



Iraq National Deployment and Vaccination Plan for COVID-19 Vaccines

COVID-19 Vaccine National Coordinating Committee

In partnership with:

WHO, UNICEF, EMPHNET, WB

The Iraq NDVP is a dynamic document and will be continuously revised based on the latest scientific evidence and available information about vaccines for COVID -19 and their delivery.

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1.Introduction:

Covid-19 is an infectious disease caused by the last detected virus from the coronavirus strain. There was no knowledge of the existence of the new virus and its disease before the outbreak began in December 2019.

Coronaviruses are a vast strain of viruses that may cause disease to animals and humans. It is known that a number of these cause respiratory diseases in humans ranging from common colds to more severe diseases such as Middle East Respiratory Syndrome (MERS) and severe acute respiratory syndrome (SARS).

The most common symptoms of Covid-19 are fever, fatigue and dry cough. Other potentially common symptoms include pain and aches, nasal congestion, headaches, conjunctivitis, sore throat, diarrhea, loss of sense of taste or smell, rash or discoloration of fingers and/or toes. These symptoms are sometimes mild and begin gradually. Some people become infected with very severe symptoms and face the risk of mortality as well as long term sequelae.

The outbreak of Covid-19 disease began in The Chinese city of Wuhan in December 2019 and then began to spread to the rest of China and the world.

The first case of Covid-19 disease was recorded in Iraq on February 24, 2020, after which the pandemic began to spread among citizens and turned into clusters. By June 2nd, 2020 Iraq moved to the stage of community transmission.

After the World Health Organization (WHO) announced on March 11, 2020 that Covid-19 had become a global pandemic, there was a real and rapid need to produce a virus vaccine. Since the beginning of the spread of the disease, international institutions, organizations and manufacturing companies have begun to work on the provision of a vaccine against coronavirus and conduct laboratory and clinical trials to demonstrate its effectiveness and safety.

Until recently, the number of experimental vaccines against the disease exceeded 200, some of which are beyond the second stage of clinical trials and some of which were approved for use. The Iraqi Ministry of Health, represented by the Directorate of Public Health/Immunization Department, has joined the COVAX facility since its inception, through which Iraq will be provided with sufficient doses to cover (20%) of the population. More than 8 million people or 16 million doses are expected to arrive by the end of the first quarter of 2021 in partial shipments.

In addition, the Ministry of Health has signed a binding heads of term agreement with Pfizer to provide Iraq with 1,500,525 doses of Pfizer-Biotech vaccine.

In the light of the available data, this plan for the Covid-19 vaccine has been prepared and would be updated as the government procures more vaccines.

To ensure acceptance and uptake of the COVID-19 vaccination, the MOH will provide timely and focused communication on the COVID-19 vaccines and vaccination processes in lay language.

Health Care Workers (HCWs) will play a unique role in promoting COVID-19 vaccination, as the first recipients of vaccines and as the trusted influencers of public opinion related to vaccination. Special efforts will be made to communicate with target populations and communities and to build public confidence in the safety and efficacy of the COVID-19 vaccines.

This document has been developed to establish a national deployment and vaccination plan to scale up preparedness for the roll-out of COVID-19 vaccines in Iraq based on the World Health Organization (WHO) and United Nations International Children's Emergency Fund (UNICEF) interim guidance on developing a national deployment and vaccination plan for COVID-19 vaccines. It is a dynamic living document that will be updated on regular basis depending on the evolving situation in Iraq.

The guidance outlines preparedness for managing the deployment, implementation and monitoring of COVID-19 vaccines with a focus on COVAX and Pfizer vaccines; details on the vaccines provided through the COVAX Facility will be added later when there is more clarity on the vaccine which will be provided. This plan follows the core principles of the WHO Strategic Advisory Group of Experts (SAGE) values framework for the allocation and prioritization of COVID-19 vaccination, the prioritization roadmap, adapted to the country context. Due to the current uncertainties around the COVID-19 vaccine, the guidance is based on key assumptions, best available at this time. As the situation evolves, there is a high likelihood that these assumptions will require updating over time as more information becomes available and data unfolds.

The purpose of the plan is:

To outline the mechanisms for the storage, distribution of the COVID-19 vaccines and the vaccination of the target groups in Iraq, and related logistical matters, so that they are a reference source for all health departments and stakeholders for the development of similar micro plans at the level of the health districts, sectors and health institutions, to ensure that there is no waste or misuse in the distribution of the vaccine and to ensure that it reaches the target groups fairly and safely.

The overall objective of the plan is to reach above 60% coverage with COVID-19 vaccination in order to reach a level of population immunity (herd immunity) which will stop the spread of infection.

The basic principles of the plan:

1. Develop a coordination mechanism for the vaccination process based on scientific foundations and solid decisions.
2. Give priority to vaccination to those most in need of a vaccine while ensuring equitable distribution.

3. Ensure that all logistical requirements are met for the storage, transport and delivery of the vaccine.
4. Ensure that a safe and effective vaccine is provided and that there is no shortage or delay in processing it.
5. Properly distribute human and financial resources and provide trained staff to implement the plan and its components
6. Engage the community during the implementation of the plan, use the available means of communication and ensure the transparency of information.
7. Ensure safe vaccination practices and follow up on possible adverse events following immunization (AEFI).
8. Employ a “whole of government” approach to vaccination as different sectors can contribute to the vaccination campaign.
9. Use a phased approach in which certain interventions (targeting, communications, etc.) can be specific to each phase
10. Update the plan periodically as needed to reflect the latest scientific developments and country’s rollout lessons (any update will require NCC approval)
11. Maximize the use of the digital registry for preregistration and scheduling, minimize walk-ins and onsite registration, especially in the early phases of vaccination when demand outstrips the supply
12. Hold each vaccination site accountable for their performances by making public detailed vaccination information by sites

Plan objectives:

1. Describe the most important features and characteristics of Covid-19 vaccines, the target groups and how to deliver the vaccine to them in the shortest period.
2. Identify strategic plans for all vaccine supply chains from the moment of contracting with the manufacturer until it reaches the target population.
3. Outline the mechanism of vaccination of the target groups in terms of determining the location and time of access to each of them, while considering the preventive measures for the spread of coronavirus during vaccination sessions.
4. Develop mechanisms for documenting and validating data related to the target populations who will get the vaccine in coordination with higher authorities.
5. Form the basis for immunization teams and health workers to develop micro plans at the lower levels.
6. Identify mechanisms of supervision and follow-up on the vaccination process and monitor the possible AEFI and coordinate response.
7. Set the basic guidelines for social and community mobilization in order to raise awareness about the importance of being vaccinated, who are the target groups and the place and time of vaccination sessions.

Expected characteristics of the Covid-19 vaccine:

Based on the information and data available so far, there are multiple vaccine candidates for Covid-19 vaccines that have been through clinical trials, some of which have been approved by some countries or have received WHO Emergency Use Listing some organizations, while others have not yet been approved:

- 1) Astrazeneca/Oxford (directly or through Serum Institute of India (SII))
- 2) Pfizer -BioNTech
- 3) Johnson & Johnson
- 4) Novavax
- 5) Sanofi/GSK/GSK
- 6) Sputnik V Russia
- 7) Sinopharm / China

(This list will be updated as needed, taking into account additional vaccines available in the future)

Below are the characteristics of vaccines that need to be stored in ice-lined refrigerators, these features are updateable with future information:*

Property	Details
Vaccine-making technology	By Manufacturer
Number of doses	2 (often)
Interval between doses	4-12 weeks
Target groups	≥ 18 years old
The method of giving	Intra Muscular
Place of Injection	IM (In deltoid muscle)
Storage temperature	(+2) to (+8) °C
Packing type	Single-dose, multi-dose vial (5), (8) or (10) doses
Packing size	By manufacturer it is expected to be within 2 -3 cm ³
Pharmaceutical form	Ready-to-inject liquid
Amount of vaccine per vial	Depending on the size and number of doses
Volume per dose	By manufacturer and often (0.5 ml)
Syringes	AD syringes (0.5 ml)
Solvent type	doesn't need
The amount of solvent required per dose	doesn't need
Vaccine solution syringes	doesn't need
VVM vaccine vial monitor	none
Open Bottles Policy	The bottle is to be discarded six hours after it's opened.
Destruction boxes	Box per 100 doses with an additional 50% reserve (as recommended by WHO)
Possible side effects	Common symptoms (high temperature, swelling and pain at the injection site, rash, cold and cold, and rarely vascular trauma)

Cases where vaccine is postponed (at least two weeks)	High fever, acute respiratory symptoms (suspected of COVID-19 disease)
Excluded populations	Children under the age of 18 Pregnant women Nursing mothers Women planning to become pregnant soon People with severe immunodeficiency diseases Recently infected with Corona virus (less than 6 months)
Contraindication	Severe sensitivity to the components of this vaccine or any previous vaccine or food or medicine

****This information is periodically updated with new information***

Below are some of the expected specifications for Pfizer's vaccine, which needs to be stored at very low temperatures ranging from (-60) to (-80) °C:

Property	Details*
Vaccine-making technology	(mRNA)(modern technology)
Number of doses	2
Interval between doses	21-28 days
Target groups	≥ 18 years old
The method of giving	Intra muscular
Blue Place	Deltoid Muscle
Storage temperature	(-60) to (-90) °C for six months (+2) to (+8) °C for five days (Pfizer's vaccine)
Packing type	Multi-potion vial containing (6) doses
Pharmaceutical form	Concentrated, preservative-free frozen liquid in a special multi-dose glass bottle needs to be melted before use
Amount of vaccine per vial	The vial contains a quantity of vaccine the size of (0.45 ml) (before melting)
Volume per dose	(0,3 ml)
Syringes	(0,3 ml) Or (1 ml)
Solvent type	Saline solution 0.9%
Amount of solvent required	(1.8 ml)
Vaccine Dilution syringes	(3 ml) or (5 ml)
VVM vaccine vial monitor	Not present
Open Bottles Policy	The bottle is discarded six hours after it's opened.
Destruction boxes	box per 100 doses (with an additional 50% reserve (as recommended by who)
Possible side effects	Very common symptoms (mild pain and swelling at the injection site, headache, joint and muscle pain, fever (especially after the second dose) (all of which go away automatically after a few hours or using simple analgesics) Common symptoms(nausea, redness at the injection site)

	<p>Uncommon symptoms (enlarged lymph nodes, insomnia, pain in the extremities, general weakness, itching at the injection site)</p> <p>Rare symptoms (numbness and weakness in the muscles of one side of the face; Bell’s Palsy)</p> <p>Unknown symptoms (severe allergy, anaphylactic shock)</p>
Contraindication	People with a history of severe allergic reactions, or who are allergic to any of the vaccine ingredients
Precautions	People who have a rapid allergy when taking a previous vaccine, body temperature rise to (38.5), acute infections, respiratory symptoms, people who received blood plasma after contracting Coved-19 disease prefer to postpone (90) days
Excluded populations	<ul style="list-style-type: none"> Children under the age of 18 Pregnant Nursing mothers Women planning to become pregnant soon People with uncontrolled severe immunodeficiency diseases (balancing risk indicators) Near-hit Corona virus (less than 6 months) (not a priority)

**This information is periodically updateable with new information reportedly*

2. Regulatory Preparedness, Importation and Custom Clearance:

On the regulatory preparedness, the key steps for obtaining official approvals for the introduction of the vaccine through official channels include the following:

The details of the process are enlisted below:

Preparedness

- The marketing authorization holder (MAH) should submit a request to the national board of drug selection (NBDS) for the emergency use approval. Approval would take from 2-5 days, and the NBDS could also receive request for the emergency use from MOH relevant parties i.e. Public Health Directorate, based on WHO emergency use listing. The required documents are a fact sheet and proof of authorization granted to the vaccine by stringent regulatory authority (US FDA, EMA, MHRA), (please refer to the MOH reliance policy document ([Appendix 1](#))). If the request is accepted, and endorsed by the minister, the applicant will be notified officially to complete other regulatory procedures.
- The Director General of Technical Affairs Directorate will then sign the binding head of terms with the applicant in order for the company to release the official documents required, this would take 1-2 weeks. The registration department shall be notified and since the vaccine will be approved for emergency use, it will be exempted from entering by the ordinary pathway. During emergency, registration is not mandated, rather the approval by NBDS is the most important step for KIMADIA to contract the applicant
- MOH has established a committee for the release of the emergency vaccine with support from the national center for drug control and research (NCDCR) ([Appendix 2](#)) testing results provided by the MAH will be reviewed in this committee and no quality control testing will be performed at the center.
- Safety data will be shared by the MAH with the Iraqi pharmacovigilance center including the risk management plan and monthly safety report based on Iraqi pharmacovigilance guideline for the MAH (V2), module V, IX and XV ([Appendix 3](#)), and will use these documents besides data related to AEFIs collected nationally as bases for decision making related to the safety of COVID-19 vaccine in Iraq.
- KIMADIA will negotiate and sign the supply agreement with the MAH within (1-3 months), and then the vaccine will be shipped and stored and distributed by KIMADIA to all directorates of health through its warehouse branches at different governorates, except for Pfizer- BioNtech vaccine to be distributed directly by the MAH to all vaccination sites.

The authorities involved in the introduction of the vaccine and their duties and responsibilities are mentioned in ([Appendix 4](#)).

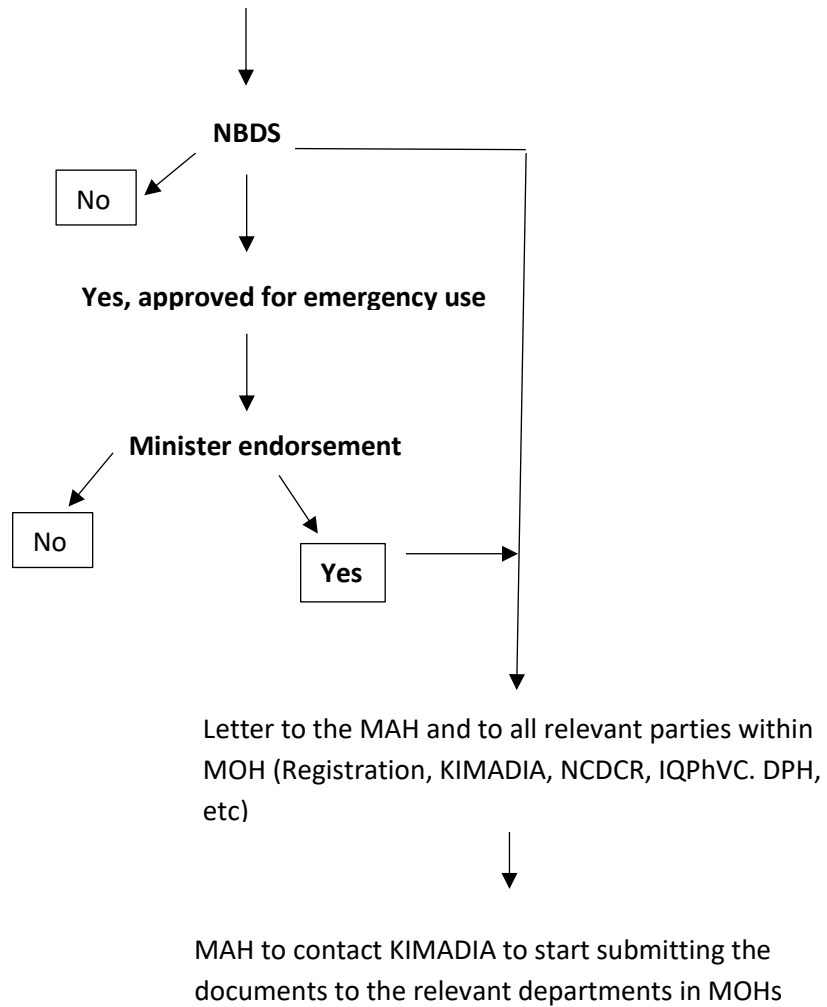
For the issue of indemnity and liability protection, the Council of Ministers adopted the task of giving the required guarantees by issuing a resolution no. 67 year 2021 authorizing the Ministry of Health to sign this document on behalf of the Government of Iraq ([Appendix 4](#)).

Importation and Custom Clearance:

- All the necessary approvals and documents will be prepared to ensure the completion of the customs transaction within two hours of the arrival of the vaccine at the port (Baghdad International Airport). A team from the customs clearance department/ KIMADIA has been assigned to be at the airport at the time of the vaccine’s arrival with all the documents required to complete the customs transaction.

The Directorate of Air Cargo Customs at Baghdad International Airport has been instructed to expedite customs clearance procedures upon arrival of the vaccine to ensure that it is not damaged.

MAH or DPH request for the emergency use of COVID-19 vaccines



NBDS= National Board for Drug Selection
NCDRC= National Center for Drug Control & Research
KIMADIA= State company for medicine importation & marketing
*Based on WHO Emergency Use Listing Guideline (attached

Traceability of Vaccines in the Context of the COVID-19 Pandemic:

Once the vaccine arrives and is released, MOH will ensure the distribution of the vaccines all over the country according to the need. Efforts will be made to ensure tracking of every vaccine batch from the first step in the airport once the shipment arrives until they are distributed and administered at each vaccination site. Vaccination type, manufacturer, expiration date and quantity will be tracked and recorded to maintain traceability through VSSM (Vaccine Stock Supply Management), In addition, the digital registry or platform being developed will include record of the vaccine type, manufacturer, batch number etc,. At the vaccination site, information will be collected through Kobo collect tool box, to be presented on a dashboard (power BI) [WHO support] to the health authorities.

3- Planning and coordination of the introduction of the vaccine:

1. Completion of the required approvals for the adoption of the vaccine and its introduction to the Republic of Iraq.
2. Establishment of committees responsible for the introduction and adoption of the vaccine:

Based on the recommendations of the World Health Organization (WHO) in the model of the National Plan for the Dissemination of The Vaccine Of COVID-19 (NVDP), which was published on their official website and based on the tool to assess the readiness of countries (VIRAT/VRAF 2.0), specialized committees were established for the introduction and adoption of vaccines, therefore official approvals for the formation of these committees has been obtained. These committees will function as committees for the introduction of emergency vaccines. There are three committees at the present time (organizational structure and the functions and duties of these committees are mentioned in (Appendix 6 a,b), established committees are:

- a) National Coordination Committee (NCC).
 - b) National Technical Working Group (NTWG)
 - c) Inter-Agency Coordination Committee (ICC)
3. The plan was presented in full along with associated documents to the National Coordinating Committee (NCC) for the introduction of emergency vaccines and approval for implementation was obtained.

4. The Inter-Agency Coordinating Committee (ICC) coordinates between the committees and agencies for the introduction of emergency vaccines to implement all the activities of this plan as well as with other committees and stakeholders.
5. Assure the appropriate storage capacity within the standard temperatures in all vaccine storage areas and in the vaccination sites (health centers or hospitals), each health directorate will coordinate with the State Company for the Marketing of Medicines and Medical Supplies (KIMADIA), to secure a means of transporting the vaccine within the vaccine supply chain.
6. For the vaccine produced by Pfizer/ BioNTech, the supplier will be responsible for delivering its vaccine shipments from the port of arrival to the vaccination sites and in line with the plan prepared in advance to distribute the vaccine in coordination with the health directorates.
7. After delivering of the vaccines to the allocated final destinations, Technical Affairs Directorate will work on the required measures to release the vaccine for use.
8. Establishment of committees at the level of the health directorates to follow up all stages of the delivery of the vaccine to the beneficiaries, and to prepare the necessary plans to organize the work in the identified vaccination sites through which the vaccine will be given to the beneficiaries and all related logistic issues.
9. Meeting was held with the partners (national and international) to explain the content of this plan and to clarify the probability of providing any possible support from them (material or technical).
10. Coordination with the crisis cell, security forces, civil society organizations, related public institutes, places of worship and schools to facilitate the vaccination of target groups and related logistical preparations and media campaigns.
11. More than 650 health facilities across Iraq (hospitals and primary healthcare centers) have been identified, and the list of these vaccination outlets is listed in (Appendix 7).

Ministry of Public Health

National Coordination
Committee (NCC)

NITAG (TWGs)

ICC

Sub National coordination

Formation of committees at the level of the governorates/districts to follow up all stages of the delivery of the vaccine to the beneficiary, and to prepare the necessary plans including the identification of the vaccination sites

4) Resources and Costing support:

A simplified top-down approach was used to estimate the costs related to vaccination and deployment with support of the World Bank using the COVAX Resource Estimates Calculator (by scenario).

The core indicators describing the health financing context in Iraq are outlined below:

Gross Domestic Product per capita (US\$)	\$5,955
Current health expenditure per capita (US\$)	\$239
Domestic general government health expenditure (% of current health expenditure)	48%
External health expenditure (% of current health expenditure)	1%
Domestic general government health expenditure per capita (US\$)	\$115
External health expenditure per capita (US\$)	\$1

The costs estimate of deploying the COVID-19 vaccine that are presented below were aligned bearing in mind the various stages of vaccine allocation to the country and the identified target populations, and a were conducted in wide consultation with stakeholders.

The main assumptions used to generate the costs to reach 30% of the Iraqi population are:

Population: To specify the country context, target populations, delivery parameters, and vaccine supply the latest population census data was used for 2021 is 41,190,700 and 2022 - 42,248,900 (Iraq Statistics Agency).

Vaccine Quantity: The vaccine quantity was calculated assuming two doses per person for an estimated 12,357,210 people (30% of the national population) with approximately 5% wastage is 25,950,141 doses.

Vaccine Cost: dose through COVAX: The price per dose for self-financing countries is \$10.55 which brings the vaccine cost to 273.8 million USD. The vaccine procurement process assumes that syringes and/or needles as well as shipping costs are included as part of the procurement price.

In-country deployment Cost: The cost of deploying the vaccine to the point of service include service delivery (\$1.38 per dose), supply chain (\$0.59 per dose) and climate-friendly cold chain storage (\$0.39 per dose) comes to a total of 58.4 million USD. These suggested unit costs per dose were modeled data provided by the WHO and WBG COVAX costing group and it assumes an estimated inflation rate to cover investments in cold-chain storage.

The figures below in Table 1 below are approximate and based on the latest available data. The MoH will be reviewing and updating the budget figures regularly using more accurate country specific figures.

Table 1 Estimated Quantity and Cost of Vaccine Deployment

Coverage	20%	30%	50%	70%
Target population	8,238,140	12,357,210	21,124,450	29,574,230
Quantity of vaccine doses	17,300,094	25,950,141	44,361,345	62,105,883
Vaccine cost	\$182,515,992	\$273,773,988	\$468,012,190	\$655,217,066
Service delivery cost	\$22,720,790	\$34,081,185	\$58,261,233	\$81,565,726
Supply chain cost	\$9,737,481	\$14,606,222	\$24,969,100	\$34,956,740
Climate-friendly cold chain	\$6,491,654	\$9,737,481	\$16,646,067	\$23,304,493
Total Cost	\$221,465,918	\$332,198,876	\$567,888,589	\$795,044,025
Cost per person vaccinated	\$26.88			

After all the administrative and preparatory procedures have been completed and appropriate plans are drawn up for the introduction of the vaccine the government will work on securing financial resources to cover the following needs:

- 1) Purchase of the vaccine from the manufacturer and related financial details according to the terms of the contract with the manufacturer.
- 2) Supply of the vaccine from the manufacturer and the associated shipment, loading, unloading and transportation until the vaccine reaches the designated vaccination sites.
- 3) Meeting the requirements of cold-chain equipment according to the need of each vaccination site and type of vaccine

- 4) Providing various vaccination kits from vaccine preservation and transport boxes, vaccine racks, ice packs, , solvents, shock medication ,personal protective equipment and more.
- 5) Documenting vaccine data at all levels such as printing special records, special vaccination cards, and monitoring of possible side effects after vaccination, portable tablets, creating an electronic authentication platform or program and related to it.
- 6) Training of the staff included in the implementation of the plan in all categories and at all levels, medical staff, health and nursing staff, administrative staff and each of them according to the task to which they will be assigned.
- 7) Implementing a broad media campaign to publicize the vaccination campaign , its importance, target groups and possible side effects, and determine the location and time of vaccination of the target groups, in coordination with the Department of Health Promotion, before the implementation of vaccination to beneficiaries at least two weeks, and through the use of all available means (satellite channels, radios, newspapers, publications, social media) or (seminars, social activities) taking into account appropriate preventive measures.
- 8) Providing the logistical needs of the terminals, outlets, vaccination teams and supervisory teams for all the vocabulary of the vaccination process and supervision.

4) Target groups and vaccination mechanisms:

Because of the nature of the spread of coronavirus, which affects all ages and all categories, the general public must be vaccinated (unless there is any contraindication for vaccination with the individual), and based on the data available at the moment we need a high percentage of vaccine coverage in the community to achieve population immunity (60% minimum) through which the virus can be eliminated, and this can also be updated with sufficient data.

Iraq seeks to vaccinate 60 percent of the total population. This includes both citizens and non-citizens residing in Iraq. The NCC technical group assumed the task of identifying high-risk population to receive the COVID-19 vaccines given the doses reserved for Iraq (either via COVAX or bilateral agreement) and possible shortages in supply worldwide. Vaccine distribution by priority will depend on evidence-based criteria to pinpoint those at risk of severe infection or exposure. Distribution will be subject to several variables including supplies, type of vaccines, public acceptance and the logistics associated with introducing mass vaccination.

As Iraq is currently in the epidemiological scenario of COVID-19 community transmission, and given the limited but gradually increasing supply categorized, initial focus will be on reduction of morbidity and mortality, focusing on critical health staff and elderly as well as those with chronic diseases or other co-morbidities or people live in deprived areas. Depending on the availability of vaccine, selection will then be expanded to focus on reduction in transmission to further reduce disruption of social and economic functions. A risk-and age-based approach for prioritization of

COVID-19 vaccine target groups will be adopted with the aim of ensuring just, efficient, and timely vaccine distribution to all eligible candidates willing to be immunized based on the below principles adapted for the Iraq situation:

- The WHO SAGE values framework;
- The WHO SAGE prioritization roadmap;
- The fair allocation mechanism for COVID-19 vaccines through the COVAX Facility

Accordingly, Iraq prioritizes the high-risk populations through a multi-phase roll-out plan. Certain groups in society, often between the ages of 18 or more, depending on the type of vaccine, and the difficulty of obtaining sufficient doses to cover the country's current need due to the global demand for a vaccine, therefore, the risk groups were classified as shown in the table below as being more susceptible to infection and severity of infection, with the remaining groups being provided later (the numbers or target groups below are adjustable):

T	Target group	Approximate number
1	Staff working in the field of health (within or outside the Ministry of Health with all their job titles)	500,000
2	People over 50 years of age	4,500,000
3	People with chronic diseases	4,000,000
4	Members of the security forces (all of them)	1,500,000
5	Mostly Deprived population, Displaced, refugees in the camps	500,000
6	People with cancers, immunodeficiency and hereditary blood diseases	50,000
7	High-risk occupations: (teaching staff, media professionals, workers in social care homes and prisons (orphanages, nursing homes ...) Workers at border crossings, airports and train stations, restaurant, prison inmates and state house inmates.	1,500,000

- According to current estimates based on the Ministry of Health's 2019 annual report and the minutes of the ministerial committee meeting, which was previously formed by the ministerial order of the issue (D.A.M.5/7/7/6016) on 23 June 2020 to calculate the risk categories of Covid-19 disease ([Appendix 8](#)), the total of the above categories is about 12,550,000 people.
- The above ministerial committee adopted a set of criteria in selecting the categories covered and setting priorities based on the guidelines of the Expanded Immunization program in Iraq, including:
 - o **Human rights:** Based on the commitments of the Government of Iraq to the decisions of the Public Health Association, immunization is a human right.

- **Justice and Equality:** All vaccines and supplies covered by the National Immunization Program must be provided free of charge to all target groups residing in Iraq, regardless of gender, race, religion and belief, who are considered eligible to receive vaccines according to the recommended schedule.
 - **Universal health coverage:** Immunization services must be provided as the part of the comprehensive health package and for the entire population equally.
 - **Based on available scientific evidence:** Decisions will be based on scientific evidence, pharmaceutical vigilance data and the decisions of the scientific institutions.
 - **Reciprocity:** To assess the efforts of groups those have taken additional risks and burdens for the benefit of the community to respond to the Covid-19 pandemic and give priority to vaccination.
- The government has ensured that about 20 percent of the vaccines are available. (COVAX facility in addition to the amount enough for about 700 thousand people through Pfizer, it is also seeking to secure the rest of the quantities through bilateral negotiations with vaccine manufacturers.
 - The priority is to vaccinate the health care workers (affiliated with the Ministry of Health with all their job titles including members of health Facility Protection Services (FPS), retirees and private sector workers), as they are classified into three subcategories according to contact with COVID-19 patients or if they are part of efforts to combat Covid-19 (high risk, medium risk, low risk), and the priority among these categories is for workers with chronic diseases. The vaccination dates of these groups are organized by their health institution (it is preferable to put an interval between each group of employees in the same institution or unit by at least 72 hours).
 - Persons over 50 years of age: they are also divided into three subcategories (over 70 years, 60-70 years, and 50-60 years of age) and priority is given to people with chronic diseases (unless there is a barrier to vaccination as recommended by the manufacturer).
 - Individuals with chronic diseases (of all categories) are classified as priority and as follows: (those who have more than two chronic diseases, those with only two chronic diseases, and those with only one chronic disease).
 - Almost all persons with comorbidities in Iraq have a medical card from Popular Medical Clinic Directorate, and if one of them did not have any card, he/she should bring his medical reports that verify his disease, else it depends on the physician decision inside the vaccination port)
 - Members of the security forces (in all categories), where priority among this category is for people with chronic diseases (unless there is a barrier to vaccination as recommended by the manufacturer).
 - Security staff were categorized into 3 groups according to contact with risk as A- High Risk: in direct contact with people (like security of governmental facilities, at check points, Traffic

police...) B- Intermediate Risk (at barracks, work in groups...) C- Low Risk (Other as administrative staff..)

- People working in professions at risk of exposure like teaching staff in educational institutions and workers in nursing homes (nursing homes, orphanages, prisons) and other social facilities (including media professionals), priority among these groups is for people with chronic diseases (unless there is no objection to vaccinating them according to the manufacturer's recommendations).
- High-risk occupation workers at border crossings, airports and train stations, aircraft crews and professionals requiring direct contact with citizens, prison inmates and state homes.
- People with chronic diseases outside the above categories (hypertension, diabetes, asthma, etc.)
- People with cancers, immunodeficiency and hereditary blood diseases (outside the above categories) unless they are vaccinated according to the manufacturer's recommendations.
- Displaced persons and refugees living in camps who are over 18 years old according to the recommendations of the manufacturer, priority among these groups is for people with chronic diseases (unless there is no risk of vaccination as recommended by the manufacturer).
- At risk members of Iraqi society are among other groups which may be considered for inclusion.
- Community influencers (politicians, media professionals, community leaders, religious figures, celebrities...etc.) may take advantage to be vaccinated in early phases (mainly Phase 1 A or B) because they may influence and encourage people to be vaccinated and then the community demand for vaccination will increase.
- Based on the above prioritization the following phased plan is suggested for implementation of vaccination with available vaccine quantities. GOI will cover 20% of the population through COVAX self-financing (Committed Purchase Agreement), while the financing from the World Bank will cover an additional 8% of the population by procuring 1.5 million doses (covering 2% of population) of the Pfizer-BioNTech vaccine as well as 5.1 million doses (covering 6% of the population) from COVAX or direct supply agreements with manufacturers:

Phase	Category/population group	Population number	Risk category	Percentage of population
Phase 1 A	Health workers	100,000	High risk	0.2%
	Elderly	450,000	>70 y	1.1%
	People with chronic disease	750,000	>2 chronic diseases	1.7%
	Cancer and immune-deficiency patients	30,000		0.07%
Phase 1 B	Health workers	300,000	Moderate risk	0.7%

	Elderly	1,350,000	>60 and < 70 y	3.2%
	People with chronic disease	1,250,000	2 chronic diseases	3.0%
	Patients with hereditary blood diseases	20,000		0.03%
Phase 2	Health workers	100,000	Low risk	0.2%
	Elderly	2,700,000	>50 and < 60 y	6.5%
	People with chronic disease	2,000,000	1 chronic disease	4.8%
	Security personnel at high risk of exposure to cases	100,000	High Risk	0.2%
	Displaced populations/refugees living in camps	500,000	Moderate risk	1.2%
	Social care staff and residents, prisons staff and prisoners	200,000		0.5%
Phase 3	Security personnel at risk of exposure to cases	900,000	Moderate risk	2.2%
	People working in professions at risk of exposure	300,000	age >40 - <50 years	0.7%
Phase 4	Security personnel at risk of exposure	500,000	Low risk	1.2%
	People working in professions at risk of exposure	1,000,000	age <40 years	2.4%
		12,550,000	TOTAL	30%

Note: Total population in 2021 is estimated at 41,190,700 (Iraq Central Statistics Agency).

Depending on vaccines' availability, shelf life, community demand and other limitations that may face the vaccination process, the above table may be modified and some categories may be preceded by others or interchangeability may occur among them.

Instructions for target groups:

- Strategies for delivering the vaccine to beneficiaries:

The strategies for delivering the vaccine to the beneficiaries depend on several factors, including the characteristics of the vaccine itself, the target groups and the nature of the geographical area. Ministry of Health will provide vaccines through fixed vaccination sites, at least in the first stage, and can later study the possibility of providing the vaccine to the beneficiaries through mobile sites based on the specifications of the vaccine itself and according to the rules and instructions allocated to it, accordingly vaccination sites were selected as follows:

- In hospitals (teaching hospitals) dedicated to Pfizer's vaccine as it needs special storage conditions that are better available in hospitals than other health institutions.

- More than 600 health centers across Iraq dedicated to vaccines that need to be stored in ice-lined refrigerators.
- The names and locations of the vaccination sites by provinces are mentioned in a separate list ([Appendix 7](#)).
- **Strategies to reach target groups:**
 - Pre-prepared lists of target groups with a special database such as members of the Ministry of Health, members of the security forces, people with cancer, immunodeficiency, displaced persons and refugees, these lists are prepared based on the priorities.
 - Pre-booking through an electronic platform prepared for this purpose through which the type of target groups, their locations and the vaccination sites they choose to vaccinate in, are determined and distributed according to priorities based on the classifications of risk factors.
 - Coordination with the Commission of Media and Communications (CMC), cell phone companies and other supporting entities to explore the possibility of sending SMS messages to remind beneficiaries of the date of the first and second dose.
 - Investment of the Vigiflow program to monitor possible adverse events following immunization.
 - Assign a phone number to link beneficiaries in each site (preferably a drug monitoring member) and print this number on the vaccination card, to facilitate the follow-up of possible side effects after vaccination, so that citizens can communicate with the health institution through this number if necessary

Members of the security forces:

- They are vaccinated through selected vaccination sites with the same mechanisms, after providing proof that they are security forces members, based on the risk classification provided above.
- This will be done in coordination with military medical centers and hospitals before the implementation, and the possibility of providing those medical institutes with vaccines and vaccination requirements explored after they provide the required numbers, ensuring that the Ministry of Health will be provided with a daily report about the beneficiaries of vaccinations, according to agreed conditions.
- Coordination between the health directorates and the security forces management to set certain dates that are agreed in advance, members of these forces will be vaccinated at the nearest health facility (either by teams going to the locations of those security forces or inside the health institutions on fixed dates), after bringing proof that they are members of the security forces.

Elderly :

- They are vaccinated through fixed vaccination sites in primary health care centers, preferably starting from the week after the completion of the vaccination of all the staff of the health center.
- The central committee will explore the possibility of :
 - establishment of an evening vaccination team (one or more) in the health center to vaccinate the elderly people who visit the popular medical clinic in the area, provided that the availability of trained staff and the accuracy of documentation to ensure that health staff and workers follow up on the date of the second dose or in the event of AEFI.
 - Coordination with places of worship or schools to determine days and dates for the vaccination of the elderly.

Patients with immunodeficiency disorders, cancers and hereditary blood diseases:

- Those patients will be vaccinated by the vaccination teams stationed at vaccination sites after they prove that they are affected by those diseases.
- The central committees at the health directorates can coordinate between the specialized centers treating those patients and health center to vaccinate these groups by organizing special appointments for them or setting certain days for their vaccination, preferably after the completion of the vaccination of the previous categories.

Displaced persons and refugees (within camps only):

- They will be vaccinated by fixed vaccination teams within the nearest health district or the nearest health center after providing proof that they are displaced or have refugee status, this is according to the approved prioritization, the vaccination process to be done after the vaccination of the above-mentioned categories, and according to time schedules.
- The central committees in the health district can use fixed or mobile MoH medical clinics located within the camps or health institutions or the sites of supporting organizations and NGOs located inside the camps provided that all the logistical requirements for vaccination are available according to the type of vaccine, and that vaccination will be under direct supervision of the health district or the health directorate and in coordination with camp directors and according to the approved priorities, after the completion of the vaccination of all previous categories.

Other categories (high-risk occupations):

- They are vaccinated by fixed vaccination teams within the health centers after providing proof about their type of work and after all the previous target groups have been vaccinated.

- The central committees at health directorate can give the required instructions to vaccinate these categories after the completion of vaccination of all previous categories and according to priorities by preparing mobile teams from the nearest health center provided that all the logistical requirements for vaccination are available, according to the type of vaccine. Vaccination should be under direct supervision of the health district or directorate.

Important note: All requirements to ensure that the vaccine is kept from being damaged must be taken into account within the standard temperatures recommended by the manufacturer and according to the type of vaccine when implementing any event to vaccinate any of the above categories, health directorates shall bear all legal and administrative consequences should the vaccine be damaged or wasted..

The GOI plans to use the security forces for logistics to protect the COVID-19 vaccine supply against possible theft, fraud, ransom, etc. The security forces might also volunteer professionally trained vaccinators as needed. All vaccination-related activities carried out by the Ministry of Defense and the Ministry of Interior under the project shall be under the control of MOH.

Vaccination registry:

The MOH developed a digital registry for vaccination with technical support from WHO and National Partners. Online preregistration will be a prerequisite for the selection of vaccine recipients. It will help determine demand for vaccination and guide the selection of recipients based on the prioritization scheme.

Individuals will be able to preregister directly in the online platform. To ensure access, staff at vaccination centers will also be able to register on behalf of the recipient. Preregistration for healthcare workers will be facilitated by medical institutions and professional orders. The front-end (user-facing) preregistration system and the backend database will require the entry, handling, and/or storage of personal information, and they will be afforded the highest possible data privacy, security/cybersecurity, and redundancy measures. Specifically, the front-end system should keep mandatory fields at a strict minimum (e.g., name, ID number, date of birth, phone number, town, comorbidities) and avoid the use of open-ended and optional fields, and the backend database should include stringent password-protected access for designated administrators only, and stringent limitations on the transmission of personal information to non-administrators. Every effort will be made to reduce paper trails, and confidential storage cabinets and proper shredding and disposal should be the norm. All vaccination centers must have a reliable Internet connection to be able to use the platform for vaccinations. The platform will have the following phases corresponding to the functionality to be developed.

Phase 1: Preregistration

It is critical to have all the data on the vaccinated population in one dataset, in order to avoid fragmentation and ensure proper follow-up and aggregate data analysis and reporting. All residents of Iraq will be eligible to register to get the COVID-19 vaccine; they could either:

- 1) self-register through the platform or
- 2) if applicable, directly register through the health centers

The preregistration module is developed in Arabic and Kurdish, a dashboard will be available for the public to see progress with preregistrations.

Phase 2: Appointment Scheduling

After the selection of priority groups based on the national deployment plan, the platform will assign selected recipients to the nearest (or desired) vaccination center and alert them on the date and time of vaccination by SMS. To reduce no-shows, the platform will provide users with a 48- or 72-hour window to select an appointment slot. Appointment reminders and rescheduling will be possible. The vaccination center will be able to track and follow up with the vaccinees through the new system and confirm the schedules for vaccination to minimize vaccine wastage and optimize opportunities for vaccination.

Phase 3: Vaccination

On the date of vaccination, the user will fill out a pre-vaccination checklist and give consent to be vaccinated. Upon vaccination, the center will upload vaccine information – such as batch and lot numbers – to the platform. The platform will also provide the user with a vaccination card. A public dashboard with details about vaccination progress nationwide will be available.

Phase 4: Tracking Adverse Events Following Immunization (AEFI)

The individual will be monitored for adverse events for 15-30 minutes following vaccination. During that time, a community healthcare worker will provide the person with the vaccination card – including the system-generated identification number – and educate the patient on the side effects of the vaccine and AEFI reporting strategy.

There is a need for a system that enables individuals who received the vaccine to self-report any side effects that might be developed after receiving a dose of the vaccine. The individual will be able to report daily (on same platform) and for up to 7 days and then once weekly for two weeks. The self-reporting is a brief safety check-in that will include basic multiple-choice questions, such as:

- How are you feeling today (good, fair, poor)?
- Fever check (yes, no)
- Symptom check on injection site (pain, redness, swelling, itching),

- General symptoms (chills, headache, joint pains, muscle or body aches, fatigue or tiredness, nausea, vomiting, diarrhea, abdominal pain, rash besides injection site). A separate box will be included for further symptoms and health conditions not in the list.
- The final question will assess the health impact, i.e., if any of the symptoms or reported health conditions cause the patient to be unable to work, perform normal daily activities, or seek healthcare.

Vaccine Administration Guidelines

- Vaccines will be accessible on rolling basis; depending on vaccine availability, delivery schedules and identifications of groups to vaccine as mentioned above.
- All individuals 18 years and above willing to be vaccinated will be offered the vaccine according to the prioritization of target population.
- Individuals 16-17 years of age, and willing (depending on vaccine in use), will be offered the vaccine after obtaining their parents consent.
- Promote – choice: vaccines are not mandatory but will be offered to all above 18 years of age; these individuals have the right to accept or defer.
- Empowerment: to help individuals make the right decision concerning vaccination through explaining the need for vaccines and the benefits as well as adverse events and contraindications.
- The recipients of the vaccines purchased through the MoH will not be charged for the price of the vaccine.
- All those residing in Iraq and qualify for vaccination (above 18 years) will be included in the immunization initiative irrespective of nationality.
- Any private purchase of vaccines will be done in coordination with the MOH.
- Any vaccine donation will be accepted in coordination with the MOH and the vaccines administered to be included in the national campaign.

Vaccination Sites

The vaccination process will start with selected vaccination sites and the number of sites is expected to increase based on quantities of doses received, the number of people registered through the registration platform, and as more vaccines are delivered to the country.

Several factors were taken into account in choosing these vaccination sites, such as:

- Regional and demographic distribution;
- Address must be known and easy to reach;
- Having the ability to adapt to weather changes;
- Presence of appropriate entrances and exits in each site;

- Respect of the rules of social distancing between people standing in lines waiting for their turn;
- Parking lot allocation, if required;
- Providing sufficient space and rooms for vaccination (more than 8 stations);
- Allocating a space for registration and preparation of necessary documents;
- Establishing a clinic to treat allergic reactions;
- Cooling and heating system;
- Waiting rooms, observing the rules of social distancing;
- Hand washing and installing sinks for this purpose;
- A room to monitor people after vaccination;
- Cooling devices (ultra-low temperature, refrigerators, freezers, etc.);
- Power supply, alternative support sources (i.e. UPS), and electrical sockets in vaccination rooms and offices;
- ICT-support (computers, internet connection);
- IPC equipment, and PPEs;
- Waste disposal: disposal of medical waste and sharp tools;
- A room for storing medical wastes;
- Willingness to be a vaccination center and to administer the vaccine without processing fees.

The vaccination unit will consist of a waiting room, a vaccination room and an observation room. The setting should allow for physical distancing measures (1.5 meters between individuals), especially in the waiting room, although crowding is not expected since all vaccine recipients will be admitted based on pre-scheduled appointments. The waiting room will have a waiting/registration area. The vaccination room will be appropriately equipped for the provision of immunization services including the required furniture, cold chain, hand washing stations and consumables whereas the observation room will consist of a resting area for vaccine recipients.

Microplanning

A detailed micro plan will be prepared to identify, by vaccination site, the human resources, supplies as well as daily expected vaccination doses to be covered at each site. A scenario is suggested for human resource team required, patient flow at vaccination site, expected capacity of each vaccination site and timing needed at vaccination site for each individual to receive vaccine.

Vaccine Recipient Journey

In order to enable and simplify understanding of the steps to be followed by a vaccine recipient, the journey of the vaccine recipient has been depicted as follows:

I. Pre-vaccination

- Individuals fill pre-registration form via the designated online digital platform, or on site registration;
- Individuals stratified by risk according to national prioritization scheme;
- Individuals contacted either by SMS to schedule date, time and place of vaccination (place to be determined by MOH to reduce traffic on certain centers);
- Patient alerted of booking date few days beforehand with designated ID number.

II. Arrival at Vaccination Site

- Patient arrives during specified time slot (5-10 min capacity for early/late arrivals);
- Traffic flow managed by administrator clerk;
- Patient directed to hand sanitizing station at entrance;
- Administrator clerk verifies patient information data, registers patient and directs him/her to designated seat in the waiting area.
- A pre-vaccination checklist for COVID-19 vaccines has been developed based on CDC form (Appendix 9) to determine if there is any reason that will prevent the individual from receiving the vaccine at the assigned day, structure for the whole process is attached (Appendix 10).
- Prior to administering the vaccine, health care worker will thoroughly explain the risks and benefits of the COVID-19 vaccine to ensure that the beneficiary understands risks and benefits of vaccination.

III. Vaccination

- Patient called in to the immunization clinic;
- Patient confirms details with personnel (Full name, individual ID while vaccinator prepares the vaccine (vial storage, thawing, dilution and handling (if needed) can be found in (Annex for guidance on use of Pfizer vaccine);
- Patient vaccinated;
- Patient is provided with a hard copy of the vaccination card (to be distributed by MOH to vaccination centers) and **an electronic copy to be** used at any time, especially for travel purposes and to be in English to be internationally used;
- Patient instructed to move to observation area.

IV. Post- Vaccination

- Patient is counseled by nurse on expected side effects;
- Once patient passes the 15 minutes waiting time, he/she is cleared to depart vaccination center;
- Patient with known allergies to vaccines will be asked to wait for 30 minutes;
- Follow up text or call to confirm date of subsequent injection/second dose;
- Patient will be instructed to report any potential adverse events to the vaccination site for COVID-19 vaccine initiative or on the digital form

- Immediate Measures in Case of a Severe Allergic Reaction/Anaphylaxis including Recognition of Anaphylaxis have been developed.

Time allocated for every step:

- Registration:5 minutes
- Waiting in waiting room: 5 minutes
- Vaccination: 5 minutes
- Observation room: 15 minutes for all people, those with previous history of allergies to be observed for 30 minutes.
- Instruction before leaving vaccination center about self-reporting of adverse events: 5 minutes

Infection Prevention and Control:

The MOH plan is consistent with WHO recommendations the plan and includes the use of standard precautions involving the following:

- Hand hygiene
- PPE according to the risk
- Respiratory hygiene (etiquette)
- Safe injection practices, sharps management and injury prevention
- Environmental cleaning
- Safe handling and cleaning of soiled linen
- Safe handling, cleaning and disinfection of patient care equipment
- Waste management

In every PHC there is a focal point for infection prevention control program (IPC programme), responsible for monitoring and improving the IPC measures. Training was conducted to all focal points (with the support of UNICEF). At the same point there is Guideline for IPC measures in light of the Corona pandemic, which is directed to primary health centers. ([Appendix 11](#)). The program is part of MOH duties and responsibilities and there is no specific fund allocated for this program.

Adherence to infection prevention and control (IPC) guidelines is key to prevent the transmission of COVID-19 through vaccination operations. With the exponential increase in COVID-19 cases, it is crucial to establish strategies aiming at preventing the circulation of the virus through vaccination.

As vaccination teams will be in direct contact with vaccine recipients, disinfectants and PPEs are required as per WHO recommendations. The required PPEs will depend on the position and duties of team members:

- Sink and soap and water to be available. In addition to 2 hand sanitizers should be available at the vaccination site daily: 1 for personnel use and 1 for vaccine recipient use.
- One surface disinfectant should be available at the vaccination site daily.

- Physician: 4 masks per day (masks to be changed every 4 hours or when it becomes damp, whichever comes first), 1 reusable face shield, gloves (1 pair for every vaccine recipient), disposable gown (1 gown per day).
- Vaccinator Nurse: 4 masks per day (masks to be changed every 4 hours or when it becomes damp, whichever comes first), 1 reusable face shield, gloves (1 pair for every vaccine recipient), disposable gown (1 gown per day).
- Registered nurse: 4 masks per day (masks to be changed every 4 hours or when it becomes damp, whichever comes first), 1 reusable face shield, gloves (as needed), disposable gown (1 gown per day).
- Data entry clerk: 4 masks per day (masks to be changed every 4 hours or when it becomes damp, whichever comes first), 1 reusable face shield, gloves (1 pair for every vaccine recipient), disposable gown (1 gown per day).
- Non-clinical observer: 2 masks and 2 pairs of gloves per day (one for every site visit at the provincial level for a total of 2 visits).
- One biohazard plastic bag per site will be available daily for disposal of used PPEs and other infectious medical waste.
- Sharp boxes (plastic one for sharps and one for used vials)
- Subsequently, PPE requirements are estimated based on the number of vaccination days and human resources required. A wastage rate of 2 percent will be added to the calculated numbers.

The below activities are crucial to minimize COVID-19 transmission during vaccination:

- I. Ensuring that vaccination personnel are exempt from COVID-19: All personnel involved in vaccination should theoretically be screened for COVID-19 through clinical screening (daily temperature check and symptoms check). Any suspected case will be replaced immediately and will be referred for PCR testing and adequate care. If a case is confirmed among vaccinators, contact tracing and follow up of those vaccinated will be conducted as per MOH protocols.
- II. Vaccine recipients will be screened for COVID-19 clinical symptoms prior to administration of the vaccine. Any suspected case will NOT be vaccinated and will be referred for PCR testing and adequate care. Individuals who were infected with COVID-19 will be allowed to receive the vaccine after at least 6 months of their infection.
- III. Instructions related to physical distancing requirements and the flow of operations will be explained in a document that will be shared with vaccination sites and self-explanatory posters will be hung at the entrance to ensure maintenance of at least 1.5 meters distance between vaccine recipients within a queue or in the waiting area.
- IV. Chairs and desks in direct contact with vaccine recipients should be disinfected after each use.
- V. An IPC section will be included in the intra-vaccination monitoring form to monitor the adherence of personnel to the required measures.

Vaccine vials used should be disposed in a separate bin, for the specific disposal, and monitoring of vaccine use purpose. All other IPC/ PPE material should as well be disposed as per WHO waste management guidelines.

. 5) Supply Chain Management (cold chain equipment, safe disposal of immunization waste):

An effectively managed supply chain is crucial to the successful deployment of COVID-19 vaccines. COVID-19 vaccine storage and distribution are important activities in supply chain management, as different staff and organizations (hospitals, health care centers, etc.) are generally responsible for handling, warehousing and distribution. Vaccines may be exposed to various risks at different stages of supply i.e. during receiving, storage, distribution, transportation and repacking. Hence, it is imperative to protect supply chains and maintain vaccines' integrity and safety.

It is worth noting that MOH with partners (UNICEF and WHO) has conducted the Effective Vaccine Management (EVM) 2.0 assessment which assess all elements of the vaccine supply chain including the cold chain.

This guideline aims to be applicable for all participating entities and institutes, starting from the moment the vaccines arrive in Iraq, to their storage, distribution, administration, and disposal.

It is worth noting that MOHE with partners (UNICEF and WHO) has conducted the Effective Vaccine Management (EVM) 2.0 assessment which examined all elements of the vaccine supply chain including the cold chain. The EVM will cover the following criteria: vaccine arrival, temperature management, storage capacity, infrastructure, maintenance, stock management, distribution, vaccine management and waste management.

EVM 2.0 Findings

EVM 2.0 assessment was implemented in Iraq in July 2019 as the first country in the world to implement that assessment through cooperation with UNICEF, WHO and EMPHNET for the purpose of developing the vaccine supply chain system where the evaluation was carried out by international experts.

Iraq was divided into three regions for the purpose of obtaining a more reliable and representative sample as follows:

- Kurdistan region includes health directorates (Erbil, Dohuk, Sulaimaniyah)
- Central and southern region includes health directorates (Baghdad/Al-Karkh, Baghdad/Al-Rusafa, Najaf al-Ashraf, Holy Karbala, Wasit, Babylon, Diyala, Basra, Maysan, Muthanna, Dhi Qar, Diwaniyah)
- Areas affected by conflicts (Nineveh, Kirkuk, Anbar, Salah al-Din)

The sample included Central and sub-vaccine stores, and major and sub-healthcare centers as follows:

Health centers	District Storage	Governate Store	Main Vaccine Store
53	44	17	1

The overall rating for Iraq was 82%, the main vaccine storage received a 90% rating, while the rate by region was as follows:

- Kurdistan region: 72%
- Conflict-affected provinces: 78%
- Central and South Region: 84%

The overall score according to the strategic objectives of the vaccine supply chain (quality, efficiency, availability) was as follows: Quality: 94% Efficiency: 94% Availability: 54%

Roles and responsibilities

Responsible bodies for implementation and supervision are:

- MoHE
- UNICEF
- WHO
- Ministry of Defense
- Ministry of Interior
- Baghdad Operations Command
- Vaccination Sites (Hospitals and other health care centers in Baghdad and Provinces)
- Other governmental and official agencies responsible for follow-up such as local municipalities

A Mapping of roles and responsibilities along supply chain from receipt of the vaccine to administration and disposal will be developed at a later stage. This national plan sets the general frameworks for all relevant aspects.

Procurement and Delivery

In addition to the bilateral agreement with Pfizer, vaccines will be procured from COVAX facility and directly by MoHE for the bilateral agreements.

Necessary vaccination supplies, including syringes, PPE and non-clinical consumables in line with standard procurement procedures, will be procured by MoHE. The list of supplies is provided later in this section.

Vaccine Arrival and Receipt

The port of entry will be Baghdad International Airport. Once the vaccines are custom cleared, they will be transported to the delivery site(s):

- Pfizer vaccine: Pfizer will be transporting the vaccines from the airport to the vaccination sites.. Vaccines will be transported in thermal shippers that keep ULT. Each shipper can hold a minimum of 1 tray (1170 doses) or up to 5 trays (5,850 doses). Each of these shippers has a reusable GPS enabled temperature monitoring device to ensure end-to-end distribution within required temperatures.
- Other COVID-19 vaccines: same transportation strategy as used for other vaccines, the vaccines will be stored at the Central Vaccines Store, then distributed to province stores by refrigerated trucks.

A Vaccine arrival report (VAR) will include data related to the status of the items received at the time of receipt (type of vaccine, the quantity dispensed and matching it with the quantity authorized for delivery, expiry date, making sure not to receive broken or frozen vials and that the packages/cartons are in good condition, and checking as well the status of the Vaccine vial monitor (VVM) if any.

Good Storage Practice (GSP)

The following practices will be taken into consideration when storing the vaccines :

- Availability of adequate cold chain equipment with sufficient storage capacity;
- Follow-up and assurance of the conditions that must be met in the cold chain before storing the vaccines;
- Arranging the vaccines inside the cold chains according to FEFO (First to expire, first out);
- Ensuring that cold chain temperatures are monitored periodically and daily; where possible, by electronic data loggers;
- In the event that the arrival of the vaccine coincides with extreme weather conditions (snow), or in case of failure of ULT at any site, an emergency plan is being prepared in cooperation with the concerned authorities to secure mechanisms to deliver the vaccines to the nearest major storage centers.

Cold Chain Equipment

- High-efficiency cold chain with enough storage capacity must be available according to the appropriate temperature for each COVID-19 vaccine, such as +2-+8 ° C, -20 ° C, or -40 to -86 ° C;
- Availability of temperature monitoring devices within the cold chain in line with the requirements for monitoring the appropriate temperature of the vaccine supply (Temperature monitoring devices/ data loggers); (Reference: HOW TO MONITOR TEMPERATURES IN THE VACCINE SUPPLY CHAIN WHO Vaccine Management Handbook, Module VMH-E2)
- Ensuring the presence of an additional back-up generator in case of power cut.
- A cold chain assessment and rehabilitation exercise is underway to ensure that the following critical conditions are met in the cold chain before storing vaccines.
- The cold chain equipment must be calibrated, clean, and operating with high efficiency. It needs to be fully functional at least 48 hours before the expected vaccine arrival date.
- Cold chain equipment must be kept clean and calibrated regularly.
- Estimating the storage capacity of each unit of cold chain equipment and matching it to the expected quantity to be received.
- Provision of devices to periodically monitor and record devices temperature periodically (data loggers) and real-time temperature monitors;
- Ensure that an additional diesel generator and uninterruptible power supply (UPS) is fully functioning in the event of a power outage or the ability to maintain the temperature for a period of not less than 24 hours until the electrical current is restored or repaired.

Supply Chain Data Management

Objectives:

- Recording the available quantities of vaccine in every warehouse or vaccination site periodically and continuously;
- Inventory control and follow up on vaccines' expiry dates;
- Coordination for the allocation of the proper second dose of the vaccine for everyone;
- Estimating the need to request additional vaccine doses;
- Recording the vaccine usage in each vaccination site;
- Determining the need to reinforce vaccination sites with additional staff;
- Reverse logistics - retrieval and redistribution of vaccine
- Continuous temperating monitoring and recording.
- Monitoring and reporting of consolidated data for decision making and corrective action.

Periodic actions:

- Daily completion of the Stock Card recording of all vaccine movements;
- Daily stock count post vaccination;
- Spot checks conducted by supervisors at national and governorate level.
- Daily recording and logging of temperatures in the cold chain at all sites.
- Daily recording of usage
- Consolidated stock status and consumption reports

Security of the Vaccine

The MoH will ensure adequate security of the vaccine to prevent theft, pilferage etc. Security arrangements will be made at storage centers, during transport of vaccines as well as at vaccination sites to maintain order and prevent attempts by groups or individuals to interfere with the vaccination process and to ensure safety of health staff and vaccine recipients. In addition, MoH will ensure appropriate tracking mechanisms for traceability of the vaccine throughout the supply chain.

The various security forces from MoD, MoI and the Operation Commands in Baghdad and provinces are responsible for implementing and managing the security plan and protecting the vaccine transmission lines, where trained cadres have been provided for this purpose. However, all decisions and control with regards to the storage, transport and use of vaccines.

Biohazards and immunization waste management

COVID-19 response activities and vaccines will have positive impacts as it will improve capacity for surveillance, monitoring and containment of COVID-19. However, it could also cause environment, health and safety risks due to the dangerous nature of the pathogen (COVID-19). Facilities treating patients may also generate biological, chemical waste, and other hazardous by-products that could be injurious to human health. These risks will be mitigated with occupational health and safety standards and specific infectious-control strategies, guidelines and requirements as recommended by WHO and Govt of Iraq legislations. Effective administrative and infectious-controlling and engineering controls would be put in place to minimize these risks.

Medical waste from COVID-19 vaccination campaigns needs special attention. Therefore, all vaccination teams will receive special training on waste segregation at vaccination sites and implement correct transportation of the medical waste to designated facilities for proper disposal along with other hazardous waste.

Operationalizing the Waste Management plan

With reference to the latest guidelines issued by the WHO, UNICEF, Centers for Disease Control and Prevention (CDC) and other scientific references, and the Iraqi environmental and health Laws, regulations, and guidelines. The MoHE will adopt the following measures:

1. Adherence to the instructions regarding the proper segregation of medical waste and the correct way to pack it in appropriate bags and containers, according to the color guide according to the following decrees:
 - **The Law for the Protection and Improvement of Environment No. 27, 2009. This law addresses the following major points:**
 - o The establishment of the Environmental Protection Council/Office which will oversee the implementation of environmental protection across the country;
 - o The environmental protection provisions such as importance of conducting Environmental Impact Assessment for projects that may impact the environment;
 - o The water protection from contamination, air quality protection and control of noise emissions, land protection, ecological protection and hazardous waste management.
 - **Management of Health Facilities Waste Instructions No. (1) for the year (2015):**

These instructions define the health institutions, non-hazard medical waste, Hazard medical waste, infectious waste, chemical waste, pressurized gases cylinders waste, and other hazardous waste. These instructions also outline the integrated methodology and requirements to handle these wastes.

- **Article No.15 from Instruction No.3 for the year 2011” Locations of hazardous waste disposal sites”**

This article specify the specifications of the hazardous waste duping site, location constraint, technical requirements, ground water level, lining requirements, and others

- **Instructions no. 12 of the year 2016: Occupational Health and Safety**

The instructions provide for the enforcement of occupational health and safety provisions at places of work and establish the functions and duties of employers and employees with regard to occupational health and safety. Regulates that all workplaces are to appoint a person in charge of occupational safety and an occupational safety committee. Provides for the appointment and

duties of the person responsible for occupational safety and for the occupational safety committee at each workplace. Establishes the functions and duties of employers and employees with regard to occupational safety.

- **Law No. 6 of 1988 concerning the National Commission for Occupational Hygiene and Safety governs the enforcement of occupational health and safety regulations.**

The Law establishes the duties and responsibilities of employer's regarding occupational health and safety, the functions of safety commissions at places of work, and it regulates the responsibilities and duties of workers with respect to occupational health and safety.

- **Directive No. 4 of 1993 concerning Occupational health, Protection of Workers against Vibration.**

Pursuant to Sections 3 and 105 of the Public Health Act (No. 89 of 1981), it establishes workplace procedures designed to minimize vibration and any harmful effects that workers might be exposed to. It also stipulates the maximum total daily limits for occupational exposure to vibration.

2. In line with WHO Interim Guidance (February 12, 2020) on "Laboratory Biosafety Guidance related to the novel coronavirus (2019-nCoV)", and other guidelines above, the plan will include training of staff to be aware of all hazards they might encounter. This provides for the application of international best practices in COVID-19 diagnostic testing and handling the medical supplies, disposing of the generated waste, road safety, fire safety, and comprehensive OHS plan.

First: Vaccines stored in cold rooms with temperatures between (+2) to (+8) Celsius:

- ❖ **Amount of vaccine: According to the MEMORANDUM of Understanding with the COVAX facility** (for example), the amount of the vaccine is approximately (16 million) doses, which is sufficient for (8 million) people in the target group with two doses per person separated by 21-28 days (or as instructed by the manufacturer).
- ❖ **Diluent: According to the available data, none of the current vaccines require a solvent, and if there is a need for solvent, each vaccine should have one vial of solvent plus 10% as Reserve balance.**
- ❖ **Syringes:**
 - A- Vaccine delivery swings:** considering that the dose size is often (0.5 ml) per person, this requires the provision of AD syringes for this dose (0.5 ml) To facilitate the immunization process. A reserve balance of 10% should be provided as wastage rate with the total quantity.

B- Dilution syringes: According to current data, there is no need for diluting solution if the vaccine is a liquid ready for injection, and if there is a vaccine that needs to be dissolved, the number of these syringes should be identical to the amount of diluent or vials by the size (2 ml), (3 ml) or (5 ml) depending on the amount of diluent required.

❖ **Destruction boxes (safety boxes):**

According to WHO recommendations, the number of boxes should be limited to one box per 100 vials, with a reserve of 50 percent at minimum.

The table below shows an example of the amount of supplies required above depending on the size of the potential vaccine vial:

T	Supplies required	One-dose vaccine vial	5-dose vaccine vial	10-dose vaccine vial	Observations
1	Vaccine doses	16,000,000	3,200,000	1,600,000	There's a load of some vaccines with 4 or 8 doses and others.
2	Diluent	17,600,000	3,520,000	1,760,000	If the vaccine needs a diluent with a 10% reserve rate
3	Vaccination Syringe	17,600,000	17,600,000	17,600,000	Mostly (0.5) ml self-deactivation
4	Diluting Syringes	17,600,000	3,520,000	1,760,000	If the vaccine needs a diluent with a 10% reserve rate
5	Safety boxes (vaccines without diluent)	264,000	264,000	264,000	One for every 100 syringes, with the addition of a reserve amount (50%)
6	Safety boxes (vaccines with diluent)	290,400	290,400	290,400	

❖ **Cold chain equipment:**

The need for cold chain equipment depends on several factors, including the size of each single dose, the size of the vaccine vial, storage temperature, the need for diluent, the number of vaccine stores and vaccination outlet and quantity received per each shipment, etc. Assuming that the vaccine will store at (+2) to (+8) Celsius and by the measurements and sizes described above, and assuming that the total amount of a vaccine will be divided into 4 shipments per shipment (4 million doses), the total need of cold chain equipment in addition to what is currently available is as follows:

Total	Number
105-litre Ice-Line refrigerators	180
75-litre Ice Line refrigerators	444

Total refrigerated rooms with a capacity of 40 m ³ *	2
Vaccine Carrier**	3500
Vaccine Cold Boxes***	1250

* There are currently eight uninstalled cold rooms in the main vaccine store.

** According to forecasting of required quantities for years 2021-2023 and based on gap analysis tool the total quantity required for vaccine carrier is 2425 and adding 1071 vaccine carriers as a buffer stock for emergencies

* ** According to forecasting of required quantities for years 2021-2023 and based on gap analysis tool the total quantity required for cold boxes is 1087 and adding 163 cold boxes as a buffer stock for emergencies

Second: Vaccines that need to be stored in Ultra Low Temperature freezers (Pfizer vaccine for example):

❖ **Amount of vaccine:** According to Pfizer's memorandum of understanding, the amount of the vaccine is about (1,500,525) doses of two doses per person separated by 21 days.

❖ **Solvent:** Pfizer will not process diluents with vaccines, which requires provision by the Ministry of Health in quantities commensurate with the amounts of the vaccine, and the recommended Pfizer vaccine diluent is a preservative-free saline solution, each vial of the vaccine needs (1.8 ml) of it. Each vaccine is supposed to have one diluent vial, and if there is no diluent vials containing this amount, diluent vials of 2 ml or more should be provided, and the amount of diluent required is the same number of vials of the vaccine added (10%) A reserve balance, the total amount of diluent vial is (275,097) vials.

❖ **Syringes:**

A. **Vaccination Syringes:** Since the dose size is (0.3 ml) per person, it requires the provision of auto destruction syringes with a low dead space for this dose to facilitate the immunization process, and if they are not available, they should provide sized syringes (1 ml) or size (0.5 ml) with clear gradients and in both cases require high training and high accuracy to control the amount of vaccine required considering addition of 10% as reserve balance.

B. **Dilution syringes:** Should be identical to the amount of diluent (250,088) syringes, size (3 ml) or (5 ml) with clear gradients.

❖ **Safety Boxes:**

According to WHO recommendations, the number of safety boxes should be limited to one box per 100 syringes, considering minimum reserve amount (50%). Since the

number of give-and-take safety boxes is (1,650,588) and the dilution syringes are (250,088); the total number of syringes will be (1,900,676), so that the number of needed safety boxes is about (30,000) boxes.

❖ **Cold chain equipment:**

Since the Pfizer vaccine needs storage temperatures up to (-80°C) i.e. it needs ultra-freezers, and this type of freezer varies in storage capacity and needs a continuous electricity because any power outage will lead to a rise in frozen temperatures. Specific sites for the storage of this vaccine have been identified, and these sites will be a government hospital (preferably teaching hospitals), knowing that the manufacturer will take care of the transfer of the vaccine from the factory to the storage points (hospitals) directly without keeping the vaccine in the main vaccine store, thus the Ministerial Committee for receiving the Coved-19 vaccine has identified the quantities of super-freezing freezers and vaccine transport equipment required as follows:

Type of equipment	Total quantity required	Observations
Ultra Freezer	50	One freezer per one vaccination site.
Special vaccine carrier for very low temperature vaccine transport (Arktek TM)	40	To transport vaccines from the storage site to remote areas, two vaccine carriers for each health directorate

Other logistical needs include:

Type of equipment	Total quantity required	Observations
RTMD remote temperature tracking device	50 devices	One for each freezer in case the freezer is not equipped with this device
Normal freezer (-20) °C	40	To freeze the ice molds of the vaccine carrier
Protective equipment (padded gloves)	150 pairs	Two pairs for each freezer with extra amount as reserve.

- The preparation in the two examples above is a matter of adjustment according to the plans of the health directorates, procured by State Company for the Marketing of Medicines and Medical Supplies (KIMADIA) in coordination with the Technical Affairs Directorate, and the Ministerial Committee to receive the Covid-19 vaccine in accordance with the specifications that ensure that the vaccine is maintained within the recommended temperatures in order to ensure that it is not damaged taking into account the storage capacity of the vaccine quantities allocated to each health directorates.

- **It should be taken into consideration that no quantity of the vaccine will be supplied unless all the requirements of proper storage are secured according to the manufacturer's guidelines.**

❖ **Other items:**

❖ **Shock medications:**

The provision of appropriate quantity of shock medications in the vaccination sites, quantities should be suitable to the number of target population at that site, those medications to be used in case of any sensitivity or side effect that may accompany the vaccination process. Those medications include (hydrocortisone vial, Chlorpheniramine maleate ampoule, Dexamethasone ampoule, Adrenaline ampoule) and this requires the addition of an appropriate amount of safety boxes, considering the guidelines of administrating these drugs.

- ❖ **Vaccine boxes, vaccine carriers and ice molds:** Each health directorate and institution will be responsible for cleaning and the inventory of all these supplies available to them, to be used during the vaccination campaign, in addition identifying the gaps and the needed quantities to carry out that campaign.

- ❖ **Personal protective equipment:** To be calculated later based on the number of health workers providing the vaccines and the number of vaccination days, adding at least 10% as a reserve.

- ❖ **Records and stationery:** This is necessary for the purpose of documenting the data of the beneficiaries and preparing a daily summary. weekly and monthly report on the remaining stock and the dispensed quantities and the number of the health workers providing the vaccines, in addition to vaccination cards for the Vaccine Covid-19. Those items need to be calculated later based on the number of vaccination teams.

- ❖ **Tablets:** For electronic documentation of supervisory teams, quantities identified based on the number of supervisory teams.

- ❖ **Computers (or laptops):** at least two per vaccination outlet with an internet connection.

6) Human resources management and training:

An integrated training plan will be developed according to the following facts:

- Issuing an administrative order to form a central committee at the level of the of Health Directorate to follow up the plan of deploying Covid-19 vaccine. This committee to be headed by the Director General of the Health Directorate and the membership of:
 - Director of Public Health Dept.
 - Director of Technical Affairs Dept.
 - Director of Pharmacy Dept.
 - Director of Operations Dept.
 - Directors of Health Districts at that Directorate.
 - Director of the Immunization Section.
 - Director of Communicable Diseases Section.
 - Director of the Health Promotion Section.
 - Director of Cold Chain at the directorate.
 - Media Coordinator of the Directorate
 - Administrative assistant.

Note: Any other member can be added according to the need and the situation at that directorate.

Committees Job Description

- a) Preparing plans for the dissemination of the vaccine at the level of their districts in along with the NVDP and in coordination with the relevant authorities to the develop detailed “micro-plans” and supervise implementation.
- b) Responsible for providing all the needed requirements to implement the plan successfully, and put the job description for the subcommittees, according to the central guidelines.
- c) Preparing schedules for the above-mentioned risk categories such as (health workers, security forces, seniors (50 years and older), chronic disease patients and other risk groups.
- d) Cooperation with the security forces to ensure the safety of the vaccine delivery to avoid leaking in one way or another.
- e) Establishment of the teams who will implement the vaccination activities according to the type of vaccination site, as follow:

First: For hospitals designated as vaccination sites for vaccines that need very low temperatures:

The central committees at the directorate level select vaccination sites from hospitals (for vaccines requiring ultra-cold chain)) according to the numbers that have been centrally identified, and provides the immunization department with a list of the names of these vaccination sites, their coordinates and focal points. It is responsible for supervising and coordinating the formation of the following teams for each vaccination site while issuing their administrative orders:

1. **Medical team:** This team consists of (one or more internal medicine specialists, a member from pharmacovigilance unit in the hospital, two health or nursing staff, administrative staff. The job description of the team are as follows:

- Check the beneficiary's data when comes to the vaccination site prior to the vaccination.
 - Check the beneficiary and make sure there is no objection to take the vaccine.
 - Monitoring the health status of the beneficiary after receiving the vaccine and for a minimum of (15 minutes) after vaccination
 - Document the AEFIs and report that (Hospital pharmacovigilance person).
 - Confirming on the vaccinee to take the second dose, confirm its date, educate citizens about the importance of the vaccine and possible side effects after vaccination.
2. **Vaccination Team:** Consisting of pharmacists(preferably a clinical pharmacist), health workers providing the vaccin, and a clerk) more than one vaccination team can be selected in one site and the selection of health workers providing the vaccine should be based on competence and professionalism. Job description of this team as follow:
- Documenting beneficiary and vaccine data in the allocated records (paper or electronic)
 - Documenting beneficiary and vaccine data on a special vaccination card
 - Dissolve the vaccine and prepare it for vaccination if needed (pharmacist)
 - Vaccination
 - Ensure that standard procedures are followed for safe disposal of the medical waste.
 - Ensure compliance with the second dose date and educate citizens about the importance of the vaccine and possible AEFIs.
3. **Cold chain team:** Consists of two pharmacists and two pharmacists' assistants. This team job description as follow:
- Follow-up the receipt and storage of the vaccine (and vaccination supplies) in accordance with the standard instructions
 - Supply vaccination teams daily with the required vaccine and vaccination requirements and according to the goals set
 - Follow-up of vaccine storage temperatures and cold chain equipment
 - Supervising the initial vaccine thawing process (in case of UCC vaccines)
 - Control of the stocks of vaccine and vaccination supplies.
4. **The monitoring team for the vaccination process** consists of (hospital director or technical assistant, director of the public health unit, media coordinator at the hospital, administrative staff) and any other member can be added who can be active in ensuring the success of the delivery plan for the Coved-19 vaccine. Job description of this team:
- Ensure that all members of the above teams are pre-trained on the vaccination process
 - Supervising the vaccination process from start to finish
 - Follow-up the application of IPC preventive measures and occupational safety by all members of the above teams
 - Supervising the documentation process and its accuracy and sign the vaccination card after vaccination.

- Issuing daily and periodic reports (no. of health workers providing the vaccines, vaccine quantities and vaccination supplies dispensed, waste, stock, AEFIs, etc.) in coordination with other teams.
- Ensure commitment to the second dose, educating citizens about the importance of the vaccine and possible AEFIs.
- Manage any emergency case might occur during the whole process.

Second: For selected health centers for vaccination with vaccines that need to be stored in ice-lined refrigerators:

- The central committees at the health directorate will identify 3-5 primary health care centers as vaccination sites in each district so that the health center is responsible for vaccinating the target groups within its geographical area. The number of vaccination sites can be increased in the future.
- The committee will identify a team in each health center consisting of (director of health center, one MD or more, one or more pharmacists, cold chain administrator, 2 health workers providing the vaccines (or more depending on population density), 2 data recorders). Vaccine Providers better to be out of EPI program, to avoid affecting the fluency of the program. A large and suitable place is equipped for the work of vaccination teams away from the National EPI rooms. Relevant committees at health directorates will establish the teams (in coordination with the primary health care districts) and submit them to the headquarters of the Ministry/Department of Public Health/Immunization Department, with a summary of the total numbers of each district.
- The committee will establish a medical team at health district, composed at least of one physician, two pharmacists, a medical assistant and one administrative staff, and a similar team at the level of the health directorate.
- The central committees are responsible for supervising the distribution of tasks below to the teams that are established at the health centers and in coordination with the primary health care districts, taking into account the possibility of adding other members to some teams to ensure the proper implementation of the vaccination in a safe, fair and easy manner:

- Medical examination of the beneficiary:

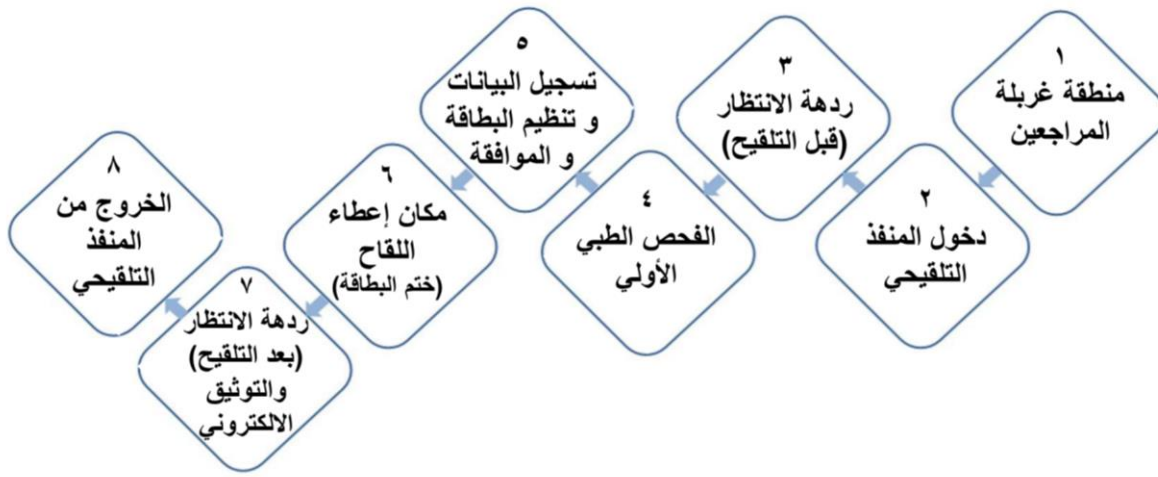
- Check the vaccine beneficiary's data when visit the vaccination site prior to the vaccination.
- Apply medical examination to the beneficiary and make sure there is no objection to the vaccination.
- Monitoring the health status of the beneficiary after receiving the vaccine for a minimum of (15 minutes).
- Document AEFIs

- Ensure compliance with the second dose date. Educate citizens about the importance of the vaccine and possible AEFIs.
- **Vaccination:**
 - Documenting beneficiary and vaccine data in special records (paper or electronic)
 - Documenting beneficiary and vaccine data on the vaccination cards.
 - Dissolve or dilute the vaccine and prepare it for vaccination in case the vaccine needs to be dissolved or diluted.
 - Administer the vaccine to the beneficiary.
 - Ensure that standard procedures are followed for safe disposal of medical waste.
 - Ensure compliance with the second dose date. Educate citizens about the importance of the vaccine and possible AEFIs.
- **Follow-up of the vaccine supply chain:**
 - Follow-up the receipt and storage of the vaccine (and vaccination supplies) in accordance with the standard instructions
 - Supplying vaccination teams daily with the required vaccine and vaccination requirements and according to the goals set.
 - Follow-up of vaccine storage temperatures and cold chain equipment
 - Supervising the process of preparing the vaccine
 - Control the stock of vaccine and vaccination supplies
- **Supervision and follow-up:**
 - Ensure that all the members of the above teams are pre-trained on the vaccination process.
 - Supervising the progress of the vaccination process from start to finish.
 - Follow-up the implementation of IPC measures and occupational safety by all team members
 - Supervising the documentation process and its accuracy and sealing the vaccination card after vaccination
 - Issuing daily and periodic reports (preparation of health workers providing the vaccines, quantities of vaccine and vaccination supplies spent, waste, stock, AEFIs etc.) in coordination with other teams.
 - Ensure compliance with the second dose date and to educate citizens about the importance of the vaccine and possible AEFIs.
 - Manage any emergency case might occur during the whole process

General instructions:

- The Immunization Department conducts training courses in cooperation with supporting organizations to explain everything related to the delivery of the vaccine to the beneficiar, training package is attached (Appendix 12).
- Code of conducts for vaccinators will be part of the training and site readiness agendas

- The Immunization Department is responsible for identifying central supervisors to follow up on the mechanisms and requirements of the implementation of the campaign in coordination with the central and regional operating rooms and the national committees and arrange all the required logistics.
- Below is a chart of the flow of reviewers to the vaccination site:
Let's



7) . Media Advocacy, Communication and Social Mobilization (Demand Generation and Community Engagement)

In coordination with international UN agencies and supporting organizations, the Department of Information and Awareness, the Health Promotion Department, the Media and Communications Authority and other key media departments in various ministries and agencies and other relevant authorities will organize a mass media and social mobilization campaign to generate demand among the communities and publicize the vaccine and its importance and in accordance with the media plan that was approved by the minister in advance and organized in cooperation with the World Bank, which aims to:

1. Raise awareness and build trust between the community and vaccine service providers
2. Explain the importance of the vaccine to generate demand and uptake of vaccines by beneficiaries.
3. Provide the community with the right information about vaccines and the measures taken regarding deployment (timings of arrival, source, importance of the second dose)
4. Generate national solidarity to promote the idea that taking the vaccine is a social and national responsibility.

A three pronged approach is being outlined for this purpose:

- a. Demand Generation
- b. Social Media and planning
- c. Community Mobilization and Engagement

7.1 DEMAND GENERATION

1. Social Data Collection and Use:

- Ongoing behavioral and social data surveys e.g Time series data, KABPs (Knowledge, Attitude, Behaviour and Practices) , social media surveys are available to inform the overall communication plan , coordinated and supported by MoH and other UN/non-UN entities.
- Social media listening tools will be utilized one of the most useful ways to track public perceptions.
- Monitoring social media and mainstream media to understand the rumours, misinformation and public sentiments, which will be useful to decide the communication interventions.

2. Communication Planning:

- Communication planning will address various intended audiences as per the phases in vaccine delivery. Vaccination for the first cohort will most likely be prioritised for health workers, elderly population and people with comorbidity. To reach this priority population, appropriate traditional and nontraditional communication channels and messages based on evidence will need to be selected and used.
- Targeted communication campaigns will be rolled out based on the geographic coverage and priority groups.
- As everyone will not be eligible for COVID-19 vaccine in initial phases, it will be important to continue with the RCCE approaches being used for COVID-19 prevention. In this case, reaching out to all populations with key preventive behavior promotion will be important.

3. Coordination:

- Demand generation/social mobilization and communication activities will be coordinated by taskforces under the Ministry of Health. Three key taskforces that have been committed to the response – MoH, RCCE TWG (lead by Health Promotion), Subcommittees on Media and communication planning (led by Media department, MoH) and the UN RCCE TWG (lead and co-lead by UNICEF and WHO), are set up to work in specific areas.
- The coordination groups will lead on the development of communication plans, training and communication material, and monitoring of demand generation activities. The coordination mechanism will be established both at national level as well governorate levels.

- The three taskforces will meet from time to time to discuss and harmonize plans and messaging that promotes/generates demand for vaccines.

7.2 SOCIAL and MASS MEDIA PLANNING AND MANAGEMENT (External Communications and Advocacy)

4. Implementation of mass media plan:

- Social Mass media plan will include focused messages through short and simple public service announcements, which will be delivered via social media, radio, TV and print material, led by the Subcommittee of media and communications.
- It is important to build trust among people about vaccines its advantages and safety. Dedicated radio and TV programmes, can be produced and disseminated, which can feature experts talking about the subject matter. The programs TV and Radio programmes can also feature highly influential people in society such as high ranking Government Officials, Religious leaders and celebrities getting vaccinated. These will be complemented by community engagement activities and interpersonal communication by health workers and social mobilization.

5. Social Media Monitoring and Rumour Management:

6. A mechanism to regularly track information on both social media and main-stream media from early on, analyse the impact of anti-vaccine sentiments, fake news, misinformation and disinformation. Based on the social media analysis, relevant people will need to assess the situation and provide quick real time response as much as possible to mitigate rumours, disseminate accurate information. **Crisis Communication**

- The Vaccine safety monitoring, AEFIs, and injection safety disposal Technical Working Group have established SOPs for processes of evaluation and monitoring the situation, as well as determining actions needed and further communication on AEFI which could be coincidental or in rare cases vaccine-related. Crisis communication will be part of the training at the national and sub-national levels. In the event of a crisis, designated spokespersons who are trained in crisis communication will communicate transparent and accurate information with the media and the general population to mitigate conflicting messages being given through various sources.
- Crisis communication should be part of the training at national and sub-national levels and roles and responsibility of different people will need to be clearly spelled out, eg: spokespersons, EPI managers, health workers, vaccinators, social mobilizers etc. When it comes to crisis, only designated people can speak to media and the general population. This will help to mitigate conflicting messages being given through different sources. The spokespersons will need to be trained on crisis communication management. Transparent and accurate information to media will be critical at all stages of crisis communication.

7. Advocacy and stakeholder engagement:

- Advocacy meetings will also need to be organized at sub-national levels with relevant stakeholders. At community level, advocacy with community influencers, community leaders and religious leaders etc will need to be done to garner support for COVID vaccine and creation of an enabling environment.
- Advocacy kit including Frequently Asked Questions (FAQ), fact sheets and relevant materials will need to be developed and disseminated to build the commitment of in-country partners and stakeholders for COVID-19 vaccine introduction.

7.3 COMMUNITY ENGAGEMENT AND SOCIAL MOBILIZATION

8. Community Engagement and Social Mobilization:

Community engagement will include all social mobilization activities and efforts should be made to engage community leaders, religious leaders, local CBOs, youth groups, mothers and fathers' groups etc. Social mobilizers, elders forums and community health workers will be the vehicles to provide timely accurate information to communities, distribute print materials, and engage with communities in relation to COVID-19 vaccine introduction. Specific efforts will be made to reach refugees, migrant population and vulnerable groups will be a priority.

9. Capacity building in communications:

Capacity building of health workers, social mobilisers, CSOs, community leaders is going to be very important. The interpersonal communication training modules for health workers will need to be integrated into the training being organized at national, sub-national and community levels. Capacity building of spokespersons, RCCE taskforce members, media will also need to be factored in during the planning phase.

7.4 MONITORING, SUPERVISION AND EVALUATION

Monitoring and supervision of communication activities will be important to show the effectiveness of communication interventions. Therefore, demand planning should include plans and activities for the monitoring and evaluation of communications activities. This will also include developing monitoring checklist and rapid surveys to assess the effectiveness of communication activities, analysis. Post introduction evaluation should also include questions related to External communication and community engagement.

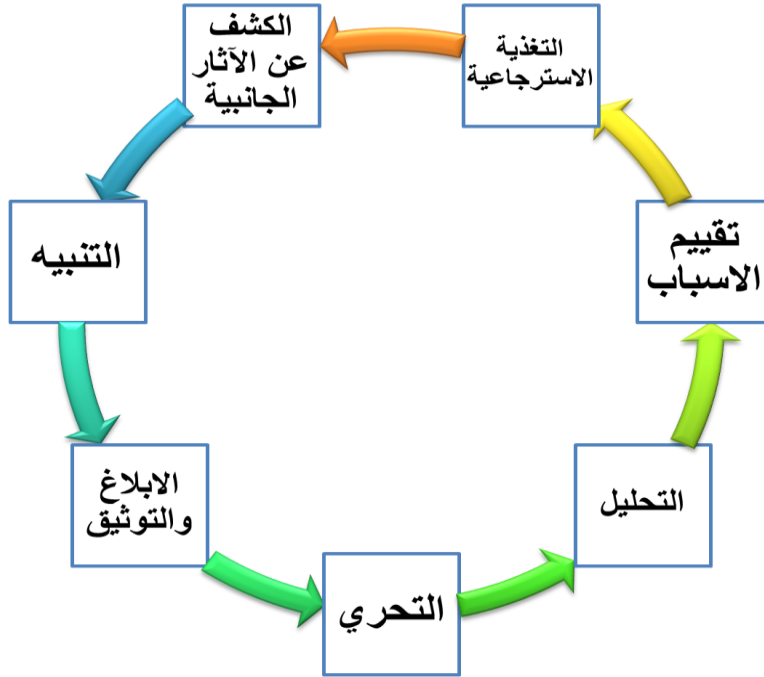
Demand planning will include plans and activities for the monitoring and evaluation of communications activities to demonstrate the effectiveness of communication interventions this will also include developing monitoring checklists to assess the effectiveness of communication activities. The monitoring and evaluation plan will cover knowledge, perception, vaccine eagerness, confidence, online platforms (pre-campaign and during new vaccine introduction) with the support of development partners. All data emerging should be compiled and shared across stakeholders to inform programme interventions.

To ensure vaccine demand generation and vaccination campaigns are on track, its pertinent for taskforce members of the three-sub committed to conduct onsite visits or community visits as per of support supervision of the communication plans. These will ensure that the messages being passed to the target populations at all levels (community and vaccination points) are being utilized as guided.

- To engage community leaders and influential people from all walks of life, and to engage specialists in disseminating the right information about the vaccine and its importance.
- Investing young university students and influential website owners in spreading the right information about the vaccine and defeating rumors.

8) Documentation and follow-up of possible side effects after vaccination:

The WHO and other scientific bodies recommend monitoring potential side effects after vaccination, while ensuring exceptional and additional efforts are in place to investigate and monitor, highlighting the need for the cooperation of all stakeholders and the need to engage the community in a transparent way regarding possible side effects after vaccination so that reporting any possible side effects. Below is a chart of the process of documentation and reporting of possible side effects recommended by WHO:



To ensure that the of monitoring possible side effects after vaccination is strengthened, its viability and ease of investigation are maintained, some important instructions should be followed::

- 1) Providing the necessary supplies for the documentation process mentioned above.
- 2) Processing and providing a Template for COVID-19-19 vaccine vaccination cards, documentation records and records to follow up possible side effects after vaccination, printing them and providing them to all the sites prior to the launch of the vaccination event (in the annexes are models of vaccination cards and the registration of vaccination data).
- 3) Coordination with the Information Division of the Public Health Department or at the ministry's headquarters to design an electronic documentation program and a vaccination scheduling program (if possible).
- 4) During the provision of the vaccination service, all the required data is documented for the persons who are vaccinated in the records of the Covid-19 vaccine and at the same time their data is entered into an electronic program (pre-prepared) in the computer or tablet mobile with the need to install the correct phone number of the beneficiary, then the date of the take of the vaccine and the date of the second dose is fixed on the special vaccination card and signed and stamped and delivered to the beneficiary with the emphasis on the need to keep the vaccination card and return to the second dose on time. The need to notify the health institution or attend again in case of any side effect after vaccination
- 5) The need to adhere to preventive measures during the provision of vaccination service as follows:
 - Hand washing or disinfection before and after each vaccination
 - Wearing muzzles by inoculator sanders and vaccination beneficiaries

- Ensuring physical spacing during all stages of the delivery of the vaccination service
 - Reduce congestion inside the inoculation port
- 6) Follow the seven steps of safe injection, which include (clean working environment, hand washing or disinfection, use of sterile tools, use of the correct vaccine and solvent, skin cleanliness before injection, all acute residues, safe disposal of insemination residues).
 - 7) The supervision team or medical support team will follow up on possible side events after vaccination and follow up on the beneficiary, take the necessary measures and follow special instructions to monitor and investigate these incidents.
 - 8) Daily positions on the number of health workers providing the vaccines, the amounts of vaccine spent, wasted and other data are raised according to a schedule (paper or electronic) prepared specifically for this event.
 - 9) Field supervisors follow up and check the empty pollen bottles returned from the vaccination teams with the preparation of health workers providing the vaccines and ensure that no one who is not in the target group is vaccinated. (It is preferable to place empty bottles in a separate destruction box from the box for viles, to facilitate the calculation of empty bottles after the return of the vaccination teams.)
 - 10) Each vaccination team is equipped with a sufficient amount of shock medications, and any case of side effects that may occur during the campaign period is documented and followed up by the health center (or vaccination team) and raise its daily position with the daily position of the results of the event.
 - 11) The formation of a committee for the destruction of vaccination residues within each health center and the opening of a record with daily records of destruction, and this committee is responsible for monitoring the mechanism of safe disposal of vaccination residues on a daily basis after the end of the vaccination session and coordinating in sending these residues to the regular incinerators and in accordance with the official contexts followed.

CLASSIFICATION OF AEFI

1. Vaccine product and quality-related reaction:

An AEFI is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product or quality defects of the vaccine product, including its administration device as provided by the manufacturer.

2. Immunization error related reaction:

An AEFI that is caused by inappropriate vaccine handling, prescribing, or administration and thus by its nature is preventable.

3. Immunization anxiety-related reaction:

An AEFI arising from anxiety about the vaccination.

4. **Coincidental event:**

Another AEFI is not related to other causes that happen simultaneously with a temporal association with the vaccination process and anxiety.

The process for AEFI reporting and investigations includes the following:

1) **REPORTING OF AEFI**

This will be through reporting AEFI at the vaccination centers/hospitals and through an assigned hotline where subjects can call in case of a suspected AEFI. The **hotline (call center)** team will include trained agents to receive calls and categorize them to either information about vaccines, complaints, or AEFI.

Agents from the hotline (the hotline number will be provided for all vaccinated individuals) will notify the follow-up team of any subject with AEFI on the electronic system including demographic data of the vaccinated person and all details about the vaccination dose and date.

Serious AEFI (including death) and/or unusual AEFI will be immediately reported to a follow-up team and the National Safety Committee.

2). **INVESTIGATION OF AEFI**

The central follow-up team consists of medical professionals (physicians - dentists - pharmacists) who are responsible for investigating the AEFI of referred subjects from the hotline within 24 hours after notification. The purposes of investigating an AEFI case are the following:
Identify the details of vaccines administered and determine the timing between the administration of the vaccine and the onset of the event.

Establish a provisional diagnosis

Document the outcome of the reported adverse event

Determine whether the reported AEFI is a sporadic case or a cluster

Not all AEFI require detailed field investigation. However, if it is determined based on the preliminary information that a detailed field investigation is needed, it should be initiated as soon as possible.

Thus, rapid response teams on the national and subnational levels are established and well-trained for field investigation and response to serious AEFI (including death) and any AEFI that may happen in clusters.

3. **ANALYSIS AND SHARING OF AEFI DATA**

Reports will be produced on the findings of data analyses and investigations.

AEFI data must be shared periodically among all stakeholders using the electronic system. A preliminary causality assessment can be carried out for serious AEFI.

4. **CORRECTIVE AND PREVENTIVE ACTIONS**

Immunization error-related events will be immediately investigated. Also, preventive actions such as strengthening supportive supervision, training of vaccinator teams, and even logistic replacements will be implemented.

Adverse events of Special interest (AESI) are usually identified through active vaccine safety surveillance (AVSS) systems. In the case of COVID vaccination, MOH may consider establishing a system for AESI.

9) **Monitoring, Follow-up and supervision of the vaccination process:**

After identifying the vaccination sites, vaccination and supervisory teams, and all the requirements (as outlined above), the following instructions must be followed:

- The Health Directorate is responsible for creating a wide and open place for of vaccination teams to ensure physical distance and IPC preventive measures against Covid-19
- Equipping the vaccine and vaccination supplies in the appropriate quantities that match the daily goal of the single vaccination team, taking into account the manufacturer's instructions during the circulation and preparation of the vaccine.
- Equipping vaccination and support teams with personal protective equipment on a daily basis.
- The health services organize lists of their members wishing to be vaccinated before the date of vaccination and set dates for their vaccination to ensure that there is no vacuum or delay in their original work sites, preferably relying on the electronic authentication system.
- Evening vaccination sessions can be opened for members who are in hospitals after official working hours (guards) if there is a trained vaccination team.
- Preventive measures against Corona disease must be adhered to from wearing appropriate equipment and commitment to social and physical spacing, hand washing, sterilization and repudding during the campaign period, and vaccination teams (fixed or foot) are equipped with all safety and prevention equipment, in line with the instructions and central controls.
- Central and field supervisors follow up on all the mechanisms of the implementation of the campaign and follow up the availability of vaccine, vaccination supplies and personal protective equipment for all teams and in personnel and controls.
- All central instructions are followed in the implementation of the campaigns by all vaccination teams, attention to the accuracy of documentation and the method of giving and collecting the remnants of vaccination in the appropriate destruction boxes, and raising daily and weekly positions, and the results of the campaign after its completion.

- Special committees are set up at each vaccination outlet to safely destroy the insemination residues and document it in a special register and on a daily basis, including the signature of the members of the damage committee.
- The refrigeration chain officials in the sector and health centers continuously monitor the mechanisms of vaccine storage within the institution from the receipt of the vaccine to the last dose of the vaccine, and follow the return of it (not used).
- The Director of the Immunization Division of the Department (or The Chamber of Operation Room) to redistribute the amounts of the vaccine between sectors or health centres when needed to ensure that there is no shortage of inoculation at the expense of another, provided that the quantity transferred is confirmed in a record or record, in an official letter and within the context of official transportation of medicines and vaccines.
- If the vaccine requires two doses, the same mechanism that was followed in the implementation of the first round is followed, to ensure that the same person receives two doses of the vaccine.

Monitoring and evaluating the introduction of the vaccine:

- The Immunization/Vaccine Safety Division forms a national committee to monitor, monitor and investigate side effects after vaccination and the committee follows up on all relevant matters (and in the annexes the organizational structure of this area, its functions and duties).
- Joint coordination between the Department of Public Health and the Iraqi Center for Pharmacological Vigilance in monitoring and monitoring possible side effects after vaccination, and the development of an easy way to enable citizens to report any side effects that may occur after vaccination.
- Activate effective monitoring of side effects after vaccination and follow-up of the eye of vaccine recipients to inquire if they have suffered side effects after receiving the vaccine and the severity of those side effects.
- The beneficiary's telephone number should be required and properly documented in the register for the documentation of coved-19 vaccine vaccination data to facilitate the follow-up of side effects and use it for effective monitoring.
- The CDC monitors cases of Coved-19 disease after vaccination and prepares periodic reports to show how vaccine taking affects lower rates of infection.
- The relevant committees (mentioned above) and other competent authorities will follow up on the monitoring process in all its aspects and review the reports issued by the monitoring stakeholders.

Key indicators for monitoring progress:

The main indicators for measuring the progress or achievement of the coved-19 vaccine vaccination are similar to other general indicators of THE EPI, the most important of which are:

- Site readiness: Number of sites which meet readiness requirements
- **Vaccine uptake:** Number of people vaccinated at a given dose (e.g. first or second) in a specified period of time (e.g. month or year)
- **Vaccine coverage:** Percentage of the number of target groups received by the vaccine divided by the total number of target groups within a given period of time (e.g. one month or one year).
- Certain codes are used to determine the dosage type and coverage rate as follows:
 - o COV1: The number of people who received the first dose of the vaccine, and their percentage (COV1%) represents the proportion of health workers providing the vaccine to those vaccinated with the first dose of the total target number or of the population.
 - o COV2: Same as the previous indicator but for the second dose.
 - o COVc: Same as the previous indicator but for extra doses or booster doses after the second dose.
 - o COV1 - COVc Drop Out: Dropouts of the second or third dose or subsequent doses and the level of health workers providing the vaccines with the first dose minus the second dose, and to calculate the rate of leakage from the first dose, the equation $(COV1 - COVc)/COV1$ (the same as the leakage equations in the routine vaccine schedule).

Such indicators will be monitored by risk groups in phase 1, 2 and 3

- The previous indicators should be calculated in detail on the basis of a set of classifications as follows:

Classification	Definition	Use
Vaccine type (product)	Depending on the type of vaccine used	The turnout for a particular type of vaccine, the coverage rate and the dropout rate are calculated Assessment of protection in a particular population group for a particular type of vaccine Assessment of vaccine safety issues for that product
Geographical area	Health Center, Sector, Department	Monitoring equitable distribution by geographical area
Sex	Male or female	Monitoring the equitable distribution of a vaccine by sex

Age group (e.g. 10-year age group)	According to the priorities of the classification of the target age groups	Age is one of the risk factors for severe covered-19 disease, and monitoring the percentage of coverage by age groups is very important and is required to assess whether the prioritization is being done with the right process or not.
Occupation (optional)	Depending on the profession of the target group or specialization	Assess whether priorities are being prioritized in the right process or not
Other risk factors (optional)	Depending on chronic diseases or direct contact with the infected and others	Assess whether priorities are being prioritized in the right process or not
Workplace (work environment) (optional)	Depending on the working environment of the beneficiary (health institution, university, prisons,)	Assess whether priorities are being prioritized in the right process or not
Other dimensions for target group categories (optional)	For example, depending on the social, economic, national, etc.	Monitoring equitable distribution among different population groups (this may be possible through population surveys)

VACCINATION IN THE PRIVATE SECTOR

The private sector can import and administer vaccine to the people who are willing to pay on a fee-for-service basis. Vaccination offered by the private sector is not subject to the preregistration or high risk group prioritization requirements. In other words, people can walk into a private facility for vaccination even if they do not belong to a high risk group or have not been pre-registered.

However, other than those, all the other technical, social and environmental requirements discussed above for public sector vaccines are still applicable to private sector vaccines to ensure safe and effective vaccine deployment, including:

- The vaccine regulatory approval process
- Cold chain
- Health care waste management

- IPC
- Digital registry (a private sector module will be added to the digital registry and the private sector will be required to use this module to ensure alignment with the MOHE reporting mechanisms)
- AEFI

Note to NCC: One key issue to be included here is whether the indemnity and compensation law also covers private sector vaccines. Especially, it is important to clarify if the gov't's no-fault compensation program will also cover vaccine-related injuries in the private sector

STRATEGIC SEGMENTATION OF THE VACCINE PORTFOLIO:

Most likely, Iraq will need to deploy different vaccines either consequently or simultaneously to meet the demand. This will pose challenges in logistics, cold chain, digital registry and information campaign., etc. To facilitate implementation, Iraq can segment its vaccine portfolio by

- phases (e.g. different vaccines will be used for the different phases of vaccination as they become available)
- risk groups (e.g. vaccines with higher efficacy will be reserved for risk groups with higher risk of mortality such as the elderly and people with co-morbidities)
- cold chains,
- service delivery strategy, including facility type (e.g. different vaccines will be used for different levels in the system, for examples: vaccines which required ultracold chains will be used for hospital levels while others are used for lower levels in the system)
- geographical areas (e.g. different vaccines will be used for different geographical areas)
- public vs. private (e.g. different vaccines will be used in the public vs. private sectors)
- or a combination of some of the above factors

for use of Pfizer vaccine **Guidance : ANNEX**

Characteristics of BNT162b2 Vaccine

In accordance with the provided information and data, BNT162b2 vaccine characteristics are included below, and are updatable based on the availability of future information:

Vaccine Effectiveness

The effectiveness of US BNT162b2 vaccine, developed by Pfizer in cooperation with the German company “BioNTech”, reached 95%, as stated by WHO.

Logistics for Vaccine Entry and Distribution

The vaccine is stored in (-60 to -80 C°), thus requires super-cooling freezers for storage. Other freezers, with the same specifications, are also required to freeze the ice cubes used in vaccine transportation processes, which are carried out via special vaccine carriers that maintain a temperature of (-60 to 080 C°) for transportation and distribution purposes. The freezers and vaccine carriers' temperature must also be maintained. Moreover, health workers will need special gloves to be protected from such very low temperature.

After taking out the vaccine from the super cooling freezers, it can be kept for five days in (2 to 8 C°). After thawing, the vaccine must be kept in (2 to 25 C°) and used within six hours of thawing time.

As for the other logistics, these are related to syringes, thawing, vaccination, security boxes, documentation records and vaccination cards.

Vaccine Manufacturing Technology

The vaccine was developed in BioNTech laboratories. The vaccine is based on (mRNA) technology.

Method of Stimulating Immunity System

The vaccine causes the body to produce antibodies that prevent COVID-19 from entering body cells and causing the disease. The vaccine uses a new method (messenger RNA- mRNA) to assist in providing protection against the virus. The vaccine is injected in the upper arm. It consists of two shots, 21 days apart.

Clinical Experiment

Pfizer carried out the implementation and funding of clinical experiment on 44,000 people in USA, Brazil, South Africa and Turkey. Such people voluntarily participated, each took two shots, 3 weeks apart.

Contraindications

- Individuals with known history of allergic reaction to any component of the vaccine, as the vaccine shall not be administered to individuals with known history of a severe allergic reaction.
- Individuals with any symptoms that could be a result of COVID-19 infection.

Medical Substances in Vaccine Composition

Messenger RNA (mRNA).

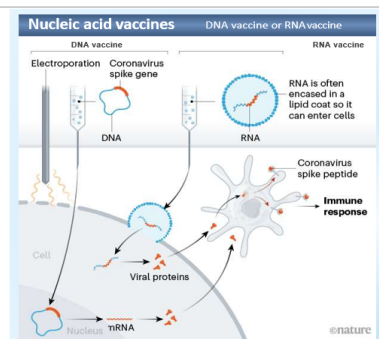
Non-Medical Substances in Vaccine Composition

- ALC-0315 = ((4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,Nditetradecylacetamide
- 1,2-Distearoyl-sn-glycero-3-phosphocholine
- Cholesterol
- Dibasic sodium phosphate dehydrate
- Monobasic potassium phosphate
- Potassium chloride
- Sodium chloride
- Sucrose
- Water for injection

Nucleic acid vaccines

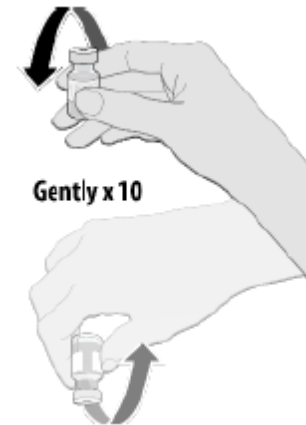
- Instead of a virus, a protein antigen, or a virus expressing the protein, **nucleic acid coding for the antigen is injected**
- DNA plasmid: enters nucleus, translated to mRNA for expression of protein
- Or mRNA can be injected. More direct (no translation required) but less stable than DNA
- This is new technology – no other vaccines for human use have used this

Source: <https://www.nature.com/articles/641586-020-01221-v>



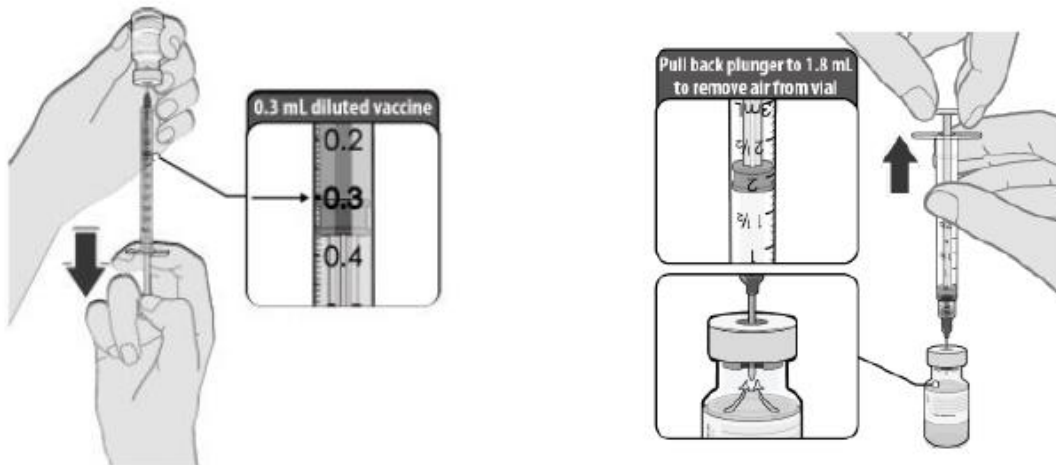
Vaccine Thawing and Dilution

BNT162b2 vaccine thawing and dilution require a very efficient administrator. The vaccine vial is 0.45 ml multi-use, provided as a frozen suspension without preservatives. The vaccine must be taken out from the super cooling freezers and allowed to thaw in the refrigerator (2 to 8 C°) for 3 hours or sit at room temperature (25 C°) for half an hour. The vial is then inverted gently for 10 times (without shaking) and the vaccine diluted using 1.8 ml of Sodium Chloride (0.9%) free of preservatives. (It is not prepared by the vaccine manufacturing company, so it is obtained from a separated source). The vial is then inverted again gently for 10 times (without shaking).



The vaccine must be used within 6 hours of dilution, after which any remaining amounts must be discarded.

Using the aseptic technique, the vaccine vial stopper must be cleansed with a single-use antiseptic swab, and 0.3 ml of the vaccine must be withdrawn. It is preferred to use a low dead-volume syringe. The vaccine vial, after dilution, contains six 0.3 ml doses.



Pharmaceutical Form

After dilution, the (diluted) solution is white to off-white suspension in the vial, containing 5 doses, each 0.3 ml with 30 µg mRNA.

Annexure on Demand Generation and Community Engagement

Examples of messages or information used in the media campaign:

- Scientific information about the vaccine, its importance, the method of its preservation, the mechanism of its administration and possible side effects.
- The safety and safety of the vaccine, its effectiveness and its importance in the elimination or control of the pandemic.
- Vaccine target groups and prioritization.

- Vaccine arrival times in Iraq and vaccination dates and places at the level of vaccination ports
- The role of the Iraqi government, in particular the role of the Ministry of Health in providing the vaccine and its efforts to maintain the safety of citizens and reduce the number of injured.
- Gain the trust of citizens by fighting rumors and refuting them by scientific methods and evidence.
- The seriousness of the spread and spread of the pandemic and its threat to the lives of citizens.
- Steps required before going to the inoculation port

Some examples of possible rumors:

- The vaccine is ineffective, unsafe and causes serious side effects.
- Belief in conspiracy theory regardless of its type (political, economic, religious ..)
- The vaccine causes genetic changes in the body of its recipients.
- The vaccine contains sensors that enable major countries to follow the vaccine recipients
- The purpose of the vaccine is the material benefit of manufacturers at the expense of the citizen's benefit.

Some proposals to counter the above rumors:

- Providing the right scientific information about the vaccine in an easy way to all citizens and transparently
- Focus the media campaign on positive topics such as pandemic eradication, virus defeat, recovery of freedom from pandemic restrictions, and avoidance of negative topics and misinformation.
- Recalling the role of previous vaccines in eliminating epidemics and diseases that were killing human lives.
- The use of social media for easy circulation and wide spread among citizens.
- Do not use mobile phone services and SMS messages to broadcast awareness messages.
- Coordinating with satellite channels and other media in broadcasting the right information, fighting rumors and holding the promoters accountable.
- Mass mobilization through the organization of scientific seminars and lectures to introduce the vaccine and its importance taking into account preventive measures during implementation