination with different implementing agencies and institutions.
6. Ensuring that the different implementing agencies are capacitated on the COVID-19 Immunization Program Implementation.

They shall virtually monitor and address issues and concerns encountered. Field monitoring may be conducted as necessary. The post training supervision and monitoring shall be conducted alongside with the DOH regional trainers and partner implementing agency focal persons.

5. COVID-19 Vaccine and Cold Chain Capacity Inventory and Logistics Management

The purpose of the vaccine "cold chain" is to maintain product quality from the time of manufacture until the point of administration by ensuring that vaccines are stored and transported within the recommended temperature ranges. Vaccine potency, meaning its ability to adequately protect the vaccinated patient, can diminish when the vaccine is exposed to inappropriate temperatures. Once lost, vaccine potency cannot be regained. It is essential that all those who handle vaccines and diluents know the temperature sensitivities and the recommended storage temperatures for all the vaccines.

In the pre-implementation phase, in order to maintain a reliable vaccine cold chain and logistics management at the LGU level, the following key procedures shall be observed:

a. Receive vaccines logistics requirement for the vaccination campaign.
b. Count ALL vaccines and logistics (syringes, SCBs, re-sealable plastic, among others) received to ensure NO short shipment.
c. Check the vaccine label and ensure that it is intact.
d. Store vaccines and diluents within the required temperature ranges at all sites/levels. Keep vaccines in appropriate vaccine refrigeration equipment. Keep all COVID-19 vaccine vials together in the same cold chain equipment at all times.
e. Label storage equipment containing COVID-19 vaccines properly.
f. Use a temperature monitoring device to ensure temperatures remain according to the recommended temperature.
g. Pack and transport vaccines to and from implementing units according to recommended procedure. Transport vaccines to immunization sessions in a vaccine carrier, correctly packed using coolant packs that have been properly prepared.
h. Keep vaccines and diluents within recommended cold chain conditions during vaccination sessions. During the vaccination sessions, fit a foam pad (if available) at the top of the vaccine carrier.

The LGU and in implementing units, one person shall be in-charge of logistics and cold chain management. An alternate shall also be identified to take over if the in-charge is absent. Their responsibilities shall include:

a. Checking and recording vaccine temperatures twice daily; in the morning and at the end of the session or day.
b. Properly storing vaccines, diluents and ice packs.

c. Handling preventative maintenance of the cold chain equipment.

6. Preparation of Vaccination Sites/Posts

A few weeks or days prior to the conduct of the vaccination activity, the LGUs and implementing units shall ensure that all vaccination posts/sites are prepared and fully equipped.

The vaccination post/site shall comply with the minimum health standards and shall have sufficient equipment for disinfection and sanitation. The dimension of the vaccination site/post shall be taken into consideration possible crowding in the post-vaccination area. It is recommended that implementing units shall utilize rooms of the health facilities for the vaccination activity, such as conference rooms, auditoriums, theaters, health facility gymnasiums, among others. If these types of facilities are not available, the implementing units can put up tents or temporary buildings within the vicinity of the implementing unit, such as in facility grounds, parking lots, and open spaces, among others.

The vaccination post/site shall have the following areas (as shown in Figure x):

1. Waiting Area. The waiting area shall be prepared for vaccinees waiting for their vaccination turn.
2. Vaccination Area: The vaccination area shall have at least three (3) vaccination teams and three (3) AEFI/AESI composite teams. Each area shall have several sanitation areas for each vaccination team. The following areas, arranged in sequential order, shall be set in placed:
    a. Registration Area: An area where the vaccinee's information and documents are checked and submitted. Each vaccination team shall have their respective areas in the registration area. Equipment needed to scan the QR code should be available in this area.
    b. Health Education Area. There shall be one health education area for the whole vaccination site/post. In this area, IEC materials, such as pamphlets, leaflets and brochures shall be made available. Also, a projector or a TV shall be set up in this area, or the least, a flipchart, for health education purposes.
    c. Screening Area. Since the screening procedure may take longer compared with other areas, it is advised that at least two screening stations per team shall be set up. Equipment needed to scan the QR code should be available in this area.
    d. Vaccination Area. Each vaccinator shall have his/her own area. The vaccination area should have an accessible cold chain equipment to store the vaccines in the vaccination post/site.
3. Post-vaccination Monitoring Area. Since the observation of vaccinees post-vaccination will take 30 minutes to one hour, it is expected that there might be pooling or crowding of vaccinees in this area. Thus, this area must be spacious enough to accommodate all vaccinees and to allow observance of physical distancing measures. In addition, equipment needed for AEFI response must be available and accessible.

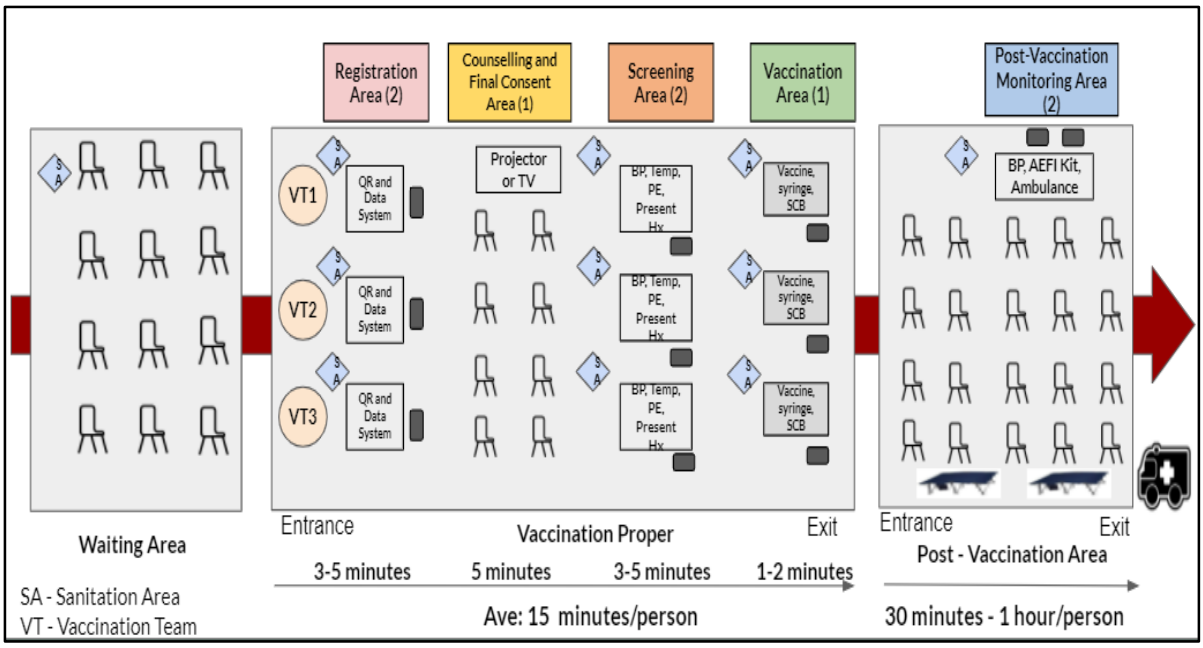


Figure 12. Vaccination site/post lay-out.

The following equipment is needed in the vaccination site/post.

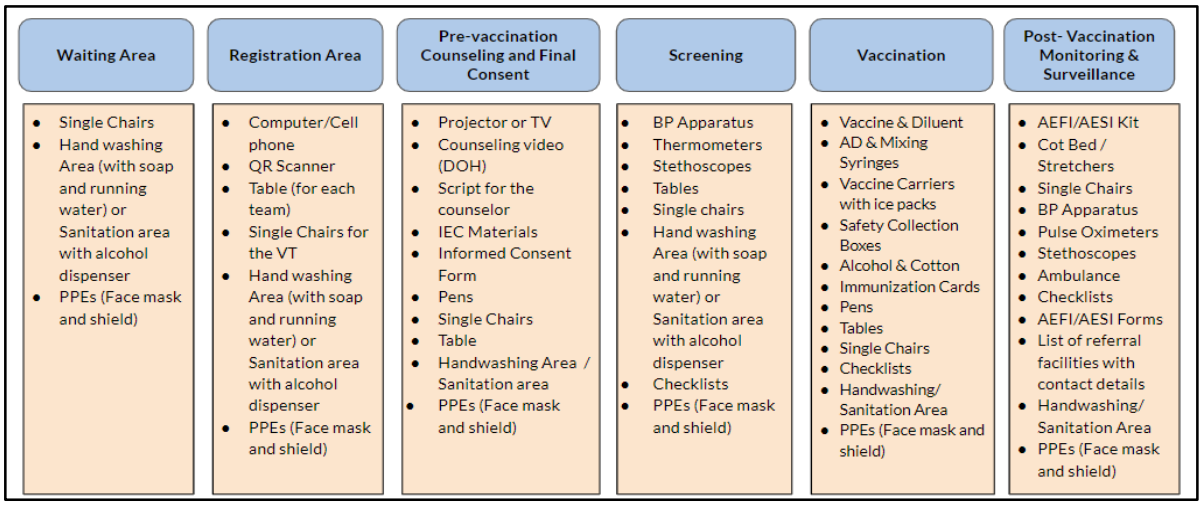


Figure 13. Equipment required in the vaccination site/post.

Implementation Phase

Mobilizing the eligible recipients

During the vaccination activity, eligible recipients who have successfully registered for vaccination shall proceed to the assigned vaccination posts/sites based on the schedule provided or they may be fetched from assigned pick-up points through previously arranged transport mechanisms. BHWs, local officials and other personnel may also do house-to-house visits to mobilize eligible recipients who have successfully registered for the vaccination, so that they can proceed to the assigned vaccination site (see Figure 12).

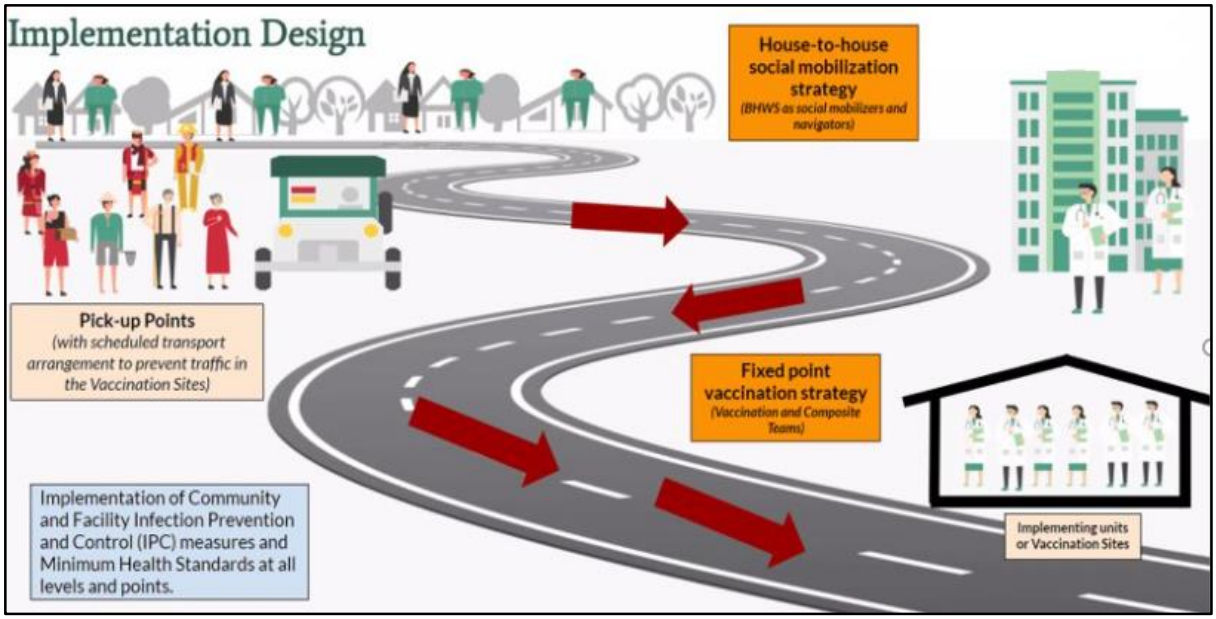


Figure 14. Illustration of the mobilization of eligible recipients for the actual COVID-19 vaccination.

Intra-campaign Vaccine Cold Chain and Logistics Management

Daily during the vaccination campaign round, the preparation of vaccines and logistics is a very important activity to be undertaken by the LGU/health facility supervisor and cold chain manager.

The following steps shall be undertaken every vaccination day:

1. Before every vaccination activity, prepare the vaccine carriers and the ice packs.
2. In each vaccine carrier, arrange the frozen ice packs exactly as recommended on the manufacturer's instruction on the inside of the lid. Do not cover the frozen ice packs in paper.
3. Prepare re-sealable plastic bags and an extra one for opened/used vials (after the vaccination day).
4. Place 20 vaccine vials in one re-sealable plastic bag. The number of vaccines to be used per vaccination team shall be determined prior to the activity.
5. Put the resealable plastic with the vaccines in the middle of the vaccine carrier to protect them from damage due to condensation.
6. Daily issuances of vaccines should be recorded in the distribution and collection form acknowledged by the vaccination team leader / supervisor.
7. At the end of each vaccination day, all vials (unopened, fully or partially used) shall be placed in resealable plastic bags and returned to the same health facility where they received the vaccines in the morning. The facility supervisor shall record the vials received at the end of each vaccination day.
8. Health facilities / vaccination distribution points must then keep the unopened usable vials in the cold chain. The vaccines can be used for the next day.

9. All opened or unusable vials contained in resealable plastic by twenties (20s) must be kept in a sack and be picked up by the CHD at the end of the vaccination round for disposal.

Table 30. The vaccine distribution and collection form.

Vaccine Distribution and Collection Form

Region:_____ Province:_____ Municipality:_____ Date (mm/dd/yyyy):_____

Name of VT/Barangay/ City/ Municipality/ Province	Target	Number Immunized	Vaccine Distribution								Name of Vaccinator	Contact Number	Signature
			Vaccine Issued		Additional Vaccine Issued		Total Vaccine Received (in Vials)	Empty / opened vials	Unopened vial returend (in Vials)	Total (in Vials)			
			Quantity (in Vials)	Lot/ Batch No.	Quantity (in Vials)	Lot/ Batch No.							

Vaccination Administration

Prior to the vaccination, the vaccinee will be provided with a vaccination date and time schedule, and an immunization card with a QR code, which he/she will bring to the vaccination post, to ensure smooth implementation of the vaccination activity and avoid congestion in the vaccination site/post. No walk-in vaccination shall be accommodated since vaccines allocated for the day are sufficiently allocated for the projected number of vaccinations to be conducted in a day. However, a walk-in eligible recipient shall be scheduled and provided with an immunization card with a QR code immediately, and advised accordingly.

Upon arrival at the vaccination site/post, the vaccinee shall wait for his/her turn in the waiting area. Upon entry in the waiting area, the vaccinee's temperature will be checked. The Safety Officer shall ensure that physical distancing measures shall be implemented at all times at the waiting area.

Each vaccinee shall be assigned to a specific vaccination team. When his/her turn arrives, he/she will proceed to the vaccination area, and in a stepwise approach, he/she will proceed from the registration area, health education area, screening area and lastly, to the vaccination area.

At the registration area, the vaccinee shall present his/her immunization card with QR code and shall be scanned. The profile of the vaccinee shall be retrieved in the computer system and the vaccinee's identity shall be verified by presenting his/her government ID (eg. driver's license, PRC license, PhilHealth ID, UMID, Passport, etc). Other relevant documents shall be presented at the registration.

The vaccinee shall then be directed to the Health Education Area where health educators shall present IEC materials and answer any question the vaccinee may have regarding the COVID-19

vaccine. Once all questions are answered, the vaccinee shall be asked to sign the Final Consent form.

At the Screening Area, the personnel assigned shall scan the patient's QR code and conduct history-taking and physical examination to ensure the eligibility of the vaccinee. Using both the CEIR and screening form hard copy, the health worker shall update the vaccinee's profile and determine whether or not he/she is qualified to receive the vaccination.

The vaccinee shall then be directed to the Vaccination Area where the vaccine shall be administered. Once vaccinated, the QR code shall be scanned and the vaccination details (e.g. date of vaccination, vaccine manufacturer, batch number, lot number, name of vaccinator and signature) shall be recorded in the CEIR and immunization card.

After vaccination, the vaccinee shall be observed for adverse reactions for 30 minutes to one hour at the post-vaccination monitoring area. The post-vaccination monitoring area must be closely linked with an identified referral health facility. After an hour, once cleared, the vaccinee shall be provided with instructions about the possible adverse reaction that the vaccinee might experience and the location of facilities where he/she can proceed should he/she experience adverse reactions.

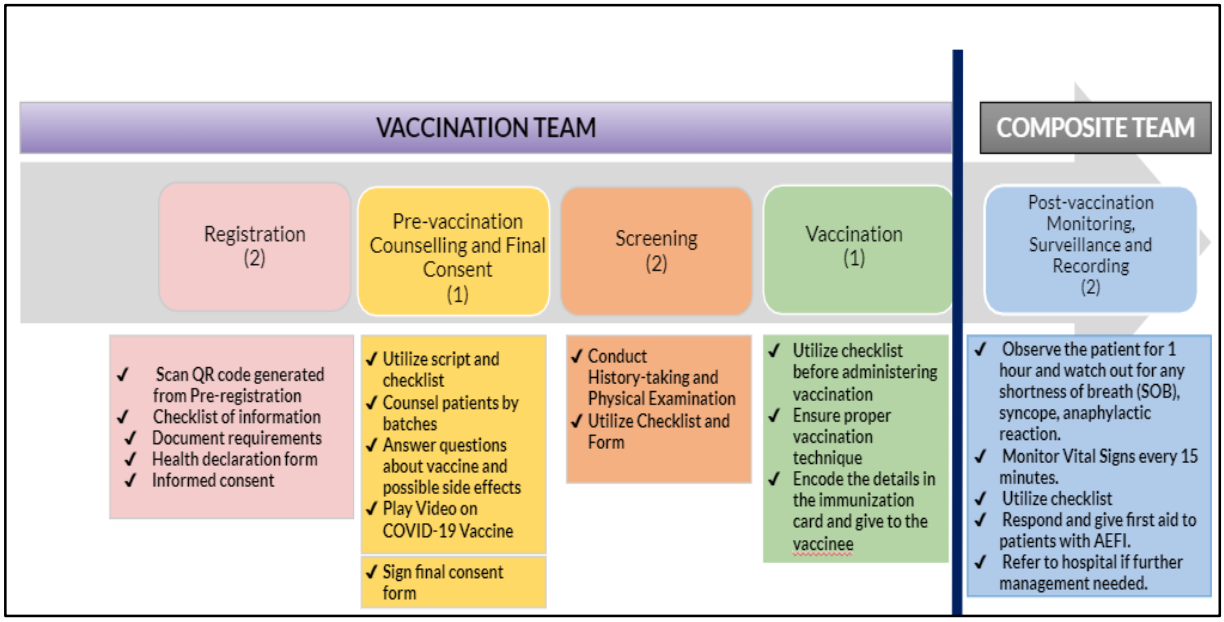


Figure 15. The vaccine administration flow.

A checklist detailing the steps to be followed by the vaccination and AEFI/AESI composite teams shall be placed in each designated area. In the vaccination area, a specific checklist for each type of vaccine shall be provided. As of January 18, 2021, information on vaccine administration of Pfizer and Moderna vaccines are available. In the checklist, the following steps are detailed:

Registration Area:

1. Ask the vaccinee to sanitize hands and get his/her temperature.
2. Scan QR Code or Register ID number.
3. Verify the vaccinee's identity with any government-issued ID (contains photo, birthday, signature) or passport.

4. Remind the vaccinee to follow the minimum health standards within the vicinity.
5. Direct the vaccinee to the Health Education and Final Consent Area.

Health Education and Final Consent Area:

1. Group the vaccinees (even those from other teams) to at least 6-12 individuals.
2. Play a DOH Explainer Video to the Group.
3. Encourage the vaccinee to ask questions and clarifications and address issues that he/she may have.
4. Explain to and educate vaccinee on COVID-19 Vaccine - what it is, how it protects, administration and possible side effects.
5. Explain to the vaccinee that he or she may opt to receive the 2nd dose from another facility provided that the 2nd dose is the same brand as the 1st dose.
6. Instruct patient on post-vaccination care:
    a. Put ice pack / ice on the injection site for 15 minutes 3x a day, in the first 24 hours after vaccination. Report any AEFI to the clinic/hospital.
    b. For any serious AEFI, proceed immediately to the nearest Emergency Room.
7. Provide educational materials (pamphlets with FAQs) at suitable reading levels to the vaccinee and available in vaccinee's local language.
8. Provide Vaccine Information Statements (VIS) or Emergency Use Authorization (EUA) forms, if required.
9. Ask vaccinee to sign the **Final Consent Form.**
10. Direct the patient to the Screening Area.

Screening Area:

1. Scan QR Code
2. Conduct history-taking
    - ❑ Focus on the present history *(past history and co-morbidities are gathered during pre-registration and profiling)*
    a. Is the vaccinee currently experiencing the ff symptoms or have experienced the ff in the past 14 days?
        - ❑ Fever
        - ❑ Headache
        - ❑ Cough
        - ❑ Colds
        - ❑ Sore throat
        - ❑ Shortness of breath or Difficulty in breathing
        - ❑ Chest pain
        - ❑ Abdominal pain

- ❑ Changes in bowel movement
- ❑ Loss of taste/smell
- ❑ Fatigue/weakness
- ❑ Others: _____

b. Is the vaccinee on any blood thinner or any medication that affects the immune system?
c. Has the vaccinee received any vaccination in the past 4 weeks?
d. Has the vaccinee experienced any serious reaction after receiving a vaccine?
e. Has the vaccinee previously received a COVID-19 Vaccine?
If yes, specify: _____
f. For women: Is the vaccinee pregnant/ breastfeeding or is there a chance she could become pregnant during the next month?

3. **Conduct Physical Examination**
   a. Take the Vital Signs
      - ❑ Heart rate: _____ beats/min (N: 60-100 bpm)
      - ❑ Respiratory rate: _____ breaths/min (N: 12-20 bpm)
      - ❑ Blood pressure: _____ (N: < 120/80)
      - ❑ Oxygen saturation: _____ % (N: 95-100%)
   b. Perform Cardiovascular Examination
      - ❑ Normal rate and rhythm
      - ❑ (+) Murmurs
      - ❑ (+) Irregular heart rate and rhythm
   c. Perform Respiratory Examination
      - ❑ Clear lung fields
      - ❑ Adventitious breath sounds, specify: _____

Vaccination Area (Pfizer Vaccine):

Prepare the Vaccine

1. Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*
2. Remove vaccine from the freezer or refrigerator. Allow vaccine to come to room temperature. Vials can be held at room temperature for up to 2 hours before mixing. After 2 hours return unmixed vials to the refrigerator.
3. Before mixing, check the expiration dates of the vaccine and diluent. **NEVER use expired vaccines or diluent.**
4. With the vaccine at room temperature, **gently invert the vial 10 times**. **Do not shake the vial.** If the vial is shaken, discard the vaccine. The vaccine is a white to off-white in color and may contain opaque particles. **Do not use it if liquid is discolored.**

5. Using a new, sterile alcohol prep pad for each vial, wipe off the stoppers of the diluent and vaccine vials.
6. Using a 21-gauge (or narrower) needle, withdraw 1.8 mL of 0.9% sodium chloride (normal saline, preservative- free) into a mixing syringe. After use, discard diluent vial and remaining diluent.
7. **Do NOT use bacteriostatic normal saline or other diluents to mix the vaccine.**
8. Inject 1.8 mL 0.9% sodium chloride (normal saline, preservative-free) diluent into the vaccine vial.
9. Using the mixing syringe, remove 1.8 mL of air from the vaccine vial to equalize the pressure in the vaccine vial.
10. **Gently invert the vial containing vaccine and diluent 10 times.** The vaccine will be off-white in color. Do not use if discolored or contains particulate matter. Do not shake. If the vial is shaken, discard the vaccine.
11. Note the date and time the vaccine was mixed on the vial.
12. Keep mixed vaccine at room temperature (2^0C to 25^0C [36^0F to 77^0F]) and administer within 6 hours. Discard any unused vaccine after 6 hours. Do not return to refrigerator or freezer storage.

Administer the Vaccine

1. Scan the QR Code and verify the patient's identity (e.g. name and birthday).
2. Perform hand hygiene and aseptic technique.
3. Ensure staff has the correct PPE before administering vaccines.
4. Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.
5. Cleanse the stopper on the vial of mixed vaccine with a new, sterile alcohol prep pad. Withdraw 0.3 mL of mixed vaccine into the syringe. Ensure the prepared syringe is not cold to the touch.
6. Remove any air bubbles with the needle still in the vial to avoid loss of vaccine. Use the same needle* to withdraw and administer the vaccine, unless contaminated or damaged.
7. Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.
8. Update the vaccinee profile system with: date of vaccination, COVID vaccine manufacturer, batch number, lot number, name of vaccinator.
9. Fill up the patient's immunization card with vaccinee's date of vaccination, COVID vaccine manufacturer, batch number, lot number, name of vaccinator.
10. Direct patient to Post-vaccination Monitoring Area.

Vaccination Area (Moderna Vaccine):

1. Scan the QR Code and verify the patient's identity (e.g. name and birthday).
2. Perform hand hygiene and aseptic technique.

3. Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product related particulates. During the visual inspection,
    - Verify the final dosing volume of 0.5 mL.
    - Confirm there are no other particulates and that no discoloration is observed.
    - **Do not administer if the vaccine is discolored or contains other particulate matter.**
4. Administer the Moderna COVID-19 Vaccine intramuscularly.
5. Update the vaccinee profile system with: date of vaccination, COVID vaccine manufacturer, batch number, lot number, name of vaccinator.
6. Fill up the patient's immunization card with vaccinee's date of vaccination, COVID vaccine manufacturer, batch number, lot number, name of vaccinator.
7. Direct patient to Monitoring Area.

Post-Vaccination Monitoring Area:

1. Monitor and record patient's vital signs every 15 minutes for 30 minutes to one hour post-vaccination.
2. Play DOH videos and provide information to the vaccinee during the observation period.
    a. Instruct the vaccinee on possible adverse reactions and when, how, and where to report if he/she manifest signs and symptoms.
    b. Provide information on post-marketing surveillance.
3. Observe the patient and watch out for any symptoms of shortness of breath, syncope and anaphylactic reaction, or any reaction as stipulated by the manufacturer.
4. Respond and give first aid to vaccinee for possible AEFI/AESI.
5. Refer vaccinee to hospital for further management needed.

Infection Prevention and Control (IPC), Injection Safety, Management of Health Care Waste and Reverse Logistics

All throughout the implementation phase, infection prevention and control measures must be practiced. Table 32 shows minimum standards for IPC that must be practiced during the vaccination.

Table 31. Minimum infection prevention and control measures during COVID-19 vaccine administration

Aspect of vaccine administration	Minimum IPC measures
Vaccination post	• Open or well-ventilated areas • Frequently disinfected areas

	● Spacious enough to implement physical distancing, crowd control measures ● Limit number of vaccinees within the vaccination area to <24 individuals at a given time.
Vaccination Team and Composite Team, and other personnel in the vaccination site	● Wear face mask and face shield ● Practice hand hygiene before and after procedure/vaccine ● Limit contact between vaccinator and vaccinee to less than 15 minutes ● Daily self-monitoring for COVID-19 symptoms ● Log-in upon entering and exiting a vaccination area on a daily basis
Vaccinees	● Wear face mask and face shield ● Frequently practice hand hygiene ● Abide to physical distancing guidelines

Injection Safety

In addition to the IPC measures, injection safety must also be ensured during the vaccination. Injection safety is the safe handling of all injection equipment, routine monitoring of the availability and use of safe injection equipment and correct disposal of contaminated injection equipment.

The following injection safety guidelines shall be implemented:

1. Follow proper infection control practices and maintain aseptic technique during the preparation and administration of vaccines (e.g., perform hand hygiene).
2. Never administer vaccines from the same syringe to more than one patient, even if the needle is changed.
3. Never enter a vial with a used syringe or needle.
4. Do not use vaccines packaged as single-dose or single-use for more than one patient.
5. After use, immediately put syringes and needles in a puncture-proof sharps container.
6. Close safety boxes when they are ¾ full and lock boxes in a secure area.
7. Know how syringes are stored and destroyed at your facility.

Disposal of Immunization Wastes

Wastes generated at the health care facilities after vaccination may pose harm and risks to the health care workers and communities if not properly managed. Health Care Waste Management (HCWM) is a process that helps in ensuring the proper management of health care waste from the point of generation until disposal.

Department of Environment and Natural Resources (DENR) AO 2013-22 categorized health care waste under the following subclassifications of miscellaneous wastes (Class M):

- Pathological or Infectious Waste (Waste No. M501)
- Pharmaceuticals and Drugs (Waste No. M503)

Understanding the health care waste management system, in general, requires proper planning and implementation of managing wastes generated in the nationwide COVID-19 vaccination, considering the complexity of the nature of the vaccines. Proper handling, storage, collection and disposal of the wastes shall be followed to ensure protection of the environment and the general public.

The health care facility or implementing unit shall identify personnel as part of the COVID-19 Vaccine Waste Team. The existing HCWM Committee of the health facility may also serve as the Team. The Team shall develop a COVID-19 Waste Vaccination Plan and implement the said plan. The plan shall include activities, resources needed, including budget, responsible person/s or unit/s, and timelines. The Team shall be responsible that the vaccinators follow the guidelines on the proper segregation or sorting, handling and disposal of the waste. The Team shall ensure that all collected wastes in the temporary storage areas of the HCF are properly collected and disposed either on-site or offsite.

The COVID-19 vaccination may generate the following types of waste:

1. Hazardous wastes: these include the contaminated sharps such as syringes and needles, infectious empty vials, and blood soiled cotton
2. Non-hazardous wastes: the plastic wrapper, paper and cotton.

Guidelines on waste segregation and management are as follows:

1. Proper segregation of the waste at source or onsite shall be strictly followed.
2. Sharps such as syringes and needles shall be placed in a safety collection box for temporary storage onsite and fill with chemical disinfectant when ¾ full.
3. Empty vaccine vials and used syringe barrels shall be considered infectious. The wastes shall be placed in a separate waste bin lined with yellow plastic bad and with cover.
4. Both bins and plastic liners shall be preferably of the same color for the type of waste intended to be placed. This is to avoid confusion and poor segregation.
5. The recommended thickness of the plastic liners is 0.07 mm (ISO 7765 2004). Plastics used for either containers or bags should be chlorine-free. Not all plastic bags can withstand temperatures of 121ºC, and some can melt during an autoclave process.
6. Proper tagging of plastic liners before placing on the waste bin is to be strictly implemented. The tag of the plastic liner shall indicate the following: a) name of the health care facility or implementing unit; b) area of the health care facility or implementing unit where the waste was generated (or the source); c) type of waste and the weight and date of collection on-site, or date and time of closure of the container; and d) name of the person filling out the label.

7. Containers should be large enough for the quantity of waste generated at that location during the period between collections;
8. All filled waste containers shall be collected only by designated staff and brought to the temporary storage area of the health care facility or implementing unit. The collected plastic container shall be tied tightly.
9. All non-hazardous wastes shall be placed in separate waste bins together with the general waste.

Guidelines on waste collection and transport are as follows:

1. The collection and transport practices shall be designed to achieve an efficient movement of waste from point of generation to storage or treatment while minimizing the risk to the personnel.
2. The general service personnel shall be assigned for the collection of wastes from the waste bins going to the on-site storage area of the health care facility or implementing unit.
3. Infectious and general waste should be collected daily (or as frequently as required).
4. Waste bags should be filled to no more than three-quarters full. Once this level is reached, they should be sealed ready for collection. Plastic bags should never be stapled but may be tied or sealed with a plastic tag or tie.
5. Sharp containers should be collected when three-quarters full.
6. Upon waste collection, the personnel must ensure that the waste bags and containers are properly labeled.
7. Replacement bags or containers should be available at each waste collection location so that full ones can immediately be replaced.
8. Transport of the collected waste must be done using wheeled trolleys/carts or wheeled bins.
9. Hazardous and non-hazardous waste should always be transported separately.
10. Infectious waste can be transported together with used sharps wastes.
11. The trolleys shall be disinfected after every use.
    a. Can be cleaned and disinfected daily using 4-5% concentration of sodium hypochlorite (NaClO).

Guidelines on central storage are as follows:

1. All collected and transported waste materials shall be stored in the designated central storage area of the health care facility.
    a. There shall be separate storage area for hazardous and non-hazardous wastes.
2. Hazardous waste should always be stored in enclosed rooms.
3. The storage place must be identified as an infectious waste area by using the biohazard sign.

Guidelines on treatment and disposal systems. The following options for treatment and disposal of all hazardous waste during vaccination may be applied:

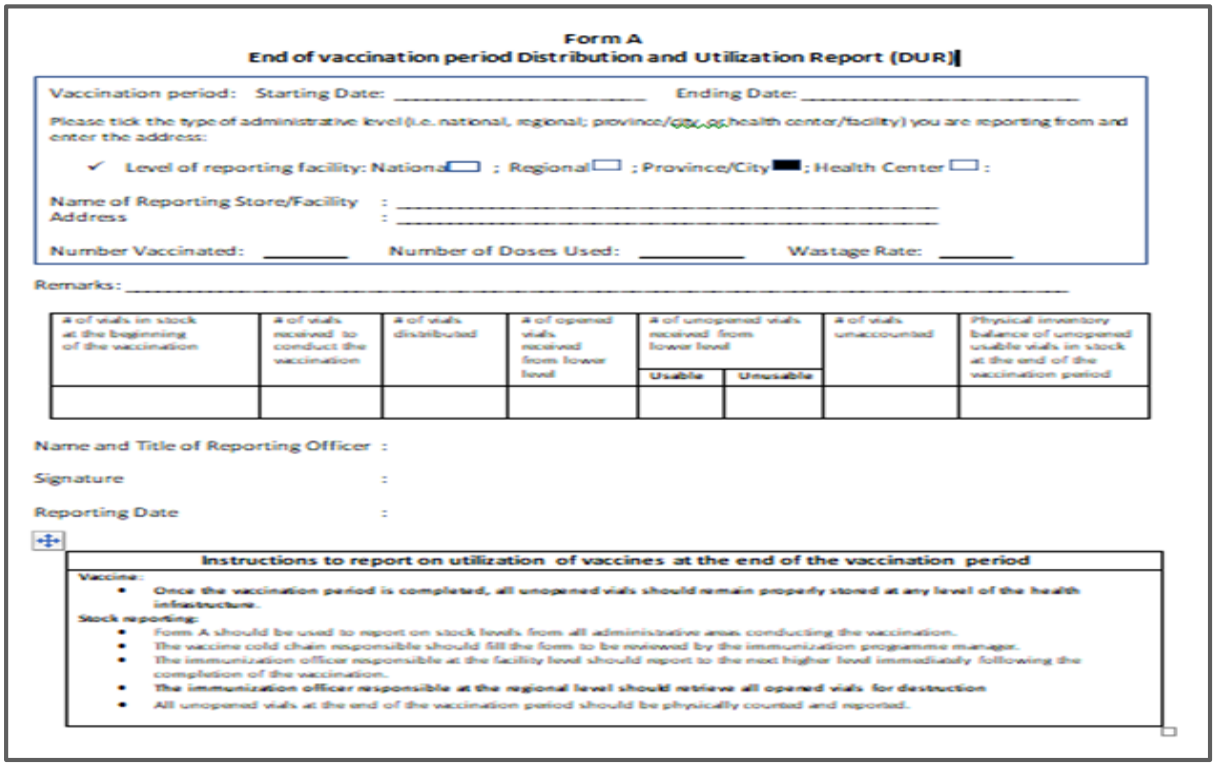
a. Onsite system. The health care facilities or implementing units may construct concrete vault within its premises to serve as the final disposal for the syringes and vials. The vault must be constructed of concrete walls and slabs with a minimum size of 1m X 1m X 1.8m.
b. Offsite system. The health care facilities or implementing units may avail the service of a DENR-accredited waste transporter to transport all the hazardous waste generated during the vaccination to the final treatment and disposal facility.

Lastly, the estimated volume or amount of waste generated particularly the hazardous waste must be recorded.

Reverse Logistics

The following are reverse logistics guidelines:

1. Empty and unopened vials should be returned daily by the Vaccination Team to the implementing unit or RHU/CHO for consolidation.
2. At the end of each vaccination period, accounted empty/opened vials should be kept in a safe and secured place in the health facility.
3. Unopened usable vials should remain stored at required temperature.
4. Properly accomplish Form A to await pick up by the CHD for destruction.



Form A
End of vaccination period Distribution and Utilization Report (DUR)

Vaccination period: Starting Date: _____ Ending Date: _____

Please tick the type of administrative level (i.e. national, regional; province/city; health center/facility) you are reporting from and enter the address:

✓ Level of reporting facility: National ☐ ; Regional ☐ ; Province/City ■ ; Health Center ☐ :

Name of Reporting Store/Facility : _____
Address : _____

Number Vaccinated: _____ Number of Doses Used: _____ Wastage Rate: _____

Remarks: _____

# of vials in stock at the beginning of the vaccination	# of vials received to conduct the vaccination	# of vials distributed	# of opened vials received from lower level	# of unopened vials received from lower level		# of vials unaccounted	Physical inventory balance of unopened usable vials in stock at the end of the vaccination period
				Usable	Unusable		

Name and Title of Reporting Officer :

Signature :

Reporting Date :

Instructions to report on utilization of vaccines at the end of the vaccination period

Vaccine:
- Once the vaccination period is completed, all unopened vials should remain properly stored at any level of the health infrastructure.

Stock reporting:
- Form A should be used to report on stock levels from all administrative area conducting the vaccination.
- The vaccine cold chain responsible should fill the form to be reviewed by the immunization programme manager.
- The immunization officer responsible at the facility level should report to the next higher level immediately following the completion of the vaccination.
- **The immunization officer responsible at the regional level should retrieve all opened vials for destruction**
- All unopened vials at the end of the vaccination period should be physically counted and reported.

Figure 16. Form A: End of vaccination period distribution and utilization report.

Computation and Terms

1. Calculate vaccine wastage rate: (number of vaccine doses used - number of eligible population) / number of vaccine doses used x 100 = vaccine wastage rate (%)
2. "Vaccine doses used" includes doses used for immunization and all doses discarded or lost for any reason (including expiry, indication of heat exposure, missing inventory, cold chain failure, freezing or discarding of open vials of vaccine at the end of a session or campaign activity).
3. The wastage rate is the percentage of vaccine doses that are wasted - in other words, doses that are not used for immunization and are discarded or lost for any reason.

Retrieval of vials from the field

1. The vaccination team should return vials in re-sealable plastic bags (a maximum of 20 vials per resealable plastic bag).
2. Supervisors should count collected empty vials at the end of vaccination day.
3. Empty vial retrieved should be well accounted and documented.

Vials accountability

Unaccounted vials should be:

1. reported to the supervisor.
2. reason/s for the unaccountability should be stated.
3. investigated with the support of the LGUs.
4. Incident report should be prepared and endorsed by the following: NIP, RHU, LGUs and submitted to overseeing VOC.

Disposal of COVID-19 vaccine vials

These are the basic principles:

1. A detailed vial collection and destruction plan should be developed.
2. Destruction of the vials should be in accordance with national regulations.
3. Used/opened vials should be inactivated prior to destruction. The recommended methods are:
    a. Inactivation by autoclaving, boiling, chemical inactivation, encapsulation or incineration.
    b. Destruction and disposal by transporting to the waste facility or burying.

Chapter 7: Assessment, Evaluation and Monitoring

The post-implementation phase starts right after the first dose of vaccine is administered. This phase has two components: the AEFI surveillance and response, and pharmacovigilance.

Vaccine Safety Monitoring, and Management of Adverse Events Following Immunization

The role of vaccine safety monitoring during COVID-19 vaccine introduction is to facilitate the early detection, reporting, notification, investigation and analysis, and feedback of Adverse Events Following Immunization (AEFIs) and Adverse Events of Special Interest (AESI), to ensure appropriate and timely case management and response. These activities shall assist vaccinees and ensure them of prompt and timely response should an AEFI occur.
The AEFI surveillance entails:

- Timely detection of serious AEFIs/AESIs to provide up-to-date and accurate data that can be shared with relevant stakeholders for appropriate response;
- Generation of data to characterize the safety of the COVID-19 vaccines in use;
- Identification, investigation, assessment and validation of safety signals and recommendation of appropriate public health interventions or other interventions; and
- High quality safety surveillance and maintenance of public and stakeholder confidence in vaccines and immunization

The WHO defines *Adverse Event Following Immunization* (AEFI) as any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. If not rapidly and effectively dealt with, AEFIs can undermine confidence in a vaccine and ultimately have dramatic consequences for immunization coverage and disease incidence. Based on consultations with experts and the latest data from published clinical trials as of 16 January 2021, the following are the identified AEFI from various brands of COVID-19 vaccination and must be reported.

Table 32. List of Adverse Events Following COVID-19 Vaccination of Selected Candidate COVID-19 Vaccine.

Manufacturer	University of Oxford and Astrazeneca						BioNTech and Pfizer	NIAID and Moderna	Novavax		
Adverse Events*											
Age	18-55		56-69		>70+			>18			
									Mild	Moderate	Severe
Pain at injection site	75%	64%	63%	54%	34%	22%	84.1%	92.0%	45% 39%	0% 12.5%	0%
Redness	7%	11%	12%	12%	11%	11%	9.5%	10.0%	0%	0%	0%

Swelling	7%	7%	12%	12%	14%	14%	10.5%				14.7%	0%	0%	0%
Tenderness	87%	75%	83%	76%	64%	62%					19.8%	36% 45.8%	16% 29.2%	0% 4.2%
Warmth	27%	25%	22%	32%	27%	14%								
Itch	14%	25%	22%	18%	14%	11%								
Induration	7%	7%	12%	12%	11%	11%								
Feverish	58%	22%	27%	32%	22%	20%								
Fever	39%	7%	12%	12%	7%	7%	14.2%				15.5%	4.2%		
Chills	50%	27%	27%	27%	14%	7%	31.9%				45.4%			
Joint Pain	48%	17%	35%	36%	27%	20%	23.6%				46.4%	8.0%	4.2%	8.3%
Muscle Ache	67%	52%	56%	44%	32%	32%	38.3%				61.5%	24% 37.5%	8% 8.3%	- 8.3%
Fatigue	87%	69%	69%	61%	56%	48%	62.9%				70%	28% 25%	12% 16.7%	0% 8.3%
Headache	78%	45%	69%	54%	56%	34%	55.1%				64.7%	28% 41.7%	4% 16.7%	4% -
Nausea/ Vomiting	41%	20%	31%	40%	20%	17%	1.1%				23%	12.5%	4%	
Diarrhea							11.1%	10. 4%	8.2%	8.3%				
Need for antipyretic							27.8%	45. %	19.9%	37.7%				
Malaise	56%	43%	46%	27%	39%	25%	0.5%					20% 12.6%	8% 16.7%	0% 8.3%

Manufacturer	**University of Oxford and Astrazeneca**	**BioNTech and Pfizer**	**NIAID and Moderna**	**Novavax**
Serious Adverse Events* Event-based	0.7% (84/12021)	0.4% (n=10841) 18-55 0.8% (n=7960) >55	1.0% (n=147)	
	haemolytic anaemia in the control group Neuroinflammatory disorders Transverse myelitis which is likely to be idiopathic, short segment, spinal cord demyelination Fever higher than 40°C Deaths Road traffic accident, blunt force trauma, homicide, and fungal pneumonia	**<u>Related to vaccine:</u>** ● 1 Lymphadenopathy ● 1 Shoulder injury due to incorrect administration ● Unsure ● Appendicitis ● Facial paralysis (Bell's palsy) ● G51.0 7,400 ● Ventricular arrhythmia ● I47.0 12,200 ● pain in the lower back/extremities/and radicular paraesthesia **<u>Coincidental</u>** *Active group* ● 1 Anaphylactoid reaction (related to bee sting) ● 1 Drug hypersensitivity (doxycycline) ● T78.2 Anaphylaxis 7600 *Placebo group* ● 1 Anaphylactoid reaction due to ant bite	● Lymphadenopathy 1.1% ● Hypersensitivity:1.5% (injection site rash and injection site urticaria) ● 3 cases of Bell's palsy ● Facial swelling ● Intractable nausea and vomiting in a participant with prior history of severe headache and nausea requiring hospitalization.	

		• 16-17 years old • 1 facial bone fracture • Deaths • 7 deaths (2 active 4 placebo) • Due to pre-existing diseases including aortic rupture	
Special population	Elderly: safety data limited in >65, no dosing adjustments Pediatric: no data available	• Pregnancy: very limited • Elderly: no specific safety concern • Immunocompromised: on stable ART for 6 months, • Pediatric: limited participants	• For use in individuals 18 years of age and older • Elderly >65 • No notable differences in the safety profiles

As can be seen on the table above, the AEFIs are divided into two groups. Minor AEFIs are local or systemic signs and symptoms that easily resolve within a few days without medical intervention and do not pose a potential risk to the health of the vaccinee. On the other hand, serious AEFIs are events that cause a potential risk to the health/life of a vaccinee leading to hospitalization, disability/ incapacity or death. A thorough investigation and retrieval of medical records are critical to determine whether the adverse event has been caused by the vaccine, immunization error or from programmatic errors.

In addition to AEFIs, Adverse Events of Special Interest (AESIs) arising from COVID-19 vaccination must also be reported. The Council for International Organizations of Medical Sciences (CIOMS) VII defines AESI as a scientific and medical concern specific to the sponsor's product or program, which can be serious or non-serious, and for which, ongoing monitoring and rapid communication by the investigator to the sponsor could be appropriate. Such an event might require further investigation in order to characterize and understand it. Depending on the nature of the event, rapid communication by the trial sponsor to other parties (e.g. regulators) might also be warranted. While AESIs are also considered important in surveillance and response, the STG has yet to formalize the list of AESIs that are deemed reportable. The following are AESIs being considered:

Table 33. Adverse Events of Special Interest relevant to COVID-19.

Body System	Diagnoses
Immunologic	Enhanced disease following immunization, cytokine release syndrome related to COVID-19 disease†, multisystem inflammatory syndrome in children (MIS-C)
Respiratory	Acute respiratory distress syndrome (ARDS)
Cardiac	Acute cardiac injury including: • Microangiopathy • Heart failure and cardiogenic shock • Stress cardiomyopathy • Coronary artery disease • Arrhythmia • Myocarditis, pericarditis
Hematologic	Coagulation disorder • Deep vein thrombosis • Pulmonary embolus • Cerebrovascular stroke • Limb ischemia • Hemorrhagic disease • Thrombotic complications
Renal	Acute kidney injury
Gastrointestinal	Liver injury
Neurologic	Guillain Barré Syndrome, anosmia, ageusia, meningoencephalitis
Dermatologic	Chilblain-like lesions, single organ cutaneous vasulitis, erythema multiforme

* COVID-19 disease manifestations associated with more severe presentation and decompensation with consideration of enhanced disease potential. The current listing is based on Safety Platform for Emergency Vaccines (SPEAC) D2.3 Priority List of Adverse Events of Special Interest: COVID-19.[5]

† Cytokine Release Syndrome related to COVID-19 disease is a disorder characterized by nausea, headache, tachycardia, hypotension, rash, and/or shortness of breath.[6]

In the context of the COVID-19 vaccination program, any health event that has occurred after vaccination must be reported and considered as AEFI, pending proper professional consultation/case classification.

AEFI surveillance shall be performed by the Surveillance Officer (stimulated passive surveillance) every two (2) weeks for the first two (2) months, then monthly for one year. This is to ensure that no health event relevant to COVID-19 shall be experienced by the recipient per incubation period of the disease.

Passive surveillance requires empowering and reinforcing the vaccinee to report any health event post-vaccination. There are two advantages to passive surveillance: 1) it may lower healthcare system burden since minor cases are catered by lower level health facilities, while higher level health facilities concentrate on treating serious AEFIs only, 2) the detection and reporting of all AEFIs, especially minor ones, will allow greater chance of detecting minor clusters of AEFIs, which will, in turn, be reported as part of global knowledge on vaccines.

Figure 17 shows the process flowchart for AEFI surveillance and response for COVID-19 vaccination. Following vaccination, the Surveillance Officer shall follow-up the vaccinee, and rematch him/her with his/her pre-existing conditions. If the Surveillance Officer identified additional findings, he/she shall provide immediate appropriate treatment and facilitate transfer to an identified referral facility, if necessary. If there are no additional findings, he/she shall check for AEFIs and classify the vaccinee as one of the following: (1) well (no AEFI), (2) minor AEFI and (3) serious AEFI.

In addition, the vaccinee can also report his/her signs and symptoms (self-reporting) by, a) calling the VOC Call Center, b) filing a report to FDA through the pharmacovigilance system or directly to the vaccine manufacturer, or c) reporting online (a system, similar to the of COVIDKaya, shall be set up). These mechanisms shall be aligned with the masterlisting and profiling data to ensure continuity of data and harmonization through the overarching Vaccine Information Management System (VIMS).

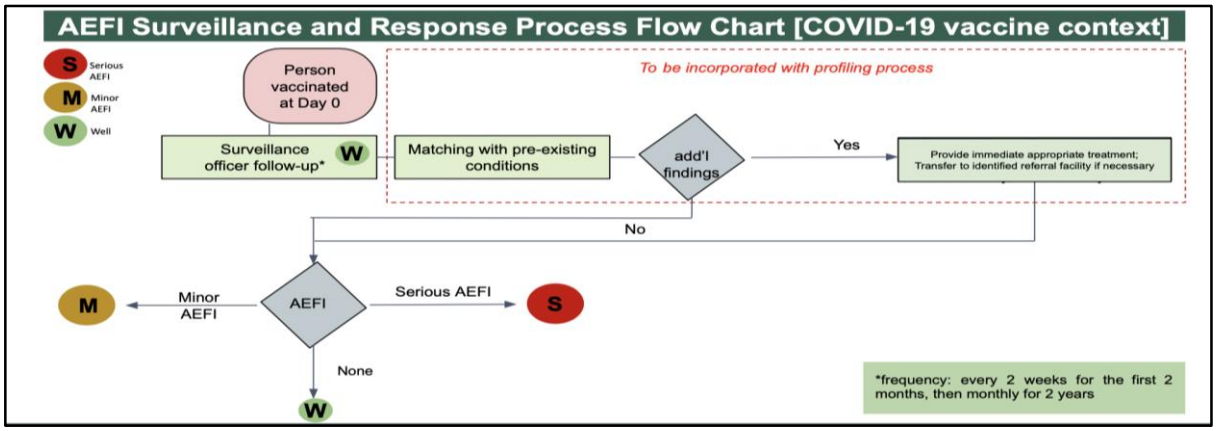


Figure 17. Process flowchart for AEFI surveillance and response in the context of COVID-19 vaccine administration.

The Surveillance Officer, as part of the AEFI/AESI Composite Team assigned in the post-vaccination monitoring area, shall provide information to the vaccinee on existing procedures and protocols in identifying and reporting AEFIs, especially serious cases.

For the routine follow-up for the vaccinee, the Surveillance Officer shall be stationed in the facility as part of the Human Resource/Administrative Department of the facility equipped with the necessary information communication technology equipment for performing its follow-up function to vaccinees. Methods of following up may be stratified phone calls, facility announcements/ memorandums, through notes upon receipt of documents/salary papers by the facility, etc.

For minor AEFIs detected through self-report or SSO assessment, QR code verification must be done by the responsible health facility. If the vaccinee with minor AEFI was deemed in need of medical assistance, he/she must be promptly referred to the identified health facility for management. If there is no need for medical assistance, he/she must be given medical advice, followed by an updating of the QR profile (Figure 18).

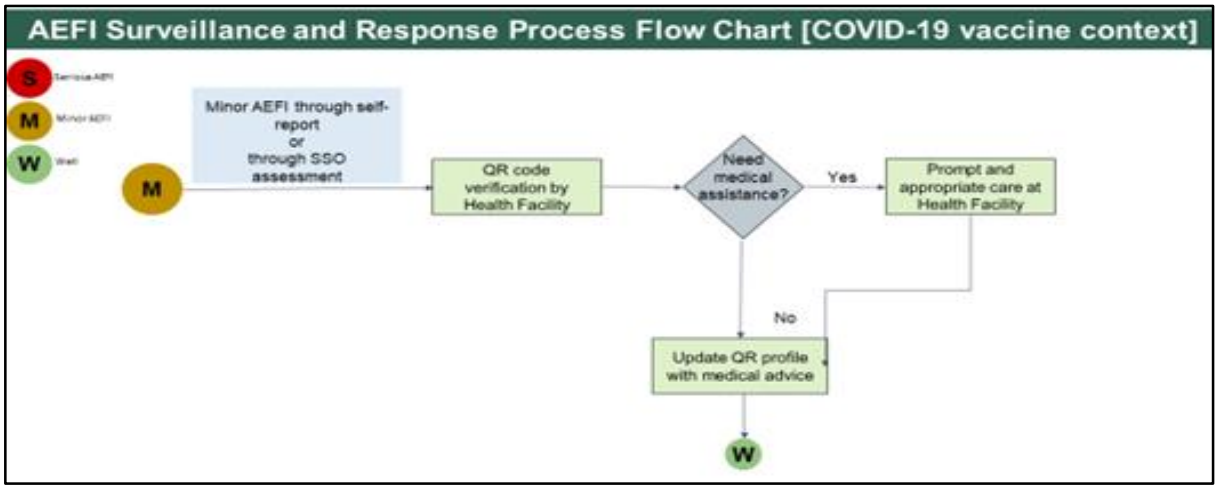


Figure 18. Process flowchart for responding to minor AEFIs of COVID-19 vaccine.

Serious AEFIs should further be investigated and reported through the Event-based Surveillance Reporting System. All serious AEFIs must be given prompt and appropriate care at a health facility, followed by investigation of the case and submission of data to the AEFI database. During investigation, initial causality assessment shall be done by the Regional AEFI Committee (RAEFIC). Based on this assessment, the final causality assessment shall be done by the National AEFI Committee (NAEFIC). Based on the final cause determined, the NAEFIC shall provide recommendations to the Epidemiology Bureau, Food and Drug Administration, National Immunization Program and Centers for Health Development for appropriate action. Response at the regional level shall also be assisted by the National AEFI Response Team. If the vaccine recipient does not recover and dies, further investigation of the death shall be conducted (Figure 19).

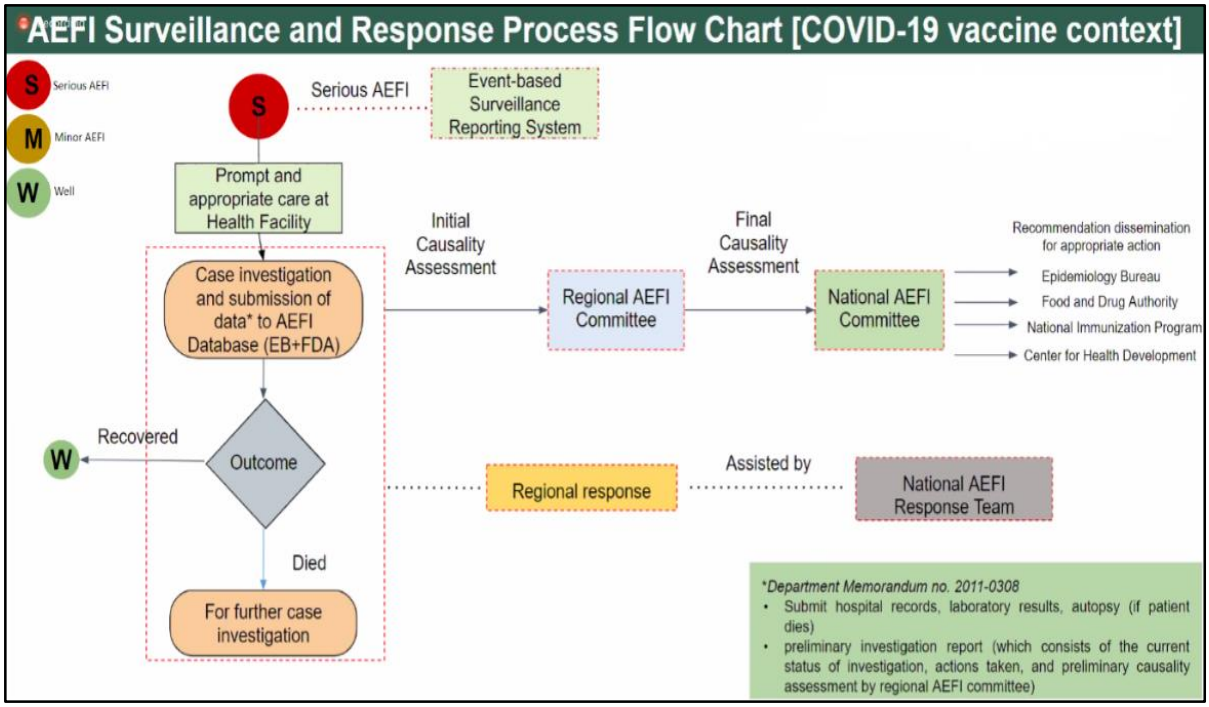


Figure 19. Process flowchart for responding to serious AEFIs of COVID-19 vaccine.

Additionally, the WHO recommends safety surveillance activities for all countries introducing COVID-19 vaccine, regardless of AEFI surveillance capacity. These are summarized in Table 35 below.

Table 34. WHO-recommended safety surveillance activities for all countries introducing COVID-19 vaccine regardless of AEFI surveillance capacity.

Objective	Recommended AEFI surveillance activities
Strengthen routine passive AEFI surveillance reporting systems for the management of increased frequency or severity of AEFI reports (mild, moderate and severe)	• Conduct training on identification and reporting of AEFI for health care professionals. • Update, print and distribute AEFI surveillance tools. • Use both vaccine tracking information and passive AEFI reporting information to perform vaccine-specific safety analyses. • Review and adapt processes for timely reporting, review and data sharing nationally, regionally and globally (e.g. uploading data to global databases such as the WHO VigiBase) • Develop clear standard operating procedures (SOPs) for the coordination process between the NRA, NIP/EIP, and other institutions with responsibilities for AEFI surveillance. • Consider coordination of activities with Public Health Emergency Units. • Consider setting up AEFI committees at subnational as well as national level, particularly in large countries
Investigate potential AEFIs causing concern, such as clusters, serious events,	• Prepare investigation teams and train them for AEFI investigation activities that are relevant in the population being vaccinated. • Update, print and distribute AEFI investigation tools to obtain information on specific outcomes.

programmatic errors, community concerns	• Ensure the collection and storage of all relevant data to help make a causality assessment (AEFI reporting and investigation forms, clinical case record, laboratory reports, autopsy reports, etc.)
Perform systematic causality assessment of AEFIs causing concern	• Constitute an National AEFI committee to review and respond to AEFI safety signals and public concerns or contact the WHO Country or Regional Office or send email to gvsi@who.int for assistance. • Provide training on causality assessment processes using WHO causality assessment guidelines for members of the National AEFI committee. • Ensure regular updates to the Committee members on COVID-19 vaccine development and safety data, including safety reports from ongoing phase III clinical trials or any events reported in clinical trials. • Foster and use the committee's expertise to identify AEFI cases in need of further investigation, such as AESIs. 5. Anticipate an increased number of AEFI reports that will need to be reviewed and consider including AEFI committees at subnational as well as national level, particularly in large countries.
Use AEFI and disease surveillance data to detect potential safety signals or clustering of events	• Regularly review and report AEFI surveillance data, particularly those relevant to AESIs or other conditions identified during pre-licensure COVID-19 vaccine clinical trials. • Explore the use of disease surveillance data to complement AEFI surveillance systems for the detecting of AESIs, if indicated. • Consider use of early signal detection methods, especially for certain AESIs.
Prepare comprehensive plans to respond rapidly to any COVID-19 vaccine-related event	• Outline roles and responsibilities of key stakeholders (including the private sector) for the implementation of safety surveillance activities and responding to vaccine-related events. • Keep stakeholders up to date with COVID-19 vaccine safety information. • Communicate with WHO regions and globally and share data on outcomes of AEFIs and AESIs in a rapid, timely and regular manner.
Address concerns of healthcare professionals and maintain community confidence. (Link to communication module to be added)	• Create and share a COVID-19 vaccine safety communication plan with relevant stakeholders. • Train and support personnel at all levels to address concerns that may arise before, during and after COVID-19 vaccine introduction. • Develop, print, and distribute messages concerning the safety COVID-19 vaccines

Note: Objectives and Recommendations were adapted from the WHO COVID-19 Vaccines Safety Surveillance Manual: Module on Establishing surveillance systems in countries using COVID-19 vaccines, 2020.

Serious AEFIs and AESIs are events that result in death, are life-threatening, require in-patient hospitalization or prolongation of existing hospitalization, result in persistent or significant disability/incapacity, or cause congenital anomalies or birth defects. If serious AEFIs or AESIs occur, all documentation generated during the management of the event, including hospitalization, should be appended to the investigation form and submitted as a dossier to the NAEFIC for causality assessment. The risk communication team should be made aware of the occurrence as soon as possible.

Specific protocols for investigating deaths following COVID-19 vaccination shall be defined. Guidance on investigating deaths following vaccination are provided in the global guidelines on AEFI surveillance. Deaths of individuals who received COVID-19 vaccines, including those classified as AESI, shall be included in the protocol for investigating deaths following COVID-19 vaccination.

Coordination with stakeholders reporting COVID-19-related deaths as well as COVID-19 vaccination-related deaths should be established. Protocols that were developed for investigating COVID-19 related deaths could be adapted in the investigation of COVID-19 vaccination related deaths. If indicated, tissue samples should be collected for in-depth pathologic, virologic and genetic testing. If an autopsy is not done, a complete verbal autopsy using standard protocol should be conducted and the findings documented and sent to the national AEFI committee.[5]

Safety Surveillance and Response

Enabling Policies and Guidelines

The guiding principles for Safety Surveillance and Response is based on the World Health Organization (WHO) Strategic Advisory Group of Experts on Immunization (SAGE) Values Framework for the Allocation and Prioritization of COVID-19 vaccination published last September 2020.

Existing policies for AEFI surveillance and response such as Administrative Order (AO) No. 2016-0006, or the *Revised Guidelines on Surveillance and Response to Adverse Events Following Immunization* details the general and specific guidelines on performing AEFI surveillance and response. For case management and support, AO No. 2016-0025, or the *Guidelines on the Referral System for Adverse Events Following Immunization (AEFI) of DOH Programs* can be used as reference. Furthermore, the AEFI Manual of Procedures published last 2014 by the DOH provides the overall operational guidelines for AEFI surveillance and response.

Other supportive administrative issuances include the following:

(1) Department Memorandum (DM) No. 2011-0308, or the *Strengthening Adverse Events Following Immunization (AEFI) Surveillance and Response at all levels* (Annex 7-D) is an important policy prior to the Data Privacy Act of 2013. The policy requires health facilities to submit all medical records of those referred for AEFI cases. However, the DM requires amendment and alignment with RA 11332, or the *Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act* and its *2020 Revised Implementing Rules and Regulation* wherein AEFI

[5] Adapted from WHO COVID-19 Vaccines Safety Surveillance Manual: Module on Establishing Surveillance Systems in countries using COVID-19 vaccine

is listed as one of the immediately notifiable diseases were notification is required at all levels within 24-48 hours upon identification and detection.

(2) DM 2020-0459 or the *Reiteration on the Implementation of AO No. 2016-0006, and AO No. 2016-0025*, reiterated the role of DOH EB and its regional counterparts on AEFI surveillance.

Restructuring of the National AEFI Committe*e* through DPO No. 2020-2996 as an independent expert panel for causality assessment of serious AEFI cases. The NAEFIC members include pediatric infectious diseases experts, vaccinology experts, forensic pathology experts, immunologist and allergologist among others. Technical resource persons can also be invited (e.g. adult infectious disease experts).

To support the NAEFIC, the National AEFI Response Team through DPO No. 2020-2772 was created with the composing of the following: EB, DPCB, FDA, HPB, RITM, HEMB.

Regulatory provisions requiring manufacturers to implement risk management plans and collect and report COVID-19 vaccine safety data to the NRA

The Risk Management Plan (RMP) provides a detailed description of the risk management system for a certain product. It is a set of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks relating to pharmaceutical products including the assessment of the effectiveness of those interventions.

Before a drug product is authorized, the FDA requires submission of the Risk Management Plan (RMP) as part of the company's obligation on the use of their product. Specific pharmacovigilance requirements and obligations are stipulated in FDA Circular No. 2020-003 *Guidelines for Pharmaceutical Industry on Pharmacovigilance*.

The RMP contains important information with regards to the safety of the product such as product overview, safety specification (important identified risk, important potential risk and missing information), the proposed pharmacovigilance plan, and proposed risk minimization measures. Routine pharmacovigilance activities include collection and reporting AEFI to the FDA, signal detection and updating of significant information as well as reporting action taken by other regulatory agencies in other countries. Other than routine is an additional pharmacovigilance activity which may include non-clinical studies, clinical trial or non-interventional studies aiming to further identify and characterize the risks of the product.

For the purpose of transparency and risk minimization, the summary of the RMP and its updates may be uploaded in the FDA website as reference in immunization programs. The FDA shall ensure availability of these information. Information related to the risk of vaccines shall be coordinated to the TG for Demand Generation and Communication for proper communication and

dissemination. Dissemination fora shall be scheduled in order to inform all relevant stakeholders on the prerequisites and foreseen processes related to risk management plans.

Any other policies deemed necessary in order to properly implement the COVID-19 vaccine immunization plan will be developed and crafted in relation to AEFI surveillance and response.

As part of the preliminary regulatory measure, the FDA Circular 2020-036 on the *Guidelines on the Issuance of Emergency Use Authorization for Drugs and Vaccines for COVID-19* stipulated the need of the market authorization holder to have a comprehensive pharmacovigilance system for their product following the system or protocol of a registered drug or biological product which includes assistance to the national initiatives on AEFI surveillance and response system.

AEFI Surveillance Cycle

In order to contextualize the operational guidelines from AEFI to have a special focus on COVID-19 vaccination, the components of the AEFI Surveillance Cycle based on the World Health Organization (Figure 13). Guidance for establishing AEFI surveillance systems shall be illustrated for the succeeding activities.

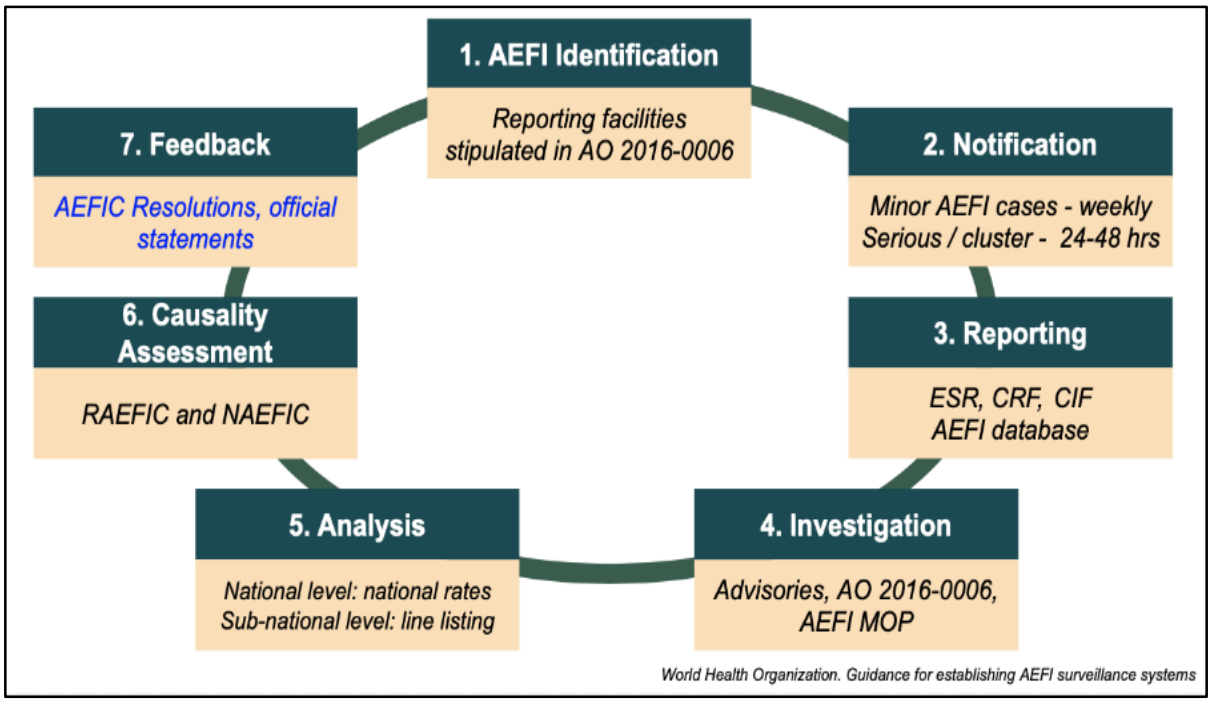


Figure 20. AEFI Surveillance Cycle.

Table 35. The AEFI Surveillance Cycle components.

AEFI Surveillance Cycle components	Main points
1. Identification	• Health care providers, vaccinators and personnel from the field • Individuals who received the vaccination • Researchers, sponsors, investigators and laboratories involved in clinical studies or field trials • Vaccine manufacturers and distributors
2. Notification	• Minor AEFI cases reported weekly to the higher ESU level. (shift to daily for COVID-19 vaccine) • Serious AEFIs and clusters of minor AEFIs are reported within 24 to 48 hours simultaneously to higher level ESUs and the EB for case investigation.
3. Reporting	• Minor AEFI through Case Report Form and Vigiflow • Serious AEFI through Case Investigation Form and Vigiflow
4. Investigation	• Only serious AEFI and clusters of minor AEFIs needed to be investigated • SOP on handling Serious AEFI cases needed to be filled up and submitted to EB as soon as possible • Case Investigation Form within 24-48 hrs
5. Analysis	• Daily bulletin
6. Causality Assessment	• All serious AEFI cases or clusters of minor AEFI should have comprehensive AEFI investigations and for endorsement to RAEFIC and forwarded to NAEFIC • For those regions without RAEFIC, AEFIs are forwarded directly to NAEFIC for causality assessment
7. Feedback	• All final resolutions shall be issued by the NAEFIC • RAEFIC resolutions shall be based on the approved official documents of NAEFIC for dissemination • Risk communication before, during, and after AEFI cases shall be made. • Post-incident evaluation shall be spearheaded by RAEFIC. • CHDs to monitor and evaluate RAEFIC / NAEFIC recommendations

In line with the components of the AEFI Surveillance Cycle: *AEFI identification* relies on the ability and initiative of AEFI reporting units/facilities to proactively identify AEFI whether it would be a minor or serious case. With this, a series of orientation sessions and refresher courses on vaccinators and officers in disease reporting units shall be informed that any health event that has occurred after vaccination must be reported and considered as AEFI pending proper professional consultation/case classification. In line with this, training modules shall be developed including FAQs on the vaccine which will be guided by WHO partners.

AEFI notification and reporting currently has a working system in place through Event-based Reporting System wherein all AEFI cases must have an accomplished ESR form submitted to the higher level Epidemiology and Surveillance Units weekly, whereas all serious AEFI cases must be notified to all higher level ESUs and EB within 24-48 hours. Training modules shall also be developed to ensure the alignment of reporting of AEFI of a novel vaccine to the existing system.

The development of training modules shall be based on existing manuals and guidelines; the list of manuals includes the following but are not limited:

a. DOH AEFI Manual of Procedures
b. DOH Event-based Surveillance (ESR) Manual
c. DOH Philippine Integrated Disease Surveillance and Response (PIDSR)
d. WHO Causality Assessment Manual 2nd edition
e. WHO Global Safety Surveillance Manual
f. WHO COVID-19 Safety Surveillance Manual
g. WHO National Vaccine Development Program

The National AEFI Committee (NAEFIC) conducts a systematic review of data about AEFI case(s) to determine the likelihood of causal association between the event and the vaccine(s) received. The readiness of the Regional AEFI Committee (RAEFIC)s were assessed through DM 2020-0415, wherein most of the regions have functional RAEFICs. As part of the follow-up action, regions needing further technical assistance shall accomplish a needs assessment tool through DM 2020-0508.

In coordination with WHO, training materials for COVID-19 vaccination include Instructor-led and Online self-learning. Some of the materials may be accessed from:

a. WHO e-Learning Course on AEFI Investigation e-Learning course: Investigating Adverse Events Following Immunization (AEFI) (vaccine-safety-training.org)
b. Causality assessment algorithm and WHO e-tool: http://gvsi-aefi-tools.org/
c. Global Vaccine Safety – E-learning course on Vaccine Safety Basics WHO | E-learning course on Vaccine Safety Basics
d. COVID-19 technical resources: page:https://www.technet-21.org/en/topics/covid-19

AEFI Reporting uses the current Event-based Surveillance Reporting and Philippine Integrated Disease Surveillance and Response (PIDSR) reporting system. However, with the novel vaccine pressing a concern on interagency operability of current systems and data sharing, a comparative evaluation of the Excel format utilized during the Measles-Rubella-Oral Polio Vaccine Supplemental Immunization Activity (MR-OPV SIA) and VigiFlow was done (Table 36). Based on the Center for Disease Control criteria for surveillance, VigiFlow, which is currently being recognized as the global standard, managed by WHO and Uppsala Monitoring Center, shall be used as the National COVID-19 AEFI Surveillance System. Moreover, the AEFI template was recently added and training of national and sub-national level staff was already performed. Moving forward,

more simulation exercises to ensure smooth usage of the VigiFlow shall be the next priority along with providing access to the determined reporting units.

Table 36. Comparative evaluation of excel format and VigiFlow.

Criteria adapted on CDC Evaluation of Surveillance Systems	Current System (Excel Template)	VIGIFLOW	REMARKS
Simplicity: refers to both the structure and ease of operation of surveillance system			
Ease of navigation and data entry and uploading of documents.	User friendly, simple and beginner level. Advantage is familiarity with Excel interface. AEFI excel template was based on the core variables of Case Report Form and Dengvaxia vaccine AEFI reporting template.	Fields are easy to understand. Some fields have drop-down options. There is a navigation panel for ease of jumping to specific parts of the report. MedDRA and WHO Drug coded. However, no uploading capability.	The current excel template is currently being used by the RESUs which are the main AEFI surveillance system at the moment. Navigation of VigiFlow will require additional orientation training which should be scheduled early January 2021
Feasibility of training schedule with the current timelines for COVID-19 vaccination	One training session was sufficient for RESUs to be able to submit the accomplished tool weekly	Online training (recorded) is available on the UMC website. The FDA PV team may also provide training for new users. VigiFlow Training Materials https://www.who-umc.org/global-pharmacovigilance/vigiflow/training-materials/english/	The Excel tool is self-explanatory and will not be overwhelming. Training schedules for Vigiflow must be set immediately as well as the targeted people to access VigiFlow to preserve data integrity.
Time spent with maintaining the system, collecting, transmitting, analyzing case information, and preparing and disseminating surveillance reports	Data cleaning of 50 AEFI cases (line listing and sending to regions for verification) and generating statistics as draft AEFI surveillance report takes one man day Bottleneck processes include time to verify and sending of reports by the regions and LGU level	No maintenance is necessary. Collecting and transmitting of data is real time. Reports may be downloaded into excel or pdf files.	The maintenance of the system for excel heavily relies on the national data managers. Whereas, for vigiflow, it is the accepted system in the WHO setting and global level. Familiarization and data encoding may bear more time for Vigiflow

Minimum technical requirement of the device (PC/Laptop)	Downloaded and saved into a local PC drive/laptop with Microsoft Excel application (93 version and above) for encoding.	Computer (laptop or PC) and internet connection are the minimum requirements. No local installations, back-ups or maintenance are necessary. No off-line functionality.	Main advantage of excel: off line functionality
Flexibility: observing how a system responded to a new demand			
Able to accommodate, for example, COVID-19 vaccine (novel vaccine), changes in case definitions, and variations in reporting sources	The system is adept to be incorporated to any vaccine with minimal edits on the needed variables specifically for COVID-19 vaccine. Currently limited platform for global data sharing. Used through google sheets / excel.	May be accommodated in the global level through the UMC. COVID-19 vaccine is coded into WHODrug.	Revising specific variables for COVID-19 to fit national needs is easier in AEFI excel. Data sharing for global level is already set up in Vigiflow
Acceptability: willingness of individuals and organizations to participate in the surveillance system			
Participation rates among internal and external stakeholders/partners	All the RESUs and CHDs are responsive and able to comply with the weekly submission of their accomplished Excel Templates.	Hospitals who regularly report to the FDA were given VigiFlow accounts and are already using the system in reporting. Pharmaceutical Companies have a system that generates reports in E2B xml files which are then uploaded to the VigiFlow either manually by the FDA or directly through eReporting for Industry. Health care professionals, non-health professionals & patients may report through the eReporting system.	A consensus on the national level must be built to roll out the specific database that the facilities and ESUs will use
Completeness and timeliness of reporting accompanied with seeking technical	There are only some regions that submitting complete and on time reports	There are several fields that are needed for a report to be submitted to the VigiFlow such as the minimum mandatory information.	Due to the nature of excel reporting, there are great instances wherein incomplete data are submitted. No mechanism

support in troubleshooting	Data submissions of RESUs and CHDs every week then followed by data verification and validation by EB. There are incomplete and delayed submissions in some regions.	Reports submitted are received real time by the FDA. Technical support in troubleshooting may be provided by the FDA PV Team. Real time reporting that may have pressing concerns on accurateness and accountability of data submitted.	is set to have minimum data requirements. Validation mechanism of reports submitted to FDA should be strengthened in the regional and national level.
Sensitivity: ability to be detected by the surveillance systems and to detect epidemics **Predictive value positive: proportion of persons identified as having cases who actually do have the condition under surveillance**			
Confirmation of cases reported through the surveillance systems (Event-based Surveillance Reporting and AEFI system)	The current system is cross validated with Event-based Surveillance System and RESU for confirmation of cases	Cases are presented in line list coded in MedDRA terminologies Pilot testing of the AEFI Vigiflow shall commence in January 2nd week of 2021	
Quality of data: clarity of surveillance forms, complete surveillance forms and appropriate data management			
Completeness of WHO core variable for AEFI reporting	Additional variables needed can be easily integrated in the Excel Template. Although based on the WHO core variables for AEFI, it may be tailored to fit contextual purposes	VigiFlow are made for reporting adverse reactions including adverse events following immunization. To adapt the current situation on COVID-19, UMC is currently developing the VigiFlow system to enhance the core variables for AEFI reporting. The target release of these developments is on the 2nd week of January. https://www.who-umc.org/media/165550/using-vigiflow-for-data-collection_covid-19.pdf	Vigiflow current has a Demo version specifically targeting AEFI reporting AEFI excel was enhanced to fit the HWO Core Variables for AEFI reporting

Data gathered are easily converted, merged and integrated to the platform	Manually performed by data managers	see above	Vigiflow is adept to perform data analysis of the entries In AEFI excel, the data managers and data analysis team will have to manually calculate and compute.
Able to produce meaningf analysis, Evaluation, and assessment; or only with desired variable/s	Manually performed by data managers therefore able to tailor the needed analysis given that sufficient variables are present	Minimum required information is necessary to successfully save and submit a report. https://www.who-umc.org/global-pharmaovigilance/vigiflow/vaccine-surveillance-in-vigiflow/	Both platforms contain necessary variable in order to perform minimum required analysis
Timeliness: reflects the speed or delay between steps in a surveillance system			
Ability to support the 24-48 hr reporting from ESU to EB for serious/clusters of minor AEFIs	It can also supports the 24 – 48 hours reporting from ESU to EB.	Real-time submission. Once the report is saved, it is readily available for the higher levels (regional or national level) to view or edit the report.	AEFI excel template relies heavily on the timeliness of submission by stakeholders In vigiflow, the same scenario but with real time reflecting submission
Timeliness of producing reports (i.e. daily reports)	Can produce daily reports. Weekly reports are drafted within a day. Delayed data submissions of RESUs and CHDs are included in the next report.	Once a report is submitted, it is ready to be generated.	
Traceability: ensure appropriate platform access on the national and sub-national levels **Security/Confidentiality of the Data**			
Can the end user update the submitted information?	Yes, the end user can update the submitted information and leave a remarks regarding to the information that was being updated	Reports submitted through the VigiFlow may be updated/edited anytime.	Both types of reports may be easily edited and updated

	The end user has a direct access to the Excel Template and can update all the information previously encoded.		
Is it traceable? (shows the name who updated the information and the date it was edited)	Yes, there is column for the name of encoder and column for date encoded. It can also use the REMARKS column for any update information. Includes the name of the encoder and date encoded. The name who updated the information and the date it was edited may be included in the remarks column. It is manually determined rather than system generated There is no user login for better traceability function	Yes. The date and name of the person who last edited the report is reflected in the report.	Traceability of whom edited is more seen in Vigiflow
Ability to have predefined data platform access per ESU level (only authorized personnel able to view and/or edit the data)	It can access down to the municipal, provincial and regional level. The interface is easy to use. However, it may be still prone to errors when not cascaded properly to the lower level ESUs. Platform access is dependent on the capabilities of ESUs and persons-in-charge	The VigiFlow has 3 level options to view/edit reports. Viewing or editing data depends on the level of access given to a specific accounts.	Platform access mechanism is yet to be set on Excel template unlike in Vigiflow

Due to the nature of the novel vaccine and the inclusion of adult population on the list of vaccinees, series of trainings and encoding workshops will be conducted. The personnel involved in the encoding of reports shall be formalized through an issuance of database logger in order to preserve data integrity and traceability of surveillance reports. Accountability of the surveillance officer is also

included in the training since data shared through the database will be disseminated to global level for our country to participate and have access also to the latest updates on the possible signals of AEFI for the novel vaccine.

Continuous harmonization of the surveillance platform is also on its development in terms of linking the registry or the vaccinee profile with the AEFI. A unique identifier code shall be its interoperability mechanism to link with the AEFI system. In order not to overload the health system to all AEFI cases (minor and serious), a self-report mechanism for minor AEFI cases shall also be developed which may be adapted to the current COVIDKAYA self-reporting platform. The automated linkage of unique identifier code shall be enhanced within the next weeks during pre-testing of the system. Furthermore, the AEFI surveillance and response systems are in the process of interlinking through using a single database platform with both EB (PIDSR) and FDA as national data managers. As mentioned, VigiFlow training, especially on AEFI reporting form which was recently added in the system was cascaded to the national and subnational staff. Furthermore, meetings with the Uppsala Monitoring Center pharmacovigilance team were already performed in order to provide inputs on the improvements on the system and enhance the applicability of the tool esp in data security, accessibility, data management in the Philippine Health system.

Strengthening *AEFI investigation* procedures requires series of orientation and capacity training on the needs and actions of the *AEFI investigations team* (Epidemiology and Surveillance Unit, EPI Coordinator/Cold Chain Manager, Food and Drug Regulation Officer, Health Promotion Officer) on conducting field investigations for AEFIs. Moreover, enhancing the appropriate case management and program support to those affected by serious AEFI or AEFIs needing professional assistance is critical for service delivery.

In terms of *response*, the NART which is a composite team of DOH offices serves as the link to every office in responding to emergency situations. To streamline the *referral system*, for AEFI cases and optimize the use of medical care services at a national level for a unified NART response, the One Hospital Command System (OHCS) shall be utilized (i.e. DO No. 2020-0653 - *Guidelines in the Creation of the One Hospital Command System*, and DO. No. 2021-0004 - *Delineation of Functions of Hospital Oversight in Alignment with Universal Health Care*). Further, the OHCS can be supported by the Health Care Provider Network under AO No. 2020-0019 - *Guidelines on the Service Delivery Design of Health Care Provider Networks*.

The Health Emergency Management Bureau along with the help of Field Implementation and Coordination Team shall be the forefront offices in coordinating and determination of ambulance services and designation of public and private facilities as AEFI referrals subject to the funds of PhilHealth through case rates, or the Quick Access Fund of the National Agencies/Regional Offices. For case management, costing estimates were calculated for minor and serious AEFI cases with the projections for minor AEFI at 2% and serious at 0.16 per 100,000 doses (based on the

National serious AEFI rates as per WHO and DOH assessment in 2013). Scenario-based analyses were calculated based on the % population of vaccinees at 20%, 60%, and 70%.

As for the *AEFI analysis*, the current templates on vaccine surveillance reports are being enhanced pending the important data needed to be analyzed specifically for COVID-19 vaccine. Currently, the following variables considered in the recently concluded MR-OPV SIA Phase 1 campaign includes the following:

- National and regional AEFI rates per 100,000 doses
- Profile of cases (age, sex, region, most common signs and symptoms)
- Rates of signs and symptoms per 100,000 doses
- Narrative profile of deaths

Feedback and risk communication before, during and after the vaccination program is critical in order not to cause mass hysteria and public panic on COVID-19 vaccine. Thus, it is recommended that the Health Promotions Bureau will handle this matter appropriately.

In terms of the *surveillance flow*, the interim proposal is status quo which states that for HCW, senior citizens, and indigents on AEFI reporting system through health facilities and ESUs; as for NGAs: geographical jurisdiction to respective ESUs (Figure 21).

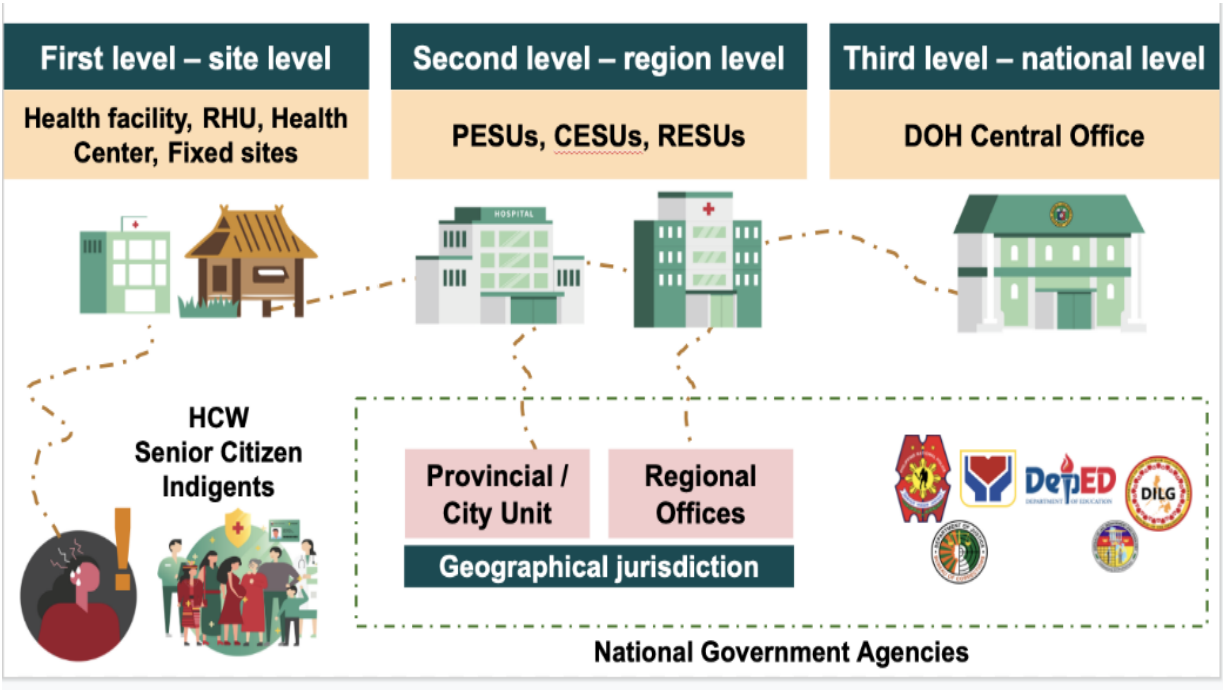


Figure 14. Surveillance referral flow.

Identify and secure channels of data sharing mechanisms to share COVID-19 vaccine safety data and findings with relevant regional and international partners: The International Health Regulation (IHR) National Focal Point shall make the necessary coordination mechanism with global and international partners in accordance with IHR guidelines and procedures. The IHR

shall manage all communications and relay to relevant offices, task groups, in charge of the query and shall consolidate all opinions and answers of the offices for their official reply.

The IHR National Focal Point acts as the international Liaison Officer for COVID-19 surveillance and manages all communications of the AEFI surveillance with international partners. The team shall respond within 24 hours upon receipt of any query.

The FDA, as a member of the WHO Programme for International Drug Monitoring, shall share relevant cases of AEFIs to the global database of adverse drug reaction to facilitate data sharing and analysis of data in the global context.

Monitoring and Evaluation Framework, and Reporting Mechanism

Prior to vaccine introduction, listing the various stakeholders, their roles and responsibilities in handling end-to-end COVID-19 vaccine safety issues will help to shorten the response time during a crisis and ensure that there is a harmonized approach to routine activities and managing a crisis and unexpected events.

As COVID-19 vaccines are being introduced, there will likely be an intense demand for data by different stakeholders, to meet the key anticipated needs of these different stakeholders, the COVID-19 Vaccine Deployment and Vaccination Program monitoring system for COVID-19 vaccines has been designed to be able to:

- Measure equitable uptake and coverage over time by geography, population groups, and risk groups.
- Monitor to what extent national policies to prioritize at-risk groups and settings (e.g. hospital and long-term care facilities) are effectively implemented.
- Provide a personal vaccination record/certificate for any health, occupational, educational and travel purposes (as per national policies).
- Ensure that the necessary records and documentation are in place for use in surveys, safety monitoring, disease surveillance and vaccine effectiveness studies.
- Ensure that individuals can be monitored for the full course, in the likely case that a multidose schedule is required, to reduce the incidence of drop-outs.

The main indicators to measure progress with COVID-19 vaccines are similar to any vaccine introduction:

Vaccine uptake: The number or proportion of people vaccinated with a certain dose of the vaccine in a certain time period (e.g. during a month or year). If expressed as a percentage, an alternative term to be used is vaccination rate.

Vaccination coverage: The vaccinated proportion of a target population, which is similar to uptake, but considers vaccination in previous time periods. Over time, coverage can be constructed by accounting for uptake in previous time periods (weeks, months, years), depending on the duration of protection of the vaccine. For the year of introduction (2021), uptake and coverage can be used interchangeably.[6]

Table 37. Dimensions for disaggregating vaccine uptake and coverage .

Disaggregation	Definition	Use
Vaccine product	By each vaccine product in use in a country	• Calculate uptake and coverage with a last recommended dose • Evaluate protection in a population, given differences in effectiveness • Evaluate vaccine safety issues that are specific to the different products in use
Geography (required)	By district, province, state etc.	• Monitor equitable distribution across regions in a country
Sex (required)	By sex of the vaccinated person	• Monitor equitable distribution by sex
Age group (required, at a minimum younger than 60, 60–69, 70–79, 80+)	By age group of the vaccinated person according to national policy for vaccine prioritization	• Age is a risk factor for severe COVID-19. Monitoring uptake among specific age groups is required to evaluate whether prioritization policies are implemented
Occupation (optional, where feasible)	By prioritized occupational group: definition/ characteristics to be decided at the country level by national health experts/NITAGs.	• Occupation is a risk factor for transmission of CoV-SARS-2, and country policies will need to ensure that essential frontline workers are protected first • Evaluate whether prioritization policies are implemented
Other risk factors (optional, where feasible)	Among people with co-morbidities or other risk factors for COVID-19 such as pregnancy	• Evaluate whether prioritization policies are implemented *Note:* this may not be feasible in all countries; foresee challenges disaggregating doses as well as establishing targets for these at-risk groups
Context (optional, where feasible)	In long-term care facilities, prisons, universities and schools	• Evaluate whether these strategies are implemented
Other equity dimensions (optional, where feasible)	By socioeconomic, ethnic, linguistic, religious, or any socially disadvantaged populations	• Monitor equitable distribution across different populations in a country *Note:* this may only be feasible to measure using surveys

Continuous monitoring for situational awareness throughout the COVID-19 Vaccination Program is crucial for a successful outcome. Prior to receiving COVID-19 vaccine, jurisdictions should establish procedures for monitoring various critical program planning and implementation elements, including performance targets, resources, staffing, and activities.

To provide situational awareness for higher officials and the general public throughout the COVID-19 vaccination response, the following dashboards will be available:

- Weekly COVID vaccination dashboard
- COVID-19 vaccine distribution planning, tracking, modeling, and analysis application

Evaluation of COVID-19 vaccine introduction

Based on the World Health Organization's "Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines", evaluation of COVID-19 vaccine introduction pertains

[6] Adapted from the WHO Interim Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines, 16 November 2020

to the “post-evaluation following the introduction of COVID-19 vaccines to assess vaccine effectiveness impact and identify any improvements to the COVID-19 vaccination process”. This may cover (a) assessment of the impact of the specificities and novelty of the COVID-19 vaccines on the immunization program and how these will input to the further optimization of the vaccine deployment, (b) assessment of vaccine effectiveness and impact after introduction into populations, and (c) documenting the lessons learned from deployment and vaccination operations.