REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH

Lebanon National Deployment and Vaccination Plan for COVID-19 Vaccines

COVID-19 Vaccine National Coordinating Committee

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The Lebanon National Deployment and Vaccination plan for COVID vaccines is a dynamic plan and will be continuously revised based on the latest available information and scientific research findings on vaccines and their delivery.

Lebanon National Deployment and Vaccination Plan for COVID-19 Vaccines

Lebanon

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Endorsement page

The Ministry of Public Health would like to extend its gratitude to all the members of the COVID-19 Vaccine National Coordinating Committee, under the leadership of Dr. Abdul Rahman Bizri, who devoted their time and effort to develop Lebanon's National Deployment and Vaccination Plan for COVID-19 Vaccines. The ministry would also like to acknowledge its partners: the World Bank, the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), the United Nations High Commissioner for Refugees (UNHCR) and the United Nations Relief and Works Agency for Palestine Refugees (UNRWA) for their valued contribution and active engagement in developing a vaccine deployment plan that aligns with the highest international standards of quality and equity.

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Abbreviations and Acronyms

ACT-Accelerator	Access to COVID-19 Tools Accelerator
EMA	European Medicines Agency
EUA	Emergency Use Authorization
EUL	Emergency Use Listing
FDA	Food and Drug Administration
GOL	Government of Lebanon
HCW	Health Care Workers
ICU	Intensive Care Unit
IPC	Infection, Prevention and Control
MoE	Ministry of Environment
MoF	Ministry of Finance
MoI	Ministry of Information
MoPH	Ministry of Public Health
NCC	National Coordinating Committee
NDVP	National Deployment and Vaccination Plan
PHC	Primary Health Care
PHCC	Primary Health Care Center
PPE	Personal Protective Equipment
PoB	Port of Beirut
RO	Reproduction Number
SAGE	Strategic Advisory Group of Experts
SDG	Sustainable Development Goals
UN	United Nations
UNICEF	United Nations International Children's Emergency Fund
UNHCR	United Nations High Commissioner for Refugees
UNRWA	United Nations Relief and Works Agency for Palestine Refugees
ULT	Ultra-Low Temperature
VIRAT	Vaccine Introduction Readiness Assessment Tool
VRAF	Vaccine Readiness Assessment Framework
WB	World Bank
WHO	World Health Organization

Executive Summary

With almost 280,000 COVID-19 infections and 2,340 deaths recorded in Lebanon to date, and with the significant increase in number of cases reported daily reaching over 6,000, and a local incidence rate of around 1,140 per 100,000, there is urgent need to introduce COVID-19 vaccines to decrease morbidity and mortality and relieve the healthcare sector that has been overwhelmed with more than 90 percent COVID-19 associated Intensive Care Unit (ICU) occupancy. Achieving high levels of herd immunity reaching 80 percent is essential to preserve the functionality of the society and reduce the burden of COVID-19.

The Ministry of Public Health (MoPH) in Lebanon has reserved vaccines for 20 percent of the population residing in Lebanon through the COVAX facility and for around 15 percent of the population through an official bilateral agreement with Pfizer. Negotiations with other pharmaceuticals, mainly AstraZeneca, are in advanced stages and may yield positive results soon increasing further the potential of vaccine coverage in the community. The first batch of the Pfizer vaccine, estimated at 250,000 doses, is expected to reach Lebanon in the first quarter of 2021, starting the first half of February 2021. Efforts are ongoing to secure other sources for vaccine. Procurement of vaccination commodities and Personal Protective Equipment (PPE), ultra and normal cold chain assessment and maintenance, pre-registration system, identification of vaccination sites, formation and training of vaccination teams are almost completed for a successful introduction of the first batch of vaccines in Lebanon.

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 Lebanon 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 and live document that will be updated on regular basis depending on the evolving situation in Lebanon.

The guidance outlines preparedness for managing the deployment, implementation and monitoring of COVID-19 vaccines with a focus on the Pfizer vaccine; 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 guidance is based on available information from the MoPH, and on 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 irrespective of nationality, and the fair allocation mechanism for COVID-19 vaccines through the COVAX Facility. Due to the current uncertainties around the COVID-19 vaccine development, 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 National COVID-19 Vaccine Coordinating Committee (NCC) was established on November 6, 2020. The NCC, presided by Dr. Abdul Rahman Bizri, is composed of senior-level officials from the MoPH, United Nations (UN) agencies, World Bank, academia, external partners and private sector providers, and is responsible for planning, coordinating and supervising the implementation of all activities related to the vaccination program and development of this plan.

This plan provides the prioritization strategies and the list of health facilities strategically mapped to cover the whole of Lebanon by population size. The health facilities will function as vaccination sites based on strict algorithms for infection, prevention and control (IPC), as well as extensive training of

personnel. The plan will be tailored to reach the target groups at every phase of vaccination, irrespective of nationality, to attain effective vaccination coverage as planned while continuously monitoring adverse events and studying the impact and vaccine effectiveness in the community.

For the desired level of immunity, most vaccines require one or more doses according to a specific schedule. Moreover, the vaccines' storage requirements differ according to the product; 2-8 degrees, -20 degrees or -70 to -80 degrees, requiring different storage conditions. Thus, the final vaccination guidelines will depend on the product used which will be reflected in the training and vaccination plans. Training efforts have so far concentrated on implementing the thermosensitive Pfizer/BioNTech vaccine. Deployment of other types of vaccine will be considered at the appropriate time.

A comprehensive communication plan has been tailored to ensure dissemination of evidence-based knowledge on the effectiveness and safety of the vaccines to increase demand. This plan was designed in close collaboration with Ministry of Information (MoI), UNICEF and the NCC sub-committee in charge of information, communication and media.

COVID-19 vaccination will bring necessary programs, sectors, and ministries together. Coordination with other ministries, such as the Ministry of Finance (MoF), Ministry of Interior, Ministry of Defense, Ministry of Environment (MoE) and other ministries and departments will be intensified to ensure sufficient financial resources, coordination, technical presence and human resources are allocated to support the vaccination efforts and that the population groups that are most at-risk will be properly targeted and reached.

Special efforts will be made to engage communities in planning, implementation, tracking and reporting on the progress with the vaccination. To ensure maximum success, a focus on healthcare workers (HCW) (given their role in protecting and providing care to the population), gender, vulnerable groups, ethics and transparency will be accorded high priority as part of the plan. The Lebanese Order of Physicians and the affiliated scientific societies along with other orders and syndicates will be actively engaged. Priority groups will be based on protecting the healthcare system through protecting the front-liners first and other HCW considered essential to maintain the system. Elderly and frail people will be given high priority as well, along with individuals with chronic co-morbid conditions. Certain sectors necessary to maintain the society function will be prioritized as well.

The Lebanon National Deployment and Vaccination Plan (NDVP) is developed in collaboration with all partners to ensure that the plan and related financing for the deployment, implementation and monitoring of the COVID-19 vaccination are well defined to achieve timely and successful introduction of COVID-19 vaccines.

1. Introduction

1.1. Country Context

Lebanon is a country of 10,452 km^2 that hosts 6.8 million inhabitants, of which around one-third are refugees (Palestinians and Syrians) and migrant workers. The country is witnessing an unprecedented financial and sociopolitical crisis, the aftermath of the Port of Beirut (PoB) explosion, compounded by the current COVID-19 outbreak. This has added to the fragility of the healthcare system, already overstretched by the protracted Syrian refugee crisis.

Lebanon's healthcare system is characterized by a dominant, private for-profit sector that offers up to 75 percent of all health services, while the public-private non-for-profit network covers the rest of the population, namely the economically deprived and the most vulnerable inhabitants. The public-private partnership was developed over the past few decades and in certain areas, such as vaccine coverage, has proven to be effective and exemplary.

Currently, Lebanon hosts more than 1.5 million Syrian and 400,000 Palestinian refugees, which is the largest refugee population per capita in the world, and 300,000 migrant workers, summing to around 30 percent of the current total population of the country. The refugees' presence has overstretched the basic healthcare services already strained by an overall stagnating economy and political instability. In fact, the overall economy of the country has been severely affected, with almost zero GDP growth over the past three years. This was reflected in the government's overall austerity policy, limiting its capacity to increase its financial contribution in terms of access to healthcare services. Meanwhile, the government has committed to the Sustainable Development Goals (SDGs), and to "leaving no one behind". MoPH has also committed into ensuring Universal Health Coverage, with focus on the most vulnerable population.

Lately, Lebanon's economy rapidly deteriorated since protests erupted in October 2019 over the economic situation in the country that has left it saddled with US$94bn of public debt as of the end of July 2020. Additionally, Lebanon's economy continued to deteriorate following the devastating PoB explosion on August 4, 2020 which killed at least 190 people, wounded over 6,000 and damaged 292 health facilities[1] which significantly reduced access to care, especially for the vulnerable populations.. Consequently, inflation continued to soar, reaching an annual 120 percent as of August 2020. Negative impacts of the economic crisis on the health sector include: (i) protracted delays in government payments of its arrears to hospitals; (ii) a dollar shortage along with unregulated restrictions on depositors' access to their funds, hindering the import of essential medical equipment, medicine and supplies; and (iii) an increase in unemployment rates leading to an increase in the number of uninsured citizens requiring government assistance to access health services. With both national and foreign demand conditions being subdued, companies including healthcare facilities continued to cut their staff numbers to salvage the increasing costs. The decrease in the number of healthcare workers, coupled with the increasing demands on healthcare services due to COVID-19 escalated the workload on hospitals.

[1] https://www.worldbank.org/en/country/lebanon/publication/beirut-rapid-damage-and-needs-assessment-rdna---august-2020

1.2. COVID-19 Situation and Response

Since the first case of COVID-19 was diagnosed in Lebanon on February 21, 2020, the epidemic in the country has started to progress relatively slowly due to the restrictive lockdown measures, however, it started to increase significantly since August 2020, following the PoB explosion. Currently, the country is experiencing an unprecedented surge in COVID-19 with a record-breaking number of confirmed cases during the first two weeks of January 2021. As of January 21, 2021, the country has a total of 269,241 confirmed cases and 2,151 deaths. Test positivity rate for the last 14 days is high at 21.2 percent (compared to the WHO suggested rate of 5 percent). This surge, coupled with a high level of infections among health workers (2,354 cases)[2], has been overstretching the health sector's capacity. On January 21, 2020, 86 percent of COVID-19 regular beds and 92 percent of COVID-19 ICU beds were occupied[3]. The Government of Lebanon (GOL) took progressive lockdown measures that became almost totally restrictive on January 8, 2021; in parallel, several preparedness activities were accelerated.

Based on the WHO guidance considerations for implementing and adjusting public health and social measures in the context of COVID-19, Lebanon is currently at level 4 of community transmission (average weekly incidence rate > 1,100/100,000), with limited capacity for response. The Government policy to contain the cases remains in effect, in an effort to flatten the epidemiologic curve as much as possible as the healthcare system is already overburdened with more than 90 percent occupancy rate of ICU beds.

1.3. COVID-19 Vaccines

The Access to COVID-19 Tools Accelerator (ACT-Accelerator) was launched in April 2020 as a global initiative to accelerate the development, production and equitable access to COVID-19 diagnostics, therapeutics, vaccines, and health system improvement. The COVAX Facility, the vaccine pillar of the ACT Accelerator, is a mechanism designed to guarantee rapid, fair and equitable access to COVID-19 vaccines worldwide, co-led by GAVI, CEPI, and WHO. The COVAX Facility is speeding up the research for an effective vaccine, and planning to supply two billion doses of the vaccine by the end of 2021. Currently, over 230 vaccines are at different stages of research and development, however, as of December 31, 2020, WHO granted emergency use listing (EUL) for the Pfizer-BioNTech vaccine only. Lebanon is participating in the COVAX Facility as a self-financing country.

1.4. The COVID-19 Various Vaccine Platforms

The three potential vaccine types that are being considered for Lebanon include:

I. **mRNA vaccines:**
   - Two vaccines are currently available and more to come. This is relatively a new technology implemented for the first time in manufacturing vaccines for infectious diseases although used before in therapeutic vaccines for cancer. One vaccine **BNT162b2 mRNA** produced by **Pfizer-BioNTech** and the other **mRNA1273** is produced by **Moderna.** They have a good safety and efficacy profiles with efficacy reaching around 94-95 percent for both. They are relatively expensive and not thermostable. They are the only vaccines, up to the current date, which have acquired both Food and Drug

[2] MoPH Daily Report – January 21, 2021; https://corona.ministryinfo.gov.lb/news/show/9218/
[3] WHO Daily Brief – January 21, 2021

Administration (FDA) and European Medicines Agency (EMA) emergency use authorization and the Pfizer vaccine is the only vaccine, to date, that was granted emergency validation by the WHO.

II. Viral vector vaccines:

- Several vaccine types are being produced using this recombinant technology. The most widely known and anticipated is the **Astrazeneca-Oxford vaccine (ChAdOx1 nCoV-19)**. Other potential vaccines in this platform include the **Russian Gamaleya Sputnik 5** and the potentially promising **Johnson & Johnson Janssen COVID-19 vaccine**. The only vaccine with published phase 3 trials and peer reviewed data is the Astrazeneca-Oxford vaccine. It has received Emergency Use Authorization (EUA) in both United Kingdom and India and is currently being evaluated by FDA and EMA. Efficacy is 70 percent and can be higher in certain groups. It is considered a potential game changer given its easy handling, thermostability and low-cost. Limitations include possible contraindication in severe immunosuppressed individuals and the need for more data about efficacy in older people.

III. Subunit vaccines:

- They are safe vaccines but usually require the addition of adjuvants, and repeated doses to elicit an adequate immune response. The **Sinopharm Chinese vaccine** is a good prototype. Phase 3 data are not published; however Phase 1/2 data seems good but no larger published studies and peer reviewed journals.

Lebanon, through the MoPH, is finalizing all legal and financial aspects needed to conclude the Pfizer-BioNTech vaccine deal to import around 2 million doses. Lebanon is already involved with the COVAX platform to obtain certain potential vaccines that are WHO endorsed. These vaccines include the likes of Astrazeneca-Oxford vaccine, Moderna vaccine, Johnson & Johnson vaccines, among others.

It is the vested interest of Lebanon to obtain 2-3 types of different vaccine platforms to allow for better and speedier immunization coverage and to include various sectors and subgroups of the society. The National Vaccination Initiative should expand efforts to contain and account for various immunization acts in the country. The private sector and various sectors of the country can contribute to this initiative. This contribution can be expressed through obtaining/ purchasing vaccines (approved by the Lebanese MoPH), financial support, human resources, assets and equipment. All efforts contributing to the vaccination efforts will be coordinated under the umbrella of the National Initiative in order to keep records of vaccines delivered, maintain transparency, ensure outreach to all vulnerable groups and keep track of immunization coverage at the national level.

1.5. The Aim of Vaccination

The aim of the National COVID-19 Vaccine Initiative is to achieve high immunization levels in the community ≥ 80 percent. Based on basic reproduction number (R0) suggested for the SARS-CoV-2 and later Re or Rt levels following viral circulation in the community, 60-85% herd immunity (protection) level is adequate to stop the epidemic. The desired end points for COVID-19 vaccination includes:

I. Prevention of infection (desired) with burden of disease (BOD) equals zero (0)
II. Asymptomatic infection (desired) with BOD equals zero (0)

III. Mild infection that does not necessitate hospitalization (desired) with BOD equals zero (0)
IV. Moderate infection that necessitates treatment and possible hospitalization (less desired) with BOD equals one (1)
V. Severe infection deserving hospital and ICU (not desired) BOD equals two (2)
VI. Mortality (not desired) BOD equals three (3)

Vaccine efficacy and efficiency will be assessed through achieving the first three (3) desired ends and avoiding mortality and ICU stay.

The GOL signed a Committed Purchase Agreement with the COVAX Facility to procure 2.73 million doses of COVID-19 vaccines for 1.36 million individuals (with a two-dose regimen), or 20 percent of the total population residing in the country (both citizens and non-citizens). The government made a down payment to the COVAX Facility through UNICEF, using the budget allocated for routine vaccinations. The MoPH has also allocated funds from its budget to cover a portion of the remaining payment to the COVAX facility. The first batch of the COVAX Facility vaccine is expected to be delivered before the end of the first quarter of 2021.

GOL has also signed a contract with Pfizer to secure 2.1 million doses for 1,350,000 individuals (with a two-dose regimen) or 15 percent of the total population. The Pfizer vaccine is expected to be the first COVID-19 vaccine to arrive in Lebanon (in the first half of February 2021).

1.6. Key Considerations for COVID-19 Vaccine Introduction

The introduction of COVID-19 vaccines is an opportunity to improve Lebanon's overall immunization program, and health system as a whole, through improving evidence-based planning and monitoring, improving the cold chain system, strengthening management of human resources, leveraging new technologies to ensure functional supply chain, and engaging communities to participate in health.

The following principles, aligned with WHO SAGE recommendations, will guide the vaccine introduction and deployment:

- A strong evidence-based decision-making process with clear accountabilities will be established to coordinate the vaccination;
- The most in need will be prioritized for the vaccination;
- Functional cold storage, logistics and vaccine management system will be in place;
- A safe and efficacious vaccine will be deployed, and all efforts will be made to ensure uninterrupted and sufficient supply;
- Sufficient human and financial resources will be allocated;
- Well-motivated and trained health workforce will conduct the vaccination;
- Communities will be actively engaged throughout multiple communication platforms to ensure transparent communication;
- Safe immunization practices will be applied, and adverse events managed in a transparent manner.

2. Regulatory Preparedness

2.1. Emergency Use Authorization

Lebanon does not have an independent drug regulatory authority; MoPH provides authorization for medication and vaccine registration, importation and marketing. MoPH issued an EUA for the Pfizer vaccine on December 16, 2020 (Annex I).

2.2. Regulating the Emerging Use of Medical Products to Combat the COVID-19 Pandemic: Indemnity and Compensation

On January 16, 2021, Lebanon enacted Law No. 211 on Regulating the Emerging Use of Medical Products to Combat the COVID-19 Pandemic (Annex II). The law shields healthcare providers, pharmacists, manufacturers, marketing certificate holders, and distributors of COVID-19 vaccines from liability for injuries associated with the development, management or use of the vaccines (except in cases of serious injuries or death caused by intentional misconduct). Aside from serious injuries or death arising from intentional misconduct, individuals will have only one recourse to seek compensation for injuries related to the COVID-19 vaccine, which will be presented to a specialized scientific/medical committee to be established by the MoPH. Individuals determined to have causal injury will be compensated from a fund established by the GOL.

Box 1. Overview of Registration Process of Vaccines in Lebanon

Vaccines are considered biological products so there are extra considerations that apply to their regulation and control. Due to the complexity and variability of vaccines, the objective of the technical committee (formed by a law and responsible for registration of any pharmaceutical product to enter the market in Lebanon) is to ensure quality, safety, efficacy and good storage and distribution practices. Every vaccine is regulated as a new product and considered "high risk", both substance and drug product production must strictly comply to good manufacturing practices.

As part of all requirements for registration of regular products, whether it is a brand or generic, registration of vaccines needs further assessment. For example, lot release for each batch imported is mandatory and the batch release certificate should be issued by the competent authority. If a vaccine is submitted for registration from a non-reference country, on the top of all requirements for registration, **the WHO prequalification is requested.**

A specialized committee will be formed at the ministry level to decide, in coordination of national vaccine committee, on registration of COVID-19 vaccines from non-reference countries if they do not hold WHO-prequalification

The standard list of requirements for the registration of vaccines includes:

Module 1:

This module includes general information: Cover letter, application form, summary of product characteristics, labeling and package insert leaflet, the free sale certificate, etc.

Module 2:

This module includes summaries of common technical document: Quality overall summary, pre-clinical overview, clinical overview, pharmacokinetics, toxicology, etc

Module 3:

This module includes information about data quality data and is considered the most important part:

PARTS: S (substance) and P (finish product)

Part S includes

1-Active and non-active substances

- Manufacture of active substance
- All Manufacturer(s)
- Description of manufacturing process and process controls
- Control of materials
- Controls of critical steps and intermediates
- Process validation and/or evaluation
- Manufacturing process development
- Impurities
- Batch analyses
- Stability and post-approval stability protocol and stability commitment

2-Part P:-Finished product

- Description and composition of the finished product
- Pharmaceutical development
- Physicochemical and biological properties
- Description of manufacturing process and process controls
- Controls of critical steps and intermediates
- Process validation and/or evaluation
- Control of finished product
- Batch analyses
- Stability and Post-approval stability

Module 4:

This module includes product safety data (nonclinical study reports):

Pharmacology, primary pharmacodynamics, pharmacokinetics: Toxicology, Immunogenicity profile …

Module 5:

This module includes information on efficacy, clinical study reports demonstrating clinical efficacy and capacity to meet therapeutic claims:

The following will be studied:

- Clinical trial site information,
- Eligibility criteria
- Clinical study reports
- Reports of efficacy and safety studies.
- Reports of post-registration experience.
- Testing of immunogenicity.
- post marketing surveillance
- Risk management plan
    - Pharmacovigilance plan (track and trace)
    - Recall plan.
    - Plan for adverse reactions (ADR) reports
    - Plan to ensure quality of the product

These requirements are needed for any vaccine to enter the private market. Some exemptions might be made by the committee to be formed to grant EUA for vaccines from non-reference countries in-line with law 211 and after thorough evaluation of submitted files.

2.3. Importation and Custom Clearance Procedure

Provision of import permits in the shortest time possible (1 to 2 working days) and immediate customs clearance will be facilitated where possible. The MoF will issue a ministerial decision to exempt vaccines from customs and tax. All entities relevant to import controls, the customs authority, and the port authority, will be in full coordination with the objective of enhancing and speeding up the importation and clearance of COVID-19 related medical products as per the ministerial decision.

Expedited vaccine lot release for prompt administration of COVID-19 vaccine to target groups is also in place.

2.4. Traceability of Vaccines in the Context of the COVID-19 Pandemic

Once the vaccine arrives and is released, MoPH will ensure the distribution of the vaccines all over the country according to the need. An automated system will be used to assure tracing of every vaccine batch from the first step in the airport once the shipment arrives.

Vaccination type, manufacturer, expiration date and quantity will be uploaded to the developed electronic system to maintain traceability.

3. Planning and Coordination of the Vaccine Introduction

Following the detection of the first COVID-19 imported case in Lebanon on February 21, 2020, an inter-ministerial Emergency COVID-19 response committee was established, headed by the Prime Minister (PM). In parallel, a National Emergency Task Force was established upon the request of the Lebanese PM, headed by representative of the PM office; its secretariat is assumed by the Disaster Risk Management team at the PM office. The Task Force meets weekly to assess the epidemiological situation and inform public health and social measures with the objective of enhancing whole-of-society coordination mechanisms to support preparedness and response, including but not limited to, health, transport, travel, trade, finance, security and other sectors. A national communicable disease committee composed of experts and relevant MoPH staff were also meeting on a weekly basis and as needed to give technical advice regarding the evolving situation.

Concordantly, Lebanon has initiated preparedness activities for COVID-19 vaccine introduction. To ensure smooth and successful COVID-19 vaccine deployment, an effective coordination mechanism is established. A COVID-19 Vaccine National Coordinating Committee (NCC) was established on November 6, 2020 for the successful planning, coordination and implementation of activities related to the vaccination plan. The NCC is presided by Dr. Abdul Rahman Bizri and is composed of senior-level officials from the MoPH, in addition to UN agencies, World Bank, academia, external partners and private sector providers, with decision-making authority (Figure 1). The primary role of the NCC is to review global level guidelines related to COVID-19 vaccines and incorporate them into the planning and preparations as needed, elaborate on the deployment plan, establish an operations room for coordination, information and communication, communicate with partners and the press, and monitor preparedness progress. The NCC is also responsible for the identification of target populations for COVID-19 vaccines. Additionally, seven national technical working groups have been appointed to focus on the main pillars of the WHO/UNICEF/World Bank (WB) preparedness tool Vaccine Introduction Readiness Assessment Tool/ Vaccine Readiness Assessment Framework (VIRAT/VRAF 2.0): 1) prioritization, 2) targeting and population calculation, 3) service delivery, vaccine supply chain and logistics, 4) regulatory pathways, 5) training, supervision and communication, 6) resources and funding, and 7) safety surveillance, monitoring and evaluation.

The committee met ten times between November 12, 2020 and January 24, 2021. Each technical working group held at least two meetings during this period to discuss issues relevant to their scope of experience and assigned duties. Several experts were invited to join meetings on a need basis. The committee held a joint meeting with representatives from the COVAX vaccine platform and Pfizer Pharmaceutical to discuss the availability of potential vaccines and the steps needed to make them available for Lebanon. The committee held one meeting with H.E. the Minister of Public Health and another dedicated meeting with the WHO Intra Action Review Mission. The chairperson of the committee Dr. Bizri meets regularly with H.E. the Minister of Public Health and all concerned persons and regularly briefs the committee members on various aspects regarding the COVID-19 vaccines implementation.

The Chairperson presented data to the National Technical Group for Infectious Diseases advising the Lebanese MoPH and to the Lebanese Order of Physicians and the Lebanese Society of Infectious Diseases and Clinical Microbiology. Feedback and remarks expressed during these meetings were taken into consideration and integrated in the NDVP.

Figure 1. Members of the COVID-19 Vaccine National Coordinating Committee and Technical Groups

- الدكتور عبد الرحمن بزري – رئيساً
- الدكتور جاك مخباط
- الدكتورة عاتكة بري – رئيسة مصلحة الطب الوقائي
- الدكتورة ندى غصن– رئيسة برنامج الترصد الوبائي
- الدكتورة رندة حمادة – رئيسة برنامج التحصين
- الدكتورة رشا حمرة – رئيسة دائرة التثقيف الصحي سابقاً
- السيدة زينب بري – رئيسة دائرة التثقيف الصحي
- الدكتورة كوليت رعيدي– رئيسة مصلحة الصيدلة
- الدكتورة ريتا كرم – رئيسة برنامج اليقظة الدوائية
- الأنسة هيلدا حرب– رئيسة دائرة الأحصاءات
- ممثل عن منظمة الصحة العالمية– الدكتورة اليسار راضي
- ممثل عم منظمة اليونيسيف–Dr. Genevieve Begkoyian
- ممثل عن البنك الدولي– الدكتورة ندوى رافع
- ممثل عن نقابة الأطباء–بيروت– الدكتور مروان زغبي
- رئيسة الجمعية اللبنانية للأمراض الجرثومية– الدكتورة مادونا مطر
- الدكتور رياض فضل الله
- الدكتور إدمون عبود
- الدكتور محمود زلزلي
- ممثل عن نقابة أطباء الشمال– الدكتور رشاد علم الدين
- نقيبة الممرضات و الممرضين – الدكتورة ميرنا ضومط
- نقيب الصيادلة– الدكتور غسان الأمين
- ممثلين عن نقابة الأسنان – بيروت و الشمال
- الصليب الأحمر اللبناني– السيد جورج كتانة
- ممثل عن الطبابة العسكرية– العميد جورج يوسف
- ممثل عن الأمن الداخلي
- ممثل عن الأمن العام
- ممثل عن أمن الدولة
- وزارة الاعلام
- جمعية Arcenciel
- ممثل عن UNRWA – الدكتور عبد الحكيم شناع
- ممثل عن UNHCR – الدكتور اسعد كاظم
- الدكتورة تاليا عراوي–خبيرة علوم الأخلاقيات
- السيد بسام طبشوري–Medical Engineer
- الدكتورة ريمة مغنية Infection Control Expert –

4. Resources and Funding

4.1. Estimated Budget for Vaccines Procurement and Deployment

With support from the World Bank, WHO and UNICEF, the COVID-19 vaccination readiness assessment using the integrated VIRAT/VRAF 2.0 instrument has been completed and the budget needed for vaccines deployment for 35 percent of the population has been estimated (Table 1).

The main assumptions used to calculate the costs are:

- Quantity of the vaccine doses: the quantity of vaccine doses is based on the agreements signed by MoPH with: (i) the COVAX Facility to procure 2.73 million doses of COVID-19 vaccines for 1.36 million individuals (with a two-dose regimen); and (ii) Pfizer to procure 2.1 million doses for 1.35 million individuals (also a two-dose regimen). The Pfizer vaccine vial contains six doses as communicated officially by Pfizer to the Lebanese MoPH with the need to use low dead-volume syringes and/or needles to ensure extraction of exact six doses from a single vial. If standard syringes and needles are used; it may not be sufficient to extract six doses.
- Cost of the vaccine dose through COVAX: price for self-financing countries is estimated at US$10.55 per dose;
- Cost of HR was estimated based on a vaccination team of 18 members in each of the 50 vaccination sites, compensated based on a flat rate salary of 2 million LBP (512.82 USD at platform rate of 3,900) per member
- Cost of vaccine-related supplies was estimated based on 6 doses per vial for Pfizer and 10 doses per vial for vaccines supplied through COVAX.
- Other unit costs (vaccine-related supplies, PPEs, training, cold chain equipment, and others) were estimated based on the costs available in the market at the time of conducting the costing exercise

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

Table 1. Estimated cost of vaccine deployment*

Supplies and PPE	$	7,565,756.53
HR and training	$	5,639,850.00
Cold chain	$	205,800.00
Waste management	$	150,000.00
Communication	$	300,000.00
IT system	$	60,000.00
Equipment for vaccination site	$	1,884,297.27
Other	$	366,761.54
Total	**$**	**16,172,465.34**

***Estimated cost of the deployment of 4.83 million doses of vaccines to cover the first 35 percent of the population. A detailed costing exercise covering the rest of the population will be conducted to arrive at an**

estimate of the total financial needs. Figures are indicative and subject to change as more information become available (including the specifications of the vaccines supplied by COVAX) and as the deployment plan evolves.

4.2. Funding Sources

The government made a down payment to the COVAX Facility through UNICEF, using the budget allocated for routine vaccinations. The Lebanese government has allocated funds from its budget to cover a portion of the remaining payment to the COVAX Facility.

On January 21, 2021, the World Bank approved a re-allocation of US$34 million under the existing Lebanon Health Resilience Project (LHRP) loan to support GOL in COVID-19 vaccines procurement and deployment.

The MoPH intends to rely on the contributions of development partners, some institutions and readily available resources to reduce operational cost.

Various development partners have been supporting COVID-19 vaccine deployment preparedness in Lebanon. Their roles are summarized in Table 2.

All partners will use this NDVP to accordingly fundraise and response for vaccine allocation.

Table 2. Development partners' support for COVID-19 vaccine deployment in Lebanon

WHO	**Financing amount (if known)**
▪ Providing technical support for vaccine introduction and deployment, including strategies, vaccine safety issues, development guidelines, conducting of training on Adverse Events Following Immunization (AEFI) surveillance for COVID-19 vaccine-related issues, and other issues of vaccine pharmacovigilance. Supporting the MoPH in procurement of COVID-19 vaccine related supplies (syringes, swabs, safety boxes). 6 new ULT freezers.	N/A
WORLD BANK	**Financing amount**
▪ The World Bank, under its current Lebanon Health Resilience Project, is expected to finance COVID-19 vaccines procurement and deployment.	US$34 Million
UNICEF	**Financing amount**

▪ Supporting the development of a roadmap for integration of COVID-19 vaccine deployment in the country; quantification and forecasting of supply needs; cold chain assessment (ULT and normal cold chain), procurement and maintenance; ▪ Procurement of consumable items required for the vaccination process; ▪ Contracting with Arc-en-ciel for waste management; ▪ Acting as the procurement agent for the COVID-19 vaccine through the COVAX facility and facilitating the procurement and delivery of vaccines; ▪ Supporting the communication strategy and community engagement. This COVID 19 response plan budget is not for COVID-19 vaccine introduction. They were raised for the COVID-19 response (PPE for continuity of service). However, this fund, with some flexibility, might be used for emergency response for very initial batches and introduction.	US$4.4 million (for COVID-19 response) From the US$4.4 million for COVID-19 response, minimal capacity to mobilize for the initial and emergency procurement of vaccine commodities and PPE, cold chain maintenance.
UNRWA:	
▪ Supporting MoPH in the delivery of COVID-19 vaccines to displaced and refugee population; ▪ 44 nurses ready to be trained and be deployed in vaccination centers if needed; ▪ Helping in fundraising to get additional vaccine doses for refugees in Lebanon	**N/A**
UNHCR	
▪ Supporting MoPH for the delivery of COVID-19 vaccines to displaced and refugee population; ▪ Helping in fundraising to get additional vaccine doses for refugees in Lebanon	N/A

In addition, the private sector (pharmaceutical sector) will be supporting the vaccine deployment and their support is summarized in table 3.

Table 3. Lebanon Pharma Group (LPG) and Pharmaceutical Importers (LPIA) contribution

Item	Donors	Quantity	Details
Syringes 1ml 27G Insulin	Roche Lebanon	250,000	For FEB & MAR
Needles 23G or 24G 1"	Roche Lebanon	250,000	
Syringe 3ml 23G 11/4	Roche Lebanon	50,000	

Alcohol Swabs	LPG/LPIA	300,000	
Nacl 0.9%	Roche Lebanon/ LPG	50,000	
Suits	LPIA	1,000	
Transport Vehicle with cooling system	Roche Lebanon	2	Donation to MoPH
Transport Vehicle with cooling system	LPIA	10	Put under the MoPH disposal
Registration Software + Call Center	Impact (GoL)		- Impact platform to develop the needed software for free. - This platform will be the property of MoPH.
	LPG (to be confirmed based on final quotation)		Equipment and Administrative Expenses

Ensuring accountability for this initiative is critical. The GOL shall have ensured accountability through partner forums such as the NCC, as the lack of such causes inconsistency and confusion with the public, therefore breaking confidence. Transparency in measuring performance and demonstrating accountability to the public, donors, and policymakers will be critical to the success of the NDVP.

An independent audit committee is suggested to be formed to ensure transparency and confidence in implementation.

The parliamentary health committee will also play its rule as an oversight entity over the implementation of this plan.

5. Target Populations and Vaccination Strategies

5.1. Pre-Registration and Follow-up

5.1.1. Front-end System and Backend Database

Online pre-registration for the COVID-19 vaccine will be a prerequisite for the selection of vaccine recipients, and it will help determine demand for vaccination and ultimately the selection of recipients based on the prioritization scheme.

Pre-registration can be done by the person who wants to be vaccinated, and in case Internet

Immunization monitoring system:
Pre-registration time & vaccination time

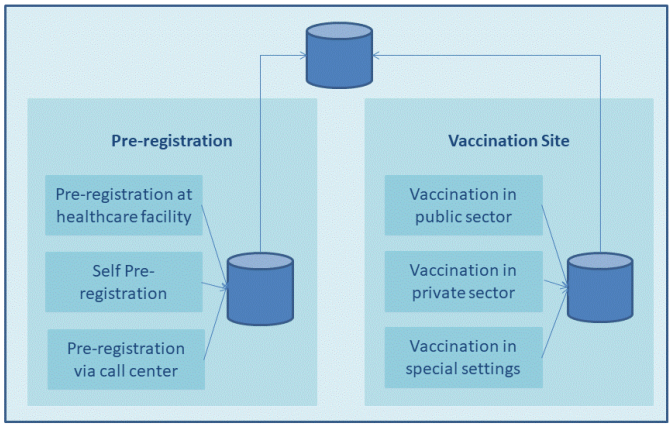


Figure 2. Immunization monitoring system

access is not available, by staff at vaccination centers and by call center agents (who will be trained) through the same platform. Pre-registration for healthcare workers will be allowed through institutions (hospitals, primary healthcare centers (PHCCs)), and other healthcare settings and professionals orders. The front-end (user-facing) pre-registration system and the backend database will require the entry, handling, and/or storage of personal information, and they should be afforded the highest possible data privacy, security/cybersecurity, and redundancy measures. Specifically, the front-end system should limit entry fields to a strict minimum (e.g., name, ID number, date of birth, phone number, town, comorbidities) and avoid the use of open-ended 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 should be made to reduce paper trails, and confidential storage cabinets and proper shredding and disposal should be the norm. For registration platform, to ensure that there will not be abuse of the system, the platform will include a verification code system, security system to prevent hackers, and a back-up system should be in place to be done on daily basis.

5.1.2. Phase 1: Pre-Registration

It is critical to have all the data on the vaccinated population in one dataset, to avoid fragmentation, and ensure proper follow-up and aggregate data analysis and reporting. All people who reside in Lebanon will be eligible to register to get the COVID-19 vaccine; they could either: (i)directly register through their institutions/orders/sectors; (ii)self-register through the application; or (iii) pre-register through a call center.

The IT capabilities of the vaccination centers should be compatible with the registration platform. Registration platform shall be developed in English, Arabic, and French is possible.

5.1.3. Phase 2: Vaccination

After allowing for the selection of priority groups based on the received doses, the new system will assign selected recipients to the nearest (or desired) vaccination center and alert them on the date and time of vaccination by SMS. The vaccination center will be able to track and follow-up with the candidates through the new system and confirm the schedules for vaccination to minimize vaccine wastage and optimize opportunities for vaccination. On the date of vaccination, the center will enter vaccine information such as batch and lot numbers.

5.1.4. Phase 3: Follow-up on Adverse Events

The individual will be monitored for adverse events for 15 minutes following vaccination.

During that time, a community healthcare worker will provide the person with the vaccination card, which includes the system-generated identification number and educate the patient on the side effects of the vaccine and AEFI reporting strategy.

The system will enable individuals who received the vaccine to self-report any side effects that might be developed after receiving the first and second doses of the vaccine.

The individual will be able to report on same platform that was used for pre-registration, on daily basis and up to seven days and then once weekly over 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, do normal daily activities, or seek healthcare.

Case-based AEFI investigation forms are further outlined in the AEFI section.

Annex III includes variables for AEFI reporting.

5.1.5. Phase 4: Follow-up for Second Dose

After three weeks, and with pre-planning for availability of doses, the system will notify the individuals with the date, time and location for the second dose of vaccination. Vaccination centers will go through phase 2 and 3 following the administration of the second dose. Once fist dose is administered for an individual, the second dose will be reserved for that individual automatically. MoPH will ensure that vaccine recipients will complete their vaccination regimen using the same brand.

5.2. Prioritization

Lebanon seeks to vaccinate 80 percent of the total population. This includes both citizens and non-citizens residing in Lebanon. The NCC technical group assumed the task of identifying high-risk population to receive the COVID-19 vaccines given the doses reserved for Lebanon (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 Lebanon is currently in COVID-19 community transmission level 4, and given the limited but gradually increasing supply categorized as Stage II-III according to WHO (10 percent-35 percent), initial focus will be on reduction of morbidity and mortality, maintenance of most critical essential services and reciprocity. 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 WHO SAGE values framework;
- The WHO SAGE prioritization roadmap;
- The fair allocation mechanism for COVID-19 vaccines through the COVAX Facility

Accordingly, Lebanon prioritizes the high-risk populations through a multi-phase roll-out plan.

Phases 1 and 2 represent the first 35 percent of the total population (both citizens and non-citizens) to be vaccinated in 2021. The stages 3 and 4 will cover the rest of the targeted population. Vaccination to

priority populations (Table 4) will be managed in an inclusive and non-discriminatory manner (including outreach activities to vulnerable groups, such as refugees).

Industrial sectors will be encouraged to secure the vaccine from the private sector once it is available to vaccinate their staff. This is essential to regain the economic cycle in the country.

Table 4. Estimated priority populations for COVID-19 vaccination in Lebanon

Phase	Target population	Population size[1]	Share of population*
First 35%[2]	High risk health workers	55,000	0.8%
	Aged 65 and older	600,143	9.2%
	Those below age 65 (55 – 64 years) but with comorbidities	237,183	3.6%
	All those between ages 55-64 not covered earlier, 16-54 years with co-morbidities[3], health workers not covered earlier	237,183 1,150,671 5,000	3.6% 17.7% 0.1%
	Persons and staff in elderly shelters, prisons, and individuals essential for preserving the essential function of the society (the national COVID-19 vaccination committee will define strict criteria to identify recipients of the latter group).	25,000	3.4%
Next 35%	Other vulnerable populations, schoolteachers and school staff**, childcare workers, other critical workers in high risk settings, remaining health care workers, family caregivers of those age ≥65 or with special needs, and all those above the age of 16 willing to be vaccinated	2,449,820	35%

***overlaps exist and sums do not add up**

**** School teachers and school staff are estimated to be around 120,000**

[1] The total population considered for calculation is 6,800,000. This includes 5,999,958 Lebanese citizens and registered refugees and approximately 800,042 unregistered refugees and migrants.

[2] This includes Phases 1 and 2 while the remining 35% includes Phases 3 and 4.

[3] An estimated figure of 30% prevalence of Hypertension has been used to estimate the number of co-morbidities in the population 16-54. Findings of recent studies in Lebanon have showed that Hypertension affects approximately one-third of the Lebanese population. (D. Matar, A. H. Frangieh, S. Abouassi et al., "Prevalence, awareness, treatment, and control of hypertension in Lebanon," The Journal of Clinical Hypertension, vol. 17, no. 5, pp. 381–388, 2015; The Lebanon STEPS 2017 database for NCD includes a prevalence of Hypertension of 35% in the age group 20-69 years.)

Sequential prioritization of HCWs:

- Frontline HCWs (ER personnel, ICU…);
- Medical, nursing and postgraduate students if involved in frontline healthcare;
- HCWs performing aerosol-generating procedures (e.g., intubation, cough induction procedures, bronchoscopies, some dental procedures and exams);
- Environmental HCWs in health care facilities (Infection control, cleaners and housekeepers);
- Healthcare or laboratory personnel collecting or handling specimens;
- Medical transport workers (e.g., ambulance vehicle operators, Red Cross);
- Mortuary workers involved in preparing (e.g., for burial or cremation) the bodies of people who are known to have COVID-19 and morgue workers performing autopsies;
- Physicians in private clinics (ID physicians, Pulmonologists);
- Midwives working outside hospitals;
- Physiotherapists;
- Community pharmacists;
- Dentists;
- PHCCs staff

Table 5. Healthcare workers categorization by risk of exposure

Category 1 High-Risk	Category 2 Intermediate-Risk	Category 3 Lower-Risk
Emergency Departments (Rooms)	Operating Rooms (theaters)	Administration
COVID Units (ICU & Regular)	Recovery Room	Admitting officers
Laboratory staff (COVID & others)	Surgical ICU	Billing department
Medical ICUs	Coronary care units	Security staff
Endoscopy Units	Medical & surgical wards	Central Sterile Department
Dialysis Units	Catheterization Labs and	Auxiliary services
Oncology units	Private clinics + OPDs	Laundry
Delivery suite	Physiotherapy	
Radiology Department	Dentists	
House Keeping	Pharmacists	
Ambulance services	Plant engineering	
Home-care	Incarceration centers HCWs	
Inhalation therapy	Shelters orphanages HCWs	
Nursing homes	Dieticians & nutrition	
COVID-19 isolation and Quarantine centers	Speech Therapy & Ergo therapists	
COCIVD-19vaccination staff	Psychologists	

Table 6. Vaccine Prioritization among nurses

Very high risk	High risk	Medium risk	Low risk
Emergency room	Coronary care + telemetry units	Endoscopy unit	Nursing faculties and technical schools
ICU (COVID and regular)	Medical surgical and pediatric	Operating room	Insurance companies
NICU and PICU	Dialysis	Recovery room	Medical companies
Inhalation therapy	Home care nursing		Administration
Cardiac surgical unit	Long stay hospitals		
Regular COVID-19 ward	Nurseries & schools		
Oncology + Palliative care	Primary care centers		
COVID-19 Vaccination team			

Sequential prioritization of underlying medical conditions based on national epidemiological data on those at greater risk of requiring hospitalization or experiencing severe illness with possible poor outcome:

- Patients on dialysis;
- Cardiovascular diseases;
- Diabetes;
- Hypertension;
- Obesity (BMI of ≥40 Kg/m^2);
- Cancer patients (particularly hematological malignancies, lung cancer, and metastatic disease);
- Chronic kidney disease and kidney transplant patients;
- Chronic obstructive lung disease (COPD – Asthma);
- Immunocompromised individuals for any reason (HIV/AIDS, TB);
- Other chronic illnesses (Neurological, rheumatologic diseases; i.e MS patients).

WHO and the U.S. FDA have issued an EUA to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 16 years of age and older. Accordingly, people under 16 years have been excluded for now and will be reviewed for inclusion later as more information on vaccine safety and efficacy among them become available. This also applies for pregnant and lactating women.

MoPH has also decided that individuals who had a severe allergic reaction after a previous dose of this vaccine and individuals who had a severe allergic reaction to any ingredient of this vaccine will not be eligible for taking the COVID-19 vaccines.

5.3. Outreach Activities

5.3.1. Reaching out to Incarcerated Individuals

A special sub-committee will be formed, composed of:

- Jacques Mokhbat MD;
- Nadine Yared MD (coordinator);

- Dr. Atika Berry, Head of Preventive Medicine Department at MoPH;
- Representative from the Internal security Forces (Prisons Division);
- Member representing the Order of Lawyers in Lebanon;
- Member representing the Order of Lawyers in North Lebanon;
- Judge representing the judiciary;
- Representative from MoPH;
- Member from Order of Nurses;
- Abdul Rahman Bizri MD (ex-officio)

This committee will plan and coordinate activities relevant to immunizing those incarcerated in jails and prisons and those responsible for them. All supplies needed and logistics required will be evaluated to ensure rapid, efficient, and safe immunization plan. The sub-committee will report its activities to the NCC and seek support from the committee to be able execute the entitled tasks.

5.3.2. Reaching out for the Elderly and Debilitated in Nursing Homes

Elderly people residing in nursing homes will be vaccinated in the tranquility of their vicinity. Mobile, refrigerated, adequately staffed, and well-equipped units will go in an organized fashion to vaccinate all those residing at these facilities. Nursing staff taking care of the elderly will be vaccinated as well. Elderly individuals acknowledged by the facility physician or administrator to be well oriented and can make their own intelligent decision will be vaccinated without consenting. Meanwhile, others who are mentally incapable of deciding, their families will consent for them. Vaccination is optional for all and decision will be individualized.

Lebanese Red Cross will be ready with more than 30 vehicles (cars and ambulances) to conduct the above-mentioned outreach activities given a clear agenda, at least a day in advance , a clear list of the individuals' names and telephones to contact them and transport them to the nearest vaccination center according to the locations provided and according to priority criteria.

5.3.3. Reaching out for those with special needs and residing in special care centers

Individuals with special needs residing in dedicated facilities will be vaccinated at their residence. Mobile, refrigerated, adequately staffed, and well-equipped units will go in an organized fashion to vaccinate all those residing at these facilities. Nursing staff taking care of those with special needs will be vaccinated as well. Individuals acknowledged by the facility physician or administrator to be well oriented and can make their own intelligent decision will be vaccinated without consenting. Meanwhile, those who are mentally incapable of deciding, their families will consent for them. Vaccination is optional for all and the decision will be individualized.

5.3.4. Vaccinating the Diplomatic and International Missions & UN Agencies Staff in Lebanon

The MoPH in coordination with the Lebanese Ministry of Foreign Affairs (MoFA) will contact all diplomatic and international missions in Lebanon including the UN affiliated missions to offer them the vaccine according to priorities set above. The Lebanese government will assume this responsibility and provide free vaccines for all diplomatic staff in the country following same priorities set. Appointments will be determined, and location of vaccine centers will be assigned as per information filled on the platform. They can register on platform like professional orders by their relevant embassies or UN agencies.

Those missions who wish to vaccinate their own staff and or dependents on their own behalf will be asked to inform the MoPH or the MoFA. Lebanese nationals who receive the vaccine through the diplomatic mission they work for will be asked to fill their own page on the platform.

5.4. Vaccine Administration Guidelines

- Vaccines will be accessible on rolling basis; depending on vaccine availability, delivery schedules and identifications of most urgent groups to vaccine as mentioned above;
- All individuals 18 years and above willing to be vaccinated will be offered the vaccine;
- Individuals 16 - 17 years of age and willing will be offered the vaccine after obtaining their parents' consent;
- Promote – choice: vaccines are not mandatory but will be offered to all above 16 years of age; these individuals have the right to accept or defer;
- Empowerment: to help individuals make an educated 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 MoPH will not be charged for the price of the vaccine;
- All those residing in Lebanon and qualify for vaccination (above 16 years) will be included in the immunization initiative irrespective of nationality;
- Any private purchase of vaccines will be done in coordination with the MoPH and the vaccines administered will be included in the national campaign;
- Any vaccine donation will be accepted in coordination with the MoPH and the vaccines administered to be included in the national campaign.

5.5. Vaccination Sites

50 private and public hospitals were identified to provide vaccination services in the early stages for health care workers and other priority groups (Annex IV; Annex V). The vaccination process will start with few 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;
- Providing sufficient space and rooms for vaccination (more than 8 rooms);
- 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.[4]

An audit committee to be formed by the MoPH to check on vaccination centers to ensure that the requirements of cold chain and other requirements of the vaccination process are in place (once it starts).

Initially one central storage site will be used which is Rafic Hariri University Hospital (RHUH) which has two ULT freezers ready for storage. At later stages, other vaccination sites might be utilized as central storage sites for Pfizer vaccines as they are equipped with ULT freezers. This decision will be made by MoPH according to the number of vaccines received.

5.6. 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 proposed for human resource team required (Table 7), patient flow at vaccination site (Figure 3), expected capacity of each vaccination site and timing needed at vaccination site for each individual to receive vaccine.

5.7. 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 (Figure 3) has been depicted as follows:

I. Pre-vaccination

- Individuals fill pre-registration form via the designated online digital application or via phone call submitted to MoPH COVID-19 vaccine call center;
- 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 MoPH to reduce traffic on certain centers);

[4] MoPH Standard Operating Procedure for COVID-19 Immunization

- 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 will be developed based on CDC form to determine if there is any reason that will prevent the individual from receiving the vaccine at the assigned day.
- For Pfizer Vaccines: Prior to administering the vaccine, administrative clerk/data entry will thoroughly explain the risks and benefits of the Pfizer-BioNTech COVID-19 vaccine that could be found (Annex VI) 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 (triple verification: Full name, individual ID and ID provided by SMS from the MoPH) while vaccinator prepares the vaccine (vial storage, thawing, dilution and handling can be found in (Annex VII);
- Patient vaccinated;
- Patient is provided with a hard copy of the vaccination card (to be distributed by MoPH 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

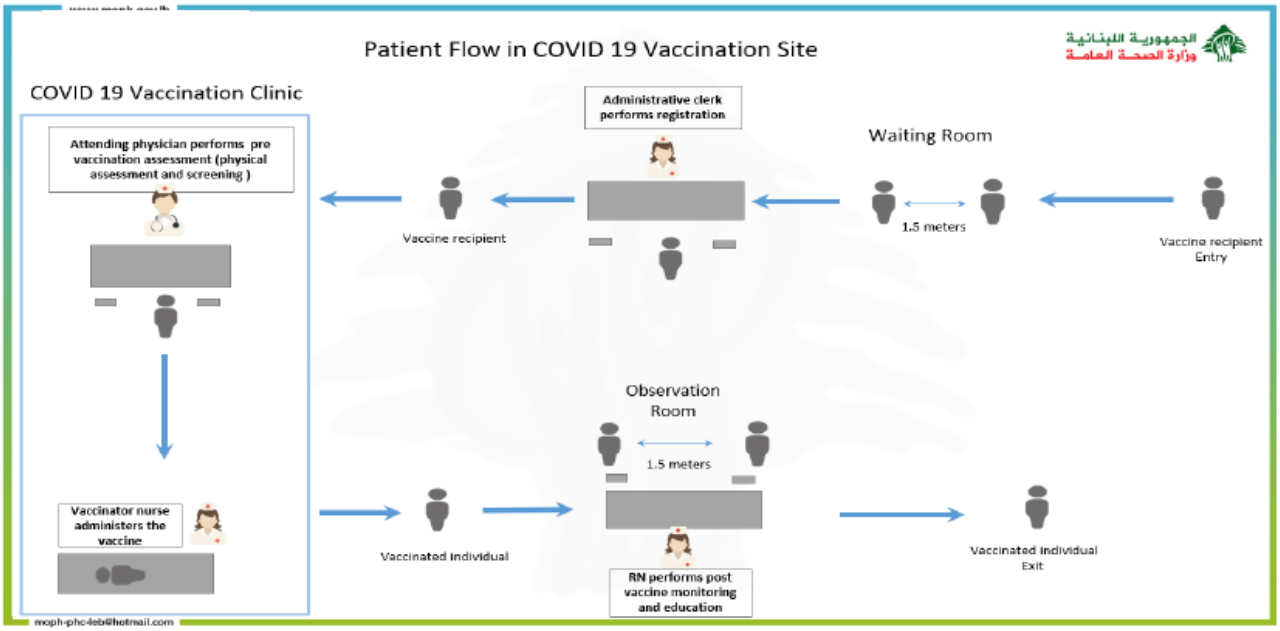
- Patient is counseled by nurse on expected side effects;
- Once patient passes the 15 minutes waiting time, he/she is cleared to depart vaccination center;
- Patient with known allergies to vaccines will be asked to wait for 30 minutes;
- Follow up text or call to confirm date of subsequent injection/second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

Immediate Measures in Case of a Severe Allergic Reaction/Anaphylaxis including Recognition of Anaphylaxis was developed (Annex VIII).

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.

Figure 3. Patient flow in COVID-19 vaccination site



5.8. Vaccination in confined areas

In elderly homes, residential health facilities and prisons, mobile teams will be organized to administer the vaccine to the elderly residents and prisoners, as well as staff taking care of them, based on a pre-registration done by the elderly home/residential health facilities (deir el salib)/prison.

Those residing in care centers who are elderly, debilitated and need assistance will be vaccinated at site. Mobile units with refrigerated (cooling) rapids and minivans will be available and well equipped and staffed to administer the vaccine. This method was preferred over other alternatives in order to:

- Protect the elderly and frail
- Keep their comfort
- Avoid psychological trauma
- Preserve their privacy
- Spare them unnecessary dramatic mobilization

The mobile cars will be donated with no extra cost to the vaccination program.

5.9. Infection Prevention and Control

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 and developing a plan of action responding to the detection of COVID-19 cases. Standard Operating Procedures (SOPs) for IPC for pre-vaccination and vaccination were developed by the NCC (Annex IX).

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.
- 1 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).
- 1 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)
- Cold chain equipment for the infectious waste resulting from vaccination

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 whether by repetitive PCR tests or 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 MoPH 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.
VI. Supervisors at the provincial level will be responsible for monitoring the adherence of vaccinators to IPC measures and will incite them regularly to oversee the compliance of their

teams to the protective measures. Supervisors will be required to report to the MoPH on the adherence of their teams to IPC measure on daily basis.

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. UNICEF in partnership with Arcen-ciel will support the waste management of all materials.

As the vaccines from Pfizer and those through the COVAX will be received in batches, vaccination will be done in phases, based on the prioritization scheme and the availability of doses.

A multi-disciplinary team of 18 persons (table 7) will be assigned in each vaccination site to manage the deployment of the vaccine.

5.10. Human resources at vaccination sites

Table 7. Human resources at vaccination sites

Human Resources at Vaccination Sites	Description
Physicians (1 physician per site)	Physical assessment of vaccine candidates, administers screening checklist, responds to emergencies (e.g. anaphylaxis shock) and oversees vaccination process
Pharmacist	Removes vaccine from cold storage, dilutes, draws up doses from multi dose vials, labels vaccine
Registered nurses **(1 register nurse for 2 vaccinator nurses)**	Physical assessment of every vaccine candidate, administers screening checklist, observe the 15 to 30 mn post vaccination, surveillance of any AEFI
Vaccinator Nurse (at least 8+ vaccinators per site)	Administers vaccine and responds to emergencies (i.e.anaphylaxis shock)
Non-clinical observer/ security officer (2 per site)	Monitors and secures vaccination storage and vaccination administration area and flow of individuals
Administrative Clerks/data operators (2 per site)	Ensures paperwork/ electronic data is complete, validates name on schedule, reminds recipient on future dose, enters data from vaccine administration and handling of certification
Center Director (senior administrator or physician)	Monitors all activities, communicate with MoPH, collaborates with NCVC

Vaccination of 1 individual is estimated to take 10 mins as per Pfizer fact sheet for healthcare workers. Assuming an 8-hour shift (with 6 hours for active vaccination), each vaccinator can vaccinate 36 recipients/day.

The vaccinator could be a trained physician or a BSN nurse meeting the following criteria:

ER trainings and practice (BTS and anaphylaxis treatment) and immunization study day

In addition to the vaccination team per site, the MoPH will assign at least 2 coordinators at the central level and 8 coordinators at the subnational level (1 in each governorate) to coordinate the delivery of the vaccines.

To ensure proper implementation at vaccination sites, one to two persons are needed to monitor the vaccination process and report centrally; around 80 persons are needed. Volunteers from orders like order of pharmacists, order of nurses, order or midwives, Red Cross and other Non-governmental Organizations (NGOs) might be an option to secure needed human resources to monitor the vaccination process.

5.11. Pfizer-BioNTech COVID-19 Vaccine

WHO and the U.S. FDA have issued an EUA to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 16 years of age and older.

Pfizer-BioNTech COVID-19 vaccine requires storage in ULT freezers. Lebanon has 13 ULT freezers in 12 public and private hospitals in all eight governorates. They were supplied by WHO between 2015 and 2017 as part of influenza pandemic preparedness. Additionally, 3 private hospitals have been identified to have ULT freezers, which brings the total number of hospitals equipped with adequate ULT cold chain to 15 hospitals. UNICEF conducted a functionality assessment of the 13 ULT freezers and it was found out that they are functioning properly and in good conditions. UNICEF will be carrying out routine maintenance and disinfections of these ULT freezers prior to vaccine arrival.

In addition to the existing ULT freezers, WHO will support the MoPH with 6 new ULT freezers.

Pfizer will supply the vaccine to a central delivery site at RHUH in early phases and over the course of implementation, 1 site per governorate for ease of transportation might be considered and the total of 12 vaccination centers might be used as storage places as well if needed.. Pfizer will deliver the vaccine using thermal shippers that contain up to 1170 doses (vial is officially announced to contain 6 doses). Transportation from central delivery site to vaccination centers will be planned accordingly. (ref. to the most recent guidance from WHO-UNICEF-GAVI in Annex X. This guidance will be contextualized to Lebanon according to the number of vaccine doses and vaccine type).

The Pfizer vaccine will be distributed to vaccination sites will be based on need and utilization, in line with the cold chain requirements for the vaccine. MoPH received 12 cars equipped with fridges (from Pharma Group) to help in transportation from central storage to vaccination sites.

The current plans represent a relatively small and gradual vaccination initiative, allowing Lebanon to learn by doing and from other country experiences, which has been the essence of the global COVID-19 response so far.

5.12. Undetermined Vaccine through COVAX Facility

With the current uncertainties around the selected vaccine, cold chain specifications and vaccination centers remain pending. The first batch of the COVAX Facility vaccine is expected to be delivered before the end of Q1 2021.

5.13. Private Market COVID-19 Vaccine Procurement

Due to the burden of COVID19 and the public health and social measures on the economy, some private companies have expressed willingness to purchase vaccine for their staff. As per the law No. 211 enacted by GOL on January 16, 2021 on Regulating the Emerging Use of Medical Products to Combat the COVID-19 Pandemic, private sector will be able to procure COVID-19 vaccines, by virtue of a license issued by a decision from the MoPH, in accordance with the rules for emergency use. MoPH will ensure strict regulations for ensuring that the private sector adheres to vaccination guidelines and standards developed by MoPH, follows the required importation and clearance regulations and adheres to AEFI reporting and performance reporting rules established by MoPH.

Regulating and coordinating the procurement distribution of vaccines by private sector:

All vaccines to be introduced through the private sector and/or as donations should be deployed under the umbrella of this plan, using the same registration platform and following same priorities set.

It is suggested to establish a special fund for those interested to donate money to be able to purchase more vaccine doses through MoPH.

Any covid-19 vaccine to be introduced under clinical trials setting in Lebanon, should follow current regulations of clinical trials in Lebanon; having an ethical approval from an authorized IRB in the country, vaccine to be given for free, in addition to other CT requirements.

Depending on the global market availability, and the cold chain requirements, the possibility of introducing COVID-19 vaccines in private pharmacies in the country is to be considered after being registered and approved to enter the private market through local suppliers/warehouses; in such a case, all pharmacies will need to use the same database and COVID-19 vaccine monitoring platform, and follow the same waste management standards and procedures.

6. Supply chain management and health care waste management

6.1 Supply chain management

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 procurement, storage, distribution, transportation and repacking. Hence, it is imperative to protect supply chains and maintain vaccines' integrity and safety.

This guideline aims to be applicable for all participating entities and institutes, starting from the moment the vaccines arrive in Lebanon through Rafic Hariri International Airport, to their storage, distribution, administration and disposal.

It is worth noting that MoPH with partners (UNICEF and WHO) is currently in the process of conducting an Effective Vaccine Management (EVM) assessment which will examine all elements of the vaccine supply chain including the cold chain. The EVM will cover 9 criteria specifically; vaccine arrival, temperature management, storage capacity, infrastructure, maintenance, stock management,

distribution, vaccine management and waste management. It is expected to be completed by the end of Q1 (including the comprehensive improvement plan).

6.1.1. Roles and responsibilities

Responsible bodies for implementation and supervision are:

- MoPH
- Ministry of Information (MoI)
- Ministry of Environment (MoE)
- UNICEF
- Ministry of Defense and Lebanese Army
- WHO
- UNHCR
- Ministry of Interior and Municipalities
- Vaccination Sites (Hospitals and other health care centers)
- Other governmental and official agencies responsible for follow-up

  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.

6.1.2. Procurement and Delivery

In addition to the bilateral agreement with Pfizer, Procurement of vaccines will be through UNICEF Supply Division on behalf of the COVAX facility and directly by MOPH for the bilateral agreements.

UNICEF and WHO will purchase necessary vaccination supplies, including syringes, PPE and non-clinical consumables in line with standard procurement procedures, as per forecasts provided by MOPH. Actual quantities will be agreed in advance by the two agencies, taking into consideration availability of funds. The list of HR and supplies and quantities required is provided as Annex XI.

6.1.3. Vaccine Arrival and Receipt

The port of entry will continue to be Rafic Hariri 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 central ee(s) as mentioned earlier in the plan. The main storage facility for the first batch of the vaccines will be Rafic Hariri University Hospital in Beirut, and two more can be added as needed. Vaccines will be transported in thermal shippers that keep ULT. Each shipper can hold a minimum of 1 tray (975 doses) or up to 5 trays (4,875 doses). Each of these shippers has a reusable GPS enabled temperature monitoring device to ensure end-to-end distribution within required temperatures.

- Other vaccines: Transportation strategy of other vaccines from the airport to the storage/vaccination sites will depend on the characteristics of the vaccines. They will be transported in refrigerated trucks by the appointed handling agent to a storage location to be determined by the temperature categorization. This will either be the MoPH cold rooms at Rafic Hariri University Hospital (or eventually to the MoPH central warehouse in Quarantina when rehabilitated).

Suppliers will provide the MoPH with a Vaccine arrival report (VAR) that 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, the date of validity, making sure not to receive broken or frozen bottles and that the packages/cartons are in good condition, and checking as well the status of the Vaccine vial monitor (VVM) if any.

6.1.4. Good Storage Practice (GSP)

The following practices will be taken into consideration when storing the vaccines in line with national GSP guidelines Annex XII:

- 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.

6.1.5. 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 uninterrupted 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.

6.1.5.1. For vaccines requiring storage temperatures of +2oC to +8oC and -20oC:

Lebanon has a well-established cold chain for routine immunization which will be leveraged for the COVID 19 vaccines that need to be stored at +2oC to +8oC and -20oC.The MoPH central warehouse at Quarantina is currently being rehabilitated following the PoB explosion and would normally have the following capacity:

- 5 prefabricated cold rooms (200cbm)
- 4 built-in cold rooms (80cbm)
- 1 built-in refrigeration room (20cbm)

The vaccines are therefore being stored temporarily at Rafic Hariri University Hospital which serves as the central storage location. The hospital has a capacity of 3 cold rooms with a total volume of 60 cbm and 3 freezers with a total volume of 3 cbm, including 1 ULT freezer. Two additional cold-rooms with a total volume of 80 cbm will be installed by end-January.

The rehabilitation of the central warehouse is expected to be completed by Q2 2021 with the following estimated capacity:

- 3 prefabricated cold rooms (120cbm)
- 4 built-in cold rooms (239cbm)
- 7 built-in refrigeration room (310cbm)

A cold chain assessment is ongoing, to be completed in Q1 2021. This will determine the exact status of the cold chain and inform any rehabilitation requirements needed to accommodate the additional COVID vaccine storage requirements if any. Additional cold chain equipment will be procured as needed.

6.1.5.2. For vaccines requiring ULT (Pfizer):

Lebanon has 13 ULT freezers in 12 public and private hospitals in all eight governorates. They were supplied by WHO between 2015 and 2017 as part of influenza pandemic preparedness. Additionally, 3 private hospitals have been identified to have ULT freezers, which brings the total number of hospitals equipped with adequate ULT cold chain to 15 hospitals. UNICEF, through a third-party service provider, conducted a functionality assessment of the 13 ULT freezers and it was found out that they are functioning properly and in good conditions. UNICEF will be carrying out routine maintenance and disinfection of these ULT freezers prior to vaccine arrival to ensure that they are fully functional to safely store the Pfizer vaccine.

Similarly, the cold chain equipment of around 40 vaccination sites is being assessed in terms of capacity and functionality, and they will be maintained appropriately.

In addition to the existing ULT freezers, WHO will support the MoPH with 6 new ULT freezers.

The ongoing cold chain assessment will provide a mapping of the cold chain at all the vaccination sites, confirm the current available cold chain capacity and enable a cold chain strategy based on the different types of potential vaccines (+2 oC to +8 oC and UCC) which will inform the distribution plan and deployment of vaccines.

The Pfizer vaccine will be delivered straight to 1 or more storage sites on arrival for safe storage in the ULT freezers. These locations will also serve as vaccination points to minimize the need for transporting the vaccine to other locations and hence risk of damage to the vaccines if taken out of the UCT.

MoPH will be using refrigerated trucks to transport vaccines from the storage sites to other vaccination sites.

For distribution of the vaccine from the storage sites to other vaccination points in the refrigerated cars and avoiding the use of dry ice as much as possible due to shortage in the country and due to negative environmental impact.

Furthermore, to ensure that the vaccine is not wasted or risk storing it at sub-optimal temperature for a long period, the pre-registration of all eligible adults who will take the vaccine must be provided with a back-up list and distributed to vaccination sites. This will ensure that if a person does not show-up to the assigned vaccination schedule, the vaccine can be given to another eligible person from the back-up list or allow walk in appointments at end of each working day at vaccination sites.

Power Supply and Back Up

The cold chain assessment and rehabilitation exercise is taking into consideration the power supply and availability thereof.

UPSs will be installed at all storage sites as per the list of Specs below:

- Wide input voltage window, generator compatible
- 220 VAC, 50 Hz single phase output
- 10 KVA True on-line double conversion design providing galvanic isolation.
- Sine wave pulse width modulation (PWM) IGBT inverter design or 12 pulse SCR with Filter
- Pure sine wave output with less than 3% THD (Linear Load)
- Battery bank with at least 8000 WH capacity (Indicate battery type(s) and quote each).
- Expandable backup time with extra batteries with cabinet space
- Load/Battery power meter, overload, on-line, battery status LED/LCD
- Advanced Battery Management with Automatic charging in off-mode
- Zero transfer time on AC mode to/ from battery mode/ bypass mode
- Smart RS-232 communication and optional SNMP

6.2. 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

6.3. Good Distribution Practice (GDP)

When first receiving the vaccines, the team will ensure the following:

- Always check the tracking of temperature and ensure adequate storage, using an appropriate temperature monitoring device; GSM thermometer or RFID;
- Ensure all vaccines are received at a required temperature;
- The vaccines were transported by refrigerated vehicles designated for this;
- Ensure the presence of a Waybill and other relevant shipping documents e.g. packing list, manufacturer's certification, country of origin certificate.
- The recipient signs the receipt after cross-checking the quantity contained in the statement with the actual quantity;
- Conduct a physical examination of the received vaccines for quality control purposes, ensuring the absence of damages; a leakage, the absence of a sticker with basic information (such as the type of vaccine, expiry date, manufacturing batch number) and other quality control parameters;
- The vaccine is stored in the appropriate cold chains and according to the appropriate temperature, as soon as it is received.
- Ensure completion of the Vaccine Arrival Report (VAR) to confirm the status of the vaccine on receipt and reporting this back to the procuring agent within 72 hours of arrival in country.

Distribution of vaccines to additional vaccination sites:

- All vaccines should be carried in specialized vaccine carriers with temperatures according to the manufacturers' instruction;
- The necessity to account for the vaccines' specific stability factor and the time spent in the shipping process;
- Ensure that the Data-logger is present with any movement of the vaccine, regardless of the shipment distance and duration;
- Vaccines are transported only by authorized refrigerated vehicles specially equipped for this purpose;
- Ensure the presence of a waybill and dismissal document signed by the authorized personnel with documented date and time of receipt;
- Physically examine the received vaccine for quality control purposes;
- The vaccine is stored in the appropriate cold chain condition and according to the appropriate temperature, as soon as it is received.
- With the 50 selected vaccination points, there will be a need for cold boxes and dry ice to transport the UCC vaccine between the 12 ULT freezer hospital and the other hospitals selected

as vaccination points however as mentioned above, wherever possible refrigerated trucks will be used to minimize the need for dry ice due to lack of availability in country and the environmental impact.

- A robust continuous temperature monitoring system during storage and distribution will be critical to ensure vaccine quality at all times.
- Vaccines not requiring the UCC will be transported as per regular well-established protocols.

6.4. Risks and mitigation measures

1) Maintaining the UCC

Noting the ultra-cold chain storage requirements (-70°C) and the short term storage at up to 5 days in refrigeration at 2-8°C before use, and noting also that initial vaccines may not come with a VVM, maintaining the ultra-cold chain throughout the supply chain is critical to ensure the quality and efficacy of the vaccine. To mitigate this risk, MoPH (with the support of partners including UNICEF and WHO) will ensure:

I. Effective and routine maintenance of the ULT equipment;
II. Temperature monitoring devices and a mechanism for continuous temperature monitoring throughout the supply chain from receipt, during storage and delivery to the vaccination point;
III. Availability of enough dry ice in case there is a need for transporting the vaccine;
IV. A clear vaccination schedule and back up to avoid extended periods of storage at the vaccination point;
V. A robust information system to manage, track and report on the vaccine stocks and consumption effectively.

The same risk mitigation measures apply to vaccines that require regular cold chain (2-8°C, -20°C) however MoPH has the structures and set up in place to leverage for these vaccines.

6.5. Security of the Vaccine

The Government of Lebanon plans to use the armed forces for logistics to protect the COVID-19 vaccine supply against possible theft, fraud, ransom, etc. All vaccination-related activities carried out by the armed forces under the vaccination deployment of the MoPH will be done under the control and with coordination of MoPH. All related goods, works, services, operating costs and training will be used under the direction and coordination of MoPH and strictly in accordance with COVID-19 vaccine SOPs and protocols.

In addition, MoPH will ensure appropriate tracking mechanisms for traceability of the vaccine throughout the supply chain.

Security arrangements for vaccine arrival, storage, transport and at vaccination sites will be coordinated among Ministry of Interior, Ministry of Defense & Army and Ministry of Public Health and national committee.

6.6. 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) and reagents and equipment used. 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 GOL legislations. Effective administrative and infectious-controlling and engineering controls would be put in place to minimize these risks. Climate change can affect the trajectory of the COVID-19 pandemic and impact groups that are most susceptible to the virus including healthcare workers, the elderly, those with pre-existing conditions, people with disabilities and other disadvantaged groups.

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. The MoPH will contract with medical waste management firm (Arcenciel) to handle this waste, in coordination with MoE. SOPs for collection, treatment and final disposal of the vaccine vials were developed by the NCC (Annex IX).

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 Lebanese Public Health Laws, the MoPH will adopt the following measures:

I. 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:

   - Lebanese decrees 8006-2002 and 13389-2004

   Decree 13389/2004, amends decree 8006/2002. 13389 regulates healthcare waste. It defines the type of healthcare wastes. It requires proper waste segregation and minimization. It sets guidelines for the collection and storage of waste. Finally, it requires an EIA for healthcare waste treatment facilities in order to get a license from MoE. PHCCs and Hospitals are required to abide by decree 13389/2004.

   - Decision 1/1294-2018 and 1/1295-2018

   These decisions regulate the transport of infectious healthcare waste (1/1294) and the construction and operation of facilities (1/1295) for the disinfection of hazardous and infectious waste. 1/1295 specifies the process for the acquisition of an environmental license to operate such facilities. For the disposal of their wastes, MoPH will make sure that contracted companies abide by these two decisions.

   - Others related (Decree 167/2017, Decision 8/1 2001 ELVs, Circular 11/2011, Law 48/2017, Circular 7/1- 2017, etc.).

II. Ensuring hand sterilization techniques after dealing with medical waste.

III. 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 planwill inlcude 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.

Vaccine Arrival

Journey of vaccine arrival, storage and distribution is in annex XIII.

7 Human resources management and training

- Summary table of a national overview of human resources by category.
- Conclusion: statement on whether additional human resources (also staff for community mobilization, cold chain and supply chain management and other required support functions) are needed.
- Define training strategy building on lessons learned from other vaccines; ensure this is reflected in readiness checklist and in budget.
- Description of supportive supervision system.
- central/organizational level: HR needed based on WB shared document –
- training for all members of vaccinating teams (MERA, Pfizer adm)
- IT staff to train vax teams –
- Pfizer to train directly vaccinating teams –

7.1. Identifying and Planning Human Resources Needs, Surges and Redeployment

In any pandemic, capacities have to be scaled up, and everyone involved needs to step up. A successful vaccination program will protect people from severe illness and help everyone on the nation to return back to normal life, and the successful introduction of COVID-19 vaccines requires having sufficient staff and providing them with high-quality training and performance support.

The current pandemic has put a strain on the health workforce at large, therefore it is important to identify, and plan, needs and surge/redeployment strategies in a holistic manner in order to deliver COVID-19 vaccine to the population while ensuring safe and effective delivery to everyone.

The plan has different stages of prioritization, each stage has its number of the vaccination sites designated for vaccine distribution and administration with a prepared human resources and work flow plans. Moreover, the MOHP is currently preparing around 20 to 50 vaccination sites depending upon availability of vaccines and type of vaccine.

7.2. Design and plan trainings

Training at the central level and the managerial/ governorates level will be virtual, in-person and blended learning (combination of online and in-person) methods. Other considerations include staff experience and motivation with online learning, as well as support mechanisms available for trouble-shooting technical problems.

For the service providers/ immunization staff, to maintain high-quality training for in-person training, the MOHP will:

- Limit the number of levels through which the training is rolled out
- Ensure the safety and health of staff being trained by equipping the facilities where trainings are held to enable hand hygiene and ability for staff to social distance;
- Schedule the training in close coordination with the COVID-19 vaccine introduction – ideally no more than 2 or 3 weeks prior to the COVID-19 vaccine launch.
- Consider ways to ensure that health workers being trained on general population vaccination have already received their COVID-19 immunization prior to training and vaccination activities.
- Follow the training with supportive supervision to ensure that health workers correctly apply the new skills and procedures.
- Use best practices of adult learning methods to ensure key points are understood and applied correctly in the job. These include small group discussions, demonstrations and skills practices.
- Share short videos or infographics to enhance learning online.

Performance support materials such as job aids, checklists and summarized reference materials that can be used for post-training reference and support. A mock trial is suggested to be done at different sites in order to determine the average time needed for an individual from entry until leaving the vaccination site. This process will help in more efficient scheduling.

WHO recommended training packages for all workers involved in implementation of COVID-19 vaccination who need to have adequate knowledge and skills in order to ensure safe and efficient COVID-19 vaccination administration, the training package is developed for front-line HCWs.

For the Pfizer vaccine, Pfizer has offered support to provide training for the vaccinators by (i) making vaccination training materials available online and (ii) supporting training sessions through videoconferencing. These training sessions already started.

For the COVAX Facility vaccine, WHO will provide two versions of a comprehensive curriculum with training materials for all aspects of COVID-19 vaccination (online and face-to-face training versions). MOPH has not determined the training modality.

Critical support measures to enhance the performance of the workforce include ensuring appropriate working hours and enforced rest periods; providing guidance, training and supplies to limit health worker exposures; providing physical security and psychosocial support; monitoring for illness, stress and burnout; and ensuring timely payment of salaries, sick leave, and overtime.

Enhance supportive supervision to monitor the introduction of COVID-19 vaccines, intensified supportive supervisory visits will be implemented by trainers and central management and HR for the first 2 months.

In addition, new supportive supervision instruments that specifically address the competencies required for the correct use of COVID-19 vaccine will need to be developed.

Trainee categories	Geographical distribution	Attendees	Training content	Training methods
Management/ Central level/ Focal points	All mohafaza	40	Management of the vaccination operation at the local (vaccination center) level: Technical and logistics issues, data management)	Virtual
Supervisors	All mohafaza	8	Management of the vaccination operation at the mohafaza level (including data management)	Virtual/ Physical
Service provider/ nurses	All mohafaza	320	Handling- Administration of vaccines- AEFI	Physical
Data collectors/ admin	All mohafaza	80	IT plateform (registration, vaccine certificate issuance, data monitoring…)	Virtual/ Physical
Cold Chain Workers	All mohafaza	26	Cold chain management: ULT freezers and regular cold chain, vaccines transportation	Virtual/ Physical
Training of Trainers (ToT) was conducted in collaboration with Order of Nurses		16	Handling- Administration of vaccines- AEFI	Physical

8 Vaccine acceptance and uptake (demand)

The NCC external communication and community engagement team has developed a three-phased communication plan:

Objectives of the communication plan :

- Increase the trust of the population in the ability of a safe and effective vaccine to reduce disease burden and refute the rumors and misleading information challenging the safety and effectiveness of the vaccine.

- Inform the population about the vaccination deployment plan including target groups, vaccination centers and vaccination timing.

Key messages of the communication campaign:

- The COVID-19 vaccine is safe and effective and can reduce the threat posed by the COVID-19 pandemic to the wellbeing and survival of populations
- The vaccine is free of charge and is available to people of all nationalities according to priorities set
- Details of the COVID-19 vaccine deployment plan
- Clarify that vaccine is free of charge for people but funded by the government.

Common rumors around the COVID-19 vaccine:

- Belief in conspiracy theory (political and economic conspiracies to eliminate third world countries)
- Fear of a change in genes.
- Fear of being tracked by the manufacturers of this vaccine.
- Fear that the vaccine is not safe and that it will cause death after several years
- Hostility towards major pharmaceutical companies

The Ministry of Information and RCCE partners will contribute to address these rumors through generic messages recommending people to consult WHO website as a global reliable source.

Among the key objectives of the communication plan is targeting and empowering health workers by increasing health worker uptake and satisfaction with the vaccine as early, priority recipients. It is important to improve health workers' ability to communicate and engage with priority groups and caregivers and endorse COVID-19 vaccination. This is part of the community engagement plan will be led by community engagement teams at UNICEF.

A draft media plan can be found in annex XIV.

8.1. External Communication Plan

Phase 0: *Starting December 2020*

- Develop a rumor tracking system that was established by Ministry of Information: Develop generic messages recommending people to consult the correct sources of info: WHO and MoPH
- Develop a spokespersons list: Identify and involve key media to be part of the COVID-19 vaccine advocacy group
- Develop Q&A (Annex XV) and Key advocacy messages adapted to different target groups: Involve the MoI & RCCE External Comms taskforce as key partners
- Develop the crisis communication plan including:
    - Assign a team for crisis communication and a single point of contact from the ERT to handle media and public statements.
    - Conduct a risk and scenario analysis.
    - Develop primary messages and strategic narratives for the potential scenarios including statements and internal comms.

- Develop tailored messaging for different channels: official websites, SM channels, trusted journalists, etc and different target groups.
- Develop a media strategy: Proactive, Transparent and Accountable.

Phase 1: Q1 2021

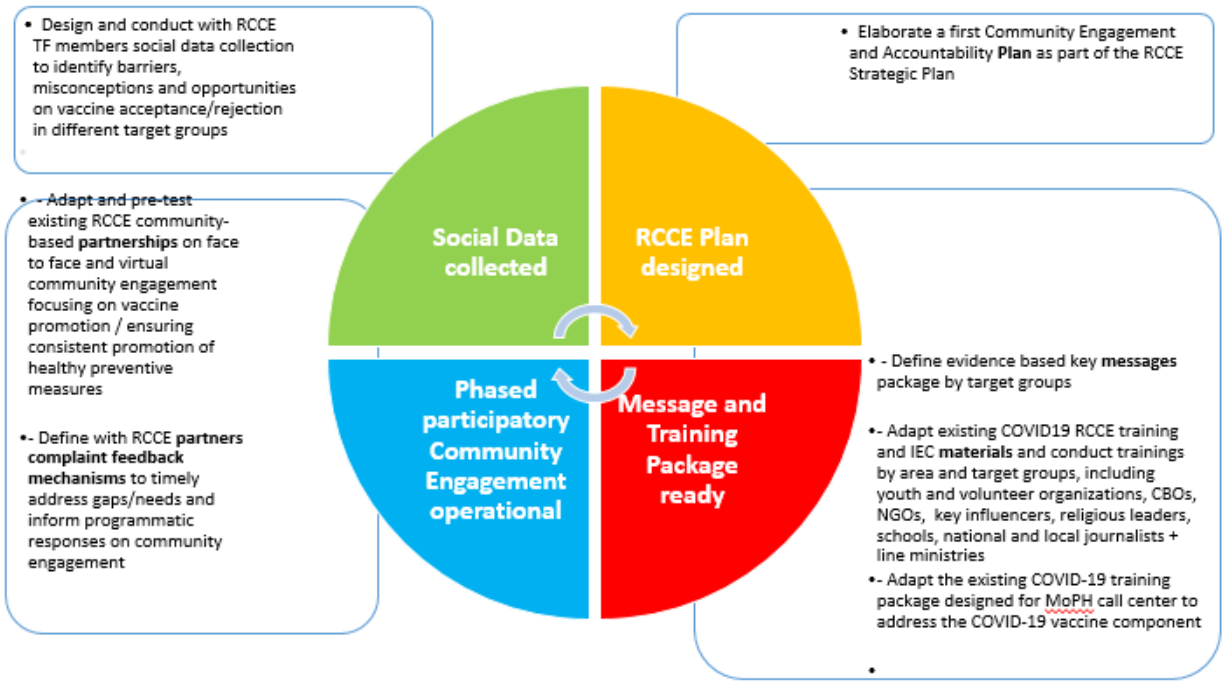
- Announce the procurement and supply of COVID-19 vaccines by Lebanese government: How, Who and When. Communication around a targeted, multicomponent and costed plan will help achieve high acceptance and uptake.
- Production and dissemination of a communication package linked to the national plan. It will include audio, visual and readable advertising materials through press, television, radio, social media and mobile messages.
- Counter fake news around the vaccine after fact-checked by WHO-MoPH
- Ongoing media briefing sessions

Phase 2: Q1-Q2 2021

- Develop an integrated public engagement campaign to address vaccine hesitancy to ensure massive dissemination of the information about the national COVID vaccines plan
- Develop an influencer Communication strategy with faith-based organizations, youth advocates, university students and eminent journalists to increase confidence in vaccines and ensure a better understanding of the national plan

8.2. Community Engagement and Accountability

Phase 0: December-February



Phase 0: December-February

- **Social Data collection:**
  - Design and conduct with RCCE Task Force members social data collection to identify barriers, misconceptions and opportunities on vaccine acceptance/rejection in different target groups
- **RCCE Plan design:**
  - Elaborate a first Community Engagement and Accountability Plan as part of the existing COVID19 RCCE Strategic Plan
- **Phased participatory Community Engagement operational:**
  - Adapt and pre-test existing RCCE community-based partnerships on face to face and virtual community engagement focusing on vaccine demand and promotion, and ensuring consistent promotion of healthy preventive measures
  - Define with RCCE partners complaint feedback mechanisms to timely address gaps and needs, and inform programmatic responses on community engagement
- **Message and Training Package:**
  - Define evidence based key messages package by target groups
  - Adapt existing COVID19 RCCE training and IEC materials and conduct trainings by area and target groups, including youth and volunteer organizations, CBOs, NGOs, key influencers, religious leaders, schools, national and local journalists and line ministries
  - Adapt the existing COVID-19 training package designed for MoPH call center to address the COVID-19 vaccine component

Phase 0: Assumptions

- Social data collection to be conducted by multiple actors and relevant ministries with respective channels and platforms. This must include behavioural and social data, digital listening and media monitoring, and other relevant sources to inform design and evaluation of interventions.
- Tentative vaccine arrival and distribution plan is announced defining role of private and public hospitals/clinics/PHCCs/ dispensaries
- Technical guidance and Q/A is provided by the Government on vaccine characteristics, procedures, side effect, priority groups and access to vaccination
- Role of PFIZER and other vaccination companies is defined in Task Force to timely address medical and technical issues/misinformation/rumors
- Face to face community engagement can be conducted based on COVID19 national procedures/lockdown; otherwise, virtual and inclusive community engagements will be conducted (see section 13)

Phase 1: Mid-February to June 2021

- Community Engagement and Accountability Plan is finalized, endorsed by relevant entities and shared with partners
- Phase I Community Engagement by area: RCCE TF members design microplans to launch and implement diversified community engagement activities based on social data, key messages, training and CFM mechanism designed.

- Train MoPH COVID-19 call center staff and frontline health workers based on their defined role in on responding to COVID-19 vaccine inquiries, including AEFI, and relevant Q&A using the existing mechanism.
- Phase II Community Engagement by area: Based on Phase 1 data and lessons learned RCCE TF members design microplans to launch and implement diversified community engagement activities based on social data, key messages, training and CFM mechanism designed.
- AAP, CFM and monitoring system is in place to track community level refusal
- Refresher trainings are conducted for priority target groups based on social and refusal data.

Phase 1: Assumptions

- Timeframe of COVID19 vaccine distribution by area is defined and access to vaccination is identified and clearly set
- Medical and technical issues as well as misinformation/rumors are timely addressed
- Face to face community engagement can be conducted based on COVID19 national procedures/lockdown
- RCCE TF and Health sector regularly coordinate during the design, implementation and monitoring.

8.3. Role of Ministry of Information:

I. The Ministry of Information should be the bridge between the National Communication Committee and the private media.
II. The committee must provide MOI the key messages to help private media build their campaigns (Reports, interviews, Talk shows…) as the message varies According to circumstances.
III. MOI's factcheck page is already established and can be used as a hyperlink to be added to WHO and MOPH websites.
IV. MOI will be involved in all the tasks of the phases above as MoI uses SM and traditional media platforms to spread infos & awareness campaigns (Facebook, Instagram, Twitter, site, webpages, etc)

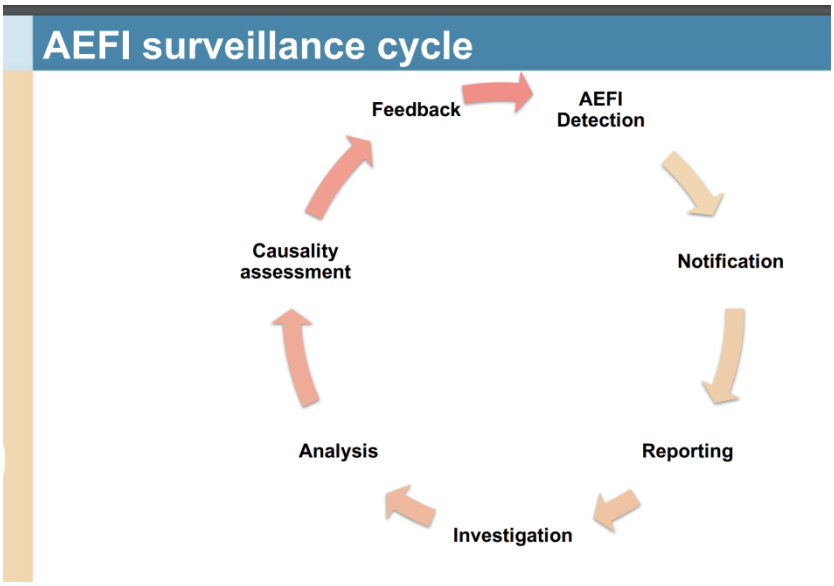
8.4. Role of NGOs and Municipalities:

NGOs and municipalities to play a vital role in their communities to facilitate registration on platform and encourage vaccination especially in rural areas in the country.

9 Vaccine safety monitoring and management of AEFI and injection safety

The COVID-19 vaccination plan includes new vaccine technology. Therefore, it is necessary to establish a strong real-time monitoring system capable of identifying and reporting any potential complications, investigating to determine the cause of the complication and provide prompt response to these events. This requires an exceptional effort and cooperation at the local, regional and global levels to activate mechanisms of information exchange and identify risks to preserve the health of the target groups.

The AEFI management processes will be in line with the WHO Global Manual for Surveillance of Adverse events following Immunization.



A surveillance system based on passive and active methodologies has been established to follow up vaccinated groups:

I. Observation following vaccination at vaccination centers
II. Self-reporting of recipients of the vaccine to ask about any side effects and complications following the vaccination
III. Setting up a hotline for vaccinated persons to notify of any symptoms or complications associated with vaccination

Responsible bodies:

- MoPH
- Supervisory teams in the vaccination centers
- Manufacturers and suppliers of the COVID-19 vaccines

As mentioned under section 5 Phase 3, the EPI department have already developed an AEFI reporting form as part of the EPI program under MERA and a zeroreporting form will be individually filled out by the recipients. In parallel, a COVID-19 AEFI reporting form (annex XVI) was also prepared at the level of the Lebanese national Pharmacovigilance Center (LNPVC) based on WHO/UMC guidance and the existing AEFI form at the EPI. All the AEFI reports will be analyzed, coded, assessed and sent via VigiFlow to the Global database Vigibase by the PV department/Center.

It is important that data related to AEFI is fed back to the relevant vaccine manufacturer.

Available tools for AEFI surveillance:

Tool	Purpose	Link to the tool
AEFI reporting form	Collect basic reports of all AEFI cases that are notified	COVID-19 AEFI reporting form (annex XVI)
AEFI line list	Collate the details in the reporting form	Generated by PV center via Vigiflow database country specific- Lebanon

AEFI investigation form	Collect detailed information for serious AEFI (defined as AEFI that results in death, hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, congenital anomaly/birth defect, or any life-threatening or medically significant condition.)	https://www.who.int/vaccine_safety/software-assistance-guiding-hq-AEFI-investigations/en/
AEFI causality assessment	Determine case classification of serious AEFI cases	https://www.who.int/vaccine_safety/software-assistance-guiding-hq-AEFI-investigations/en/

Injection safety:

Injection safety is the safe handling of all injection equipment, continuous routine monitoring, ensuring the presence and use of safe injection equipment and correct disposal of contaminated injection equipment. Medical waste disposal bins and needles are among the most dangerous categories of medical waste, if not handled and disposed of properly. Needle-stick injuries can occur easily and have a high potential for infection, including hepatitis B and hepatitis C, HIV and sepsis.

For optimal injection safety, ensure:

- • use of hand hygiene before and after each recipient. In addition to the traditional injection safety recommendations, in the context of COVID-19, vaccinators should perform hand hygiene after each recipient with soap and water or hand sanitizer containing 60–80% alcohol to prevent the spread of COVID-19;
- • availability and use of safe injection equipment;
- • safe handling of all injection equipment;
- • correct disposal of contaminated injection equipment.

10 Immunization monitoring system

As COVID-19 vaccines are being introduced, there will be an intense demand for data by:

- public health decision-makers and other national and subnational authorities.
- the public, communities, civil society organizations, and the press.
- national, regional and global immunization partners, including partner organizations.
- vaccine manufacturers and regulatory bodies, health researchers and academics.

10.1 Monitoring objectives

To meet the key anticipated needs for data collection, a monitoring system for COVID-19 vaccines should be designed/ current system should be adapted to COVID-19 vaccines to be able to:

I. Measure equitable uptake and coverage over time by geography, population groups, and risk groups.

II. Monitor to what extent national policies to prioritize at-risk groups and settings (e.g. hospital and long-term care facilities) are effectively implemented.

III. Provide a personal vaccination record/certificate for any health, occupational, educational and travel purposes (as per national policies).

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

V. Ensure that individuals can be monitored for the full course (two doses in the case of the Pfizer-BioNTech vaccine) to reduce the incidence of drop-outs.

10.2. Data needs

The needed variables to monitor progress are listed in the table 8:

Table 8: Needed variables for vaccination monitoring

A- Target groups	
Person	By age group, sex, and nationality
Place	By caza, locality of residence of vaccinated
Profession	Health care workers
Underlying conditions	By presence of chronic diseases
B- Registered beneficiaries	
Person	Age group, sex, and nationality
Place	By caza, locality of residence of vaccinated
Profession	Health care workers
Underlying conditions	By presence of chronic diseases
C- Vaccinated	
Vaccine	By vaccine brand
	By number of doses: 1st, 2nd dose, cn dose
Time	By date of vaccination (date, week, month)
Place of vaccination	By site of vaccination
Place of residence	By caza, locality of residence of vaccinated
Person: sex	By sex of vaccinated
Person: age	By age of vaccinated (10 years interval)
Person: nationality	By nationality of vaccinated (Lbn, Syr, Pal, Other)
Person: profession	By profession: health professional or not
	By health profession: md, nurse, lab, field, dentist, other
Underlying conditions	By presence of chronic diseases
	By chronic diseases: diabetes, cardiovascular, hypertension, obesity, other
D- Vaccination sites	
Time	By day
Place	By mohafaza and district
Functionality	Operational, functional cold chain, functional documentation

The vaccination monitoring will be conducted based on collected data during pre-registration and during the vaccination.

10.3 Needed indicators

As recommended by the WHO/UNICEF, "Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines", the main indicators include vaccine update and vaccine coverage. The document recommends disaggregation of vaccine uptake and coverage data to be analyzed by priority groups and risk factors:

- Vaccine product (required): as several vaccine products will be introduced in Lebanon
- Geographical coverage (required): monitor equitable distribution across regions
- Gender (required): monitor equitable distribution by gender
- Nationality: monitor equitable distribution across nationalities
- Age group (required): monitoring uptake among specific age groups is required to evaluate whether prioritization policies are implemented
- Occupation: evaluating whether prioritization policies are implemented; occupation is a risk factor, and this allow us to ensure that essential frontline workers are protected first
- Comorbidities and other risk factors for COVID-19 (such as pregnancy): evaluating whether prioritization policies are implemented and assess if there are gaps in demand for vaccination
- Context such as long-term care facilities, prisons, universities and schools: Significant social groups for informing public health measures

Table 9: Vaccine uptake and vaccine coverage

Indicator	Meaning
Vaccine uptake	The number or proportion of people vaccinated with a certain dose of the vaccine in a certain time period (e.g. during a month or year). If expressed as a percentage, an alternative term to be used is vaccination rate.
Vaccination coverage	The vaccinated proportion of a target population, which is similar to uptake, but considers vaccination in previous time periods. Over time, coverage can be constructed by accounting for uptake in previous time periods (weeks, months, years), depending on the duration of protection of the vaccine. For the year of introduction (2021), uptake and coverage can be used interchangeably.

Source: WHO/UNICEF, "Guidance on developing a national deployment and vaccination plan for covid-19 vaccines"

The needed indicators to monitor progress are listed in table 10.

Table 10: Needed indicators

INDICATOR	Measurement	Notes
▪ Functional electronic registry for COVID-19 vaccination	-Yes/No -Number	Number of registered by time
▪ Operational vaccination sites (human resources and logistics)	Number, %	Operational sites / target sites
▪ Percentage of vaccination sites with functional cold chain	%	Operational sites with functional cold chain/ Operational sites with functions

		cold chain
▪ Percentage of vaccination sites with functional vaccination documentation	%	Operational sites with functional documentation/ Operational sites with functions cold chain
▪ Registration coverage: Percentage of specific priority populations registered (total and disaggregated by age, sex and occupation) among all		Registered / target (by age group, sex, occupation)
▪ Attendance coverage: Percentage of specific priority populations vaccinated (total and disaggregated by age, sex and occupation) among registered	%	Vaccinated / registered (by age group, sex, occupation)
▪ Vaccination coverage: percentage of specific priority populations vaccinated (total and disaggregated by sex) among target	%	Vaccinated / national target (by age group, sex, occupation)
▪ COV-1 coverage: The number of people receiving a first dose of the vaccine, or the percentage of a target group that did so	Number, %	Vaccinated / target (by age group, occupation)
▪ COV-2 coverage: The number and percentage of people receiving a second dose of the vaccine	Number, %	Vaccinated / target (by age group, occupation)
▪ COV-c coverage: In case multiple vaccine products with different dose requirements are used in a country, this indicator represents the number of people who received the last recommended dose for the respective vaccine product.	Number, %	Vaccinated / target (by age group, occupation) The "c" denotes the dose that completes the schedule, which might be a first, second or third dose depending on the product that was used
▪ Drop-out from COV-1 to COV-c: The proportion of people who received at least one dose of a COVID-19 vaccine but did not receive the last dose in the schedule yet.	Number, %	(COV-1 – COV-c)/COV-1

NOTE: More doses can be added if relevant for future recommended vaccination schedules

10.4. Needed administrative system for monitoring

The COVID-19 is a new vaccine. Its introduction needs to be monitored in order to measure on timely manner, coverage and onset of adverse events. There is need to have ONE system covering all needed individual information from pre-registration to follow up.

As more than one COVID-19 vaccine will be deployed, it is vital to develop system(s) to trace:

- different types of vaccines throughout the supply chain and
- the people have been vaccinated to create a digital registry.

The IMPACT platform offers national platform for COVID-19 vaccination information system.

The information system has to cover various activities needed for immunization.

Table 11: Needed tasks for immunization information system

Activity	Main task	Details
Activity 1	Pre-registration	▪ Pre-registration by beneficiary
Activity 2	Appointment for 1st dose	▪ Automatic selection based on priority criteria ▪ Automatic generation of suggested appointment: sending SMS to beneficiaries ▪ Confirmation of appointment by beneficiary
Activity 3	Vaccination 1st dose	▪ Verification of share information: identification, medical conditions… ▪ Vaccination act ▪ Observation for short period 15 mn ▪ Issue vaccination certification
Activity 4	Daily Follow up	▪ Daily follow up during the 1st week post 1st dose, filled by the beneficiary
Activity 5	Weekly Follow up	▪ Weekly follow up during the 2nd and 3rd week post 1st dose, filled by the beneficiary
Activity 6	Appointment for 2nd dose	▪ Automatic selection based on priority criteria ▪ Automatic generation of suggested appointment: sending SMS to beneficiaries ▪ Confirmation of appointment by beneficiary
Activity 7	Vaccination 2nd dose	▪ Verification of share information: identification, medical conditions… ▪ Vaccination act ▪ Observation for short period 15 mn ▪ Issue vaccination certification
Activity 8	Daily Follow up	▪ Daily follow up during the 1st week post 1st dose, filled by the beneficiary
Activity 9	Weekly Follow up	▪ Weekly follow up during the 2nd and 3rd week post 1st dose, filled by the beneficiary

A detailed list of variables is included in Annex XVII.

Data related to the vaccines will be entered directly in the IMPACT platform. Vaccination cards/certificates (Annex XVIII) ca be issued electronically to the people who have received the vaccines.

Moreover, there is need to run some ethical hacking for the platform in order to ensure needed security and confidentiality.

MOPH's IT team is developing an online platform for (i) pre-registration of patients, (ii) sending SMS to patients on date and location for vaccination, (iii) sending reminder SMS for the second dose, (iv) issuing online vaccination certification, and (v) creating a central database for vaccine and reporting on adverse events (Pharmacovigilance). A brief about registration platform is in annex XIX

Vaccination cards will be issued electronically in addition to giving a hard copy for people who have received the vaccines, and data related to the vaccines will be entered directly in the electronic management system developed for this purpose.

10.5. Needed assessment at health facility level

In addition to individual immunization system, there is need to have daily monitoring of the vaccination sites, as part of intra campaign monitoring.

On daily basis, a site visit is conducted in order to assess the functionality of the vaccination sites (via checklist) in terms of:

- Crowding management
- Cold chain
- Human resources
- Infection control practice
- Public awareness
- Information system and access to IMPACT platform

10.6. Contribution of the call center

The objectives of the call center are:

- Assist people in pre-registration and confirmation
- Follow up with defaulter beneficiary not filling the daily/weekly form
- Answer people questions

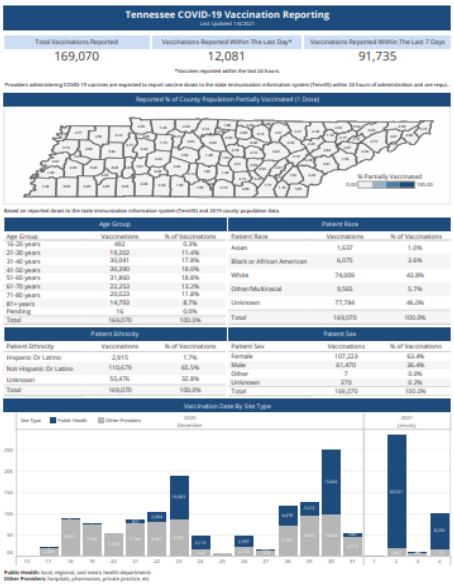
For easy access, the 1214 hotline will be used for the COVID-19 vaccination roll-out. In that way, the call center will benefit form available infrastructure at MOPH. In addition, there will be need to have support in terms of:

- Human resources: 15 person
- Additional equipment and software: ticketing system, ICT , furniture, other

10.7. COVID-19 vaccination dashboard

As output of daily monitoring, a daily report is issued by the IMPACT system and the MOPH team. In addition to the daily report, a specific automatic dashboard is issued by the IMPACT platform.

Figure 4. Template of daily report



11 Disease surveillance

The objectives and the methodology of surveillance will have to amended following introduction of the COVID-19 vaccine. Currently, the objectives of COVID-19 surveillance are the following:

- To detect cases and clusters, identify contacts, monitor trends by time, place and person, monitor incidence and mortality indicators, identify circulating strains and detect novel variants, and contribute to global COVID-19 surveillance.

In addition to the above, new objectives will be added:

- To guide vaccination policies, detect severe adverse events (ones requiring hospital admission), understand vaccine effectiveness, and understand duration of immunity

The list of notifiable diseases is updated to include “serious adverse events following COVID-19 vaccination”.

Box 1 Notifiable Communicable Diseases	
Immediately notifiable disease	▪ Acute Flaccid Paralysis: poliomyelitis, Guillain Barré, Myelitis… ▪ Anthrax ▪ Cholera ▪ Diphtheria ▪ Food poisoning ▪ Hemorrhagic fever: Ebola-Marbrug, Dengue, CCHF, Yellow fever… ▪ Influenza new virus subtypes: A(H5N1), A(H7N9)…. ▪ Invasive coronavirus infection: SARS-CoV, MERS-CoV, SARS-CoV2 (Covid19)… ▪ Invasive meningococcal disease ▪ Measles ▪ Meningitis

	▪ Mumps ▪ Pertussis ▪ Plague ▪ Rabies ▪ Rubella and Congenital Rubella Syndrome ▪ Serious adverse event following immunization ▪ Smallpox ▪ Unusual or unexpected event

Upon notification of serious AEFI, the investigation is conducted in coordination with the team in charge of AEFI COVID19 assessment.

Box 2 Case definition for serious Adverse Event Following Immunization added to the surveillance	
Serious AEFI	Any person with AEFI with one of the following: ▪ Results in death or is life-threatening ▪ Or requires in-patient hospitalization or prolongation of existing hospitalization ▪ Or results in persistent or significant disability/incapacity ▪ Or is a congenital anomaly/birth defect ▪ Or requires intervention to prevent permanent impairment or damage

The methodology of COVID-19 surveillance already includes the following components:

- Testing capacity: Reporting of number of tests by laboratories
- Positivity and incidence: Reporting of positive cases by laboratories and hospitals and healthcare facilities, reporting from sentinel sites (integration within Influenza surveillance)
- Mortality and case fatality: Reporting of COVID-19 deaths from hospitals and healthcare facilities, funeral services and community
- Case investigation: time, place and person description
- Genomic surveillance: selection of positive samples with geographical distribution for genomic sequencing

Data collection is completed at time of notification and investigation:

- Upon reporting, the following variables are collected: birth, sex, nationality, healthcare professional, caza and locality of residence. At this point, an additional field will be added: administration of covid19 vaccine. The vaccination status will be added for all reporting forms related to COVID-19 (including laboratory reporting, field testing, sentinel surveillance system). The DHIS2 reporting platform is updated in order to include the new variables.
- Once reported, case investigation is initiated with prioritization for the following: deceased, healthcare workers, inpatients, travelers, close setting. During investigation, the following data is collected: source of infection, underlying conditions. At this point, additional questions will be added: COVID-19 vaccination, if yes (date, time, number of dose, brand)
- As for advanced investigation: COVID-19 infection among vaccinated patients will constitute potential samples for genomic surveillance

Table 12. New variables for DHIS2 reporting platform

#	Variables	Format
1	Prior covid19 vaccination	Y/N
2	Dose 1, date	Date
3	Dose 1, brand	Option set: list of various brands
4	Dose 1, place	Option set: MOPH, private, other
5	Dose 2, date	Date
6	Dose 2, brand	Option set: list of various brands
7	Dose 2, place	Option set: MOPH, private, other

12 Evaluate introduction of COVID-19 vaccines

Three types of studies can be conducted for evaluation of COVID-19 vaccine introduction:

- Case control studies: cases are selected from COVID-19 reported cases. Controls are selected from non-COVID-19 patients (from administrative database or hospital database). Cases and controls will be compared for COVID-19 vaccination administration
- Case control using testing database: cases are selected from those testing positive whereas the controls are selected from those testing negative.
- Cohorts with follow up for 6 months to 1 year for vaccine effectiveness study: exposed will be selected from vaccination database. Non-exposed are selected from administrative, hospital or professional database. Follow up is done using active calls or online platform.
- Cohorts with follow up for 6 months to 1 year: exposed will be selected from vaccination database. Non-exposed are selected from administrative, hospital or professional database. Follow up is done using active calls or online platform

Table 13. Vaccine effectiveness studies evaluation

Type of study	Groups	Time line
Case control study	Conducted for specific groups, such health care workers	Starting 2 months after vaccination initiation
Case control using testing database	Conducted using the field testing and the sentinel system	Starting 2 months after vaccination initiation
Cohorts with follow up for 6 months to 1 year	Descriptive: Conducted on vaccinated persons	Starting vaccination initiation
Cohorts with follow up for 6 months to 1 year	Analytic: Conducted on vaccinated persons and non-vaccinated	Starting vaccination initiation
Cohorts with follow up for 6 months to 1 year	Descriptive: Conducted on vaccinated persons with blood samples for sero-prevalence study	Starting vaccination initiation

In addition to vaccine effectiveness, vaccine impact, and lessons learnt need to be documented and shared. Documentation of lessons learned will be done through a consultative exercise at national and subnational levels, involving different stakeholders.

As more than one COVID-19 vaccine will be deployed, it is vital to develop system(s) to trace (i) different types of vaccines throughout the supply chain and (ii) the people have been vaccinated to create a digital registry.

13 Stakeholder Engagement and Grievance Redress Mechanism

The vaccination deployment needs to be conducted in a transparent and systematic manner to ensure clear and widespread communication of the logistics of the deployment and the eligibility criteria for the priority persons (as outlined in section 5). This will be carried out in inclusive stakeholder engagement/community consultation sessions and proactive communication campaigns throughout the deployment phases of the vaccination plan. Consultations will be conducted with all stakeholders including but not limited to:

- Citizens;
- Relevant municipalities;
- Military personnel;
- Academia;
- Medical service providers (doctors and nurses);
- Vulnerable groups such as women, the elderly, refugees, persons with disabilities or underlying medical conditions; and/or
- Non-Governmental Organizations (NGOs) representing these vulnerable groups.

Due to the nationwide COVID-19 mobility restrictions, consultations will be conducted virtually and in an inclusive and effective manner and will take into consideration WHO'S Risk Communication and Community Engagement (RCCE) Action Plan Guidance COVID-19 Preparedness and Response. Minutes of the consultations will be recorded and will include a list of all the attendees. Key messages will include but will not be limited to the following:

- Voluntary basis (no coercion) of the deployment program
- Inclusive and non-discriminatory nature of the deployment program
- Mobilization of military personnel to provide security at the facilities where vaccines will be deployed
- Phasing of the deployment and location of the vaccination facilities
- The uptake channels of the Grievance Redress Mechanism (GRM) including the hotline/call center, Ministry of Public Health webpage, and mobile application, and the operational hours of the GRM
- The availability of the GRM referral pathways in the event of any complaints related to sexual exploitation and abuse and sexual harassment (SEA/SH) with the principles of anonmity and confidentiality where required
- The availability of the GRM to capture community feedback on COVID19 vaccination

The GRM will be clearly communicated during the stakeholder engagement and will be widely disseminated as part of the overall communication campaigns using, among others, social and broadcasting media. All staff and operators who will be handling the GRM will receive the necessary training for effective handling of complaints including on any potential SEA/SH related complaints. The GRM will also be clearly documented with close follow up by the responsible persons.

Information dissemination: various methods of information dissemination will be used including but not limited to broadcasting media like TV and radio channels, newspapers, MoPH website, social media (Facebook, Twitter), and the MoPH mobile application to ensure transparency and widespread dissemination reaching all stakeholders and vulnerable groups.

Transparency Committee

In addition to the above a special committee will be formed to overlook the transparency and fairness of the vaccine distribution process. It will be formed from the presidents of the Parliamentary Committee for Health Affairs. LOP-Beirut, LOP North Lebanon, the Lebanese Order of Lawyers-Beirut, the Lebanese Order of lawyers North Lebanon, the National Bio-Ethics Committee, and the National Committee for COVID-19 Vaccines (ex-officio).

The committee will meet on regular basis and when needed and can review any document relevant to the COVID vaccine initiative. The Minister of Public Health can call the committee for a special meeting and consult them on transparency and fairness issues regarding vaccine distribution.

Suggested Members include:

DR Assem Araji

Dr. Michel Daher

Dr. Charaf Abo Charaf

Dr. Salim Abi Saleh

Mr. MELHEM khalaf

Mr. Mohamed El Morad

Dr. Abdul Rahman Bizri ex-officio

In addition to the independent audit committee that was mentioned earlier to ensure confidence in the implementation of this plan, coordination is needed between all concerned ministries and stakeholders.

Also, the World Bank will set up an international independent monitoring mechanism to monitor the roll-out of the vaccination plan. An international independent Third-Party Monitoring agency will be selected and will independently monitor the compliance of the vaccination deployment with the National COVID-19 Vaccine Deployment Plan, international standards and WB requirements. Findings of this monitoring mechanism will be shared with a Joint Monitoring Committee that the World Bank will chair. Members of this committee will include relevant UN agencies (WHO, UNICEF, IOM, UNHCR and UNRWA).

List of Annexes

- **Annex I –** Emergency Use Authorization for Pfizer Vaccine- Lebanon
- **Annex II –** Law No. 211 on Regulating the Emerging Use of Medical Products to Combat the COVID-19 Pandemic
- **Annex III –** Variables for Self-Reporting
- **Annex IV –** List of Suggested Vaccination Sites
- **Annex V-** Map of Vaccination Sites
- **Annex VI –** Pfizer Fact Sheet For Recipients & Caregivers
- **Annex VII –** Pfizer Fact Sheet For healthcare providers administering vaccine (Vaccine storage, thawing, dilution and handling)
- **Annex VIII –** Covid – 19 Vaccine-Immediate Measures in Case of a Severe Allergic Reaction/Anaphylaxis
- **Annex IX –** SOPs for IPC for pre-vaccination and vaccination & SOPs for collection, treatment and final disposal of the vaccine vials
- **Annex X** - Pfizer specific training
- **Annex XI –** Assumption for Vaccination commodities , PPE and HR needs used for the Pfizer vaccine introduction cost and COVAX vaccine cost
- **Annex XII –** National Guidelines on Good Storage & Distribution Practices of Pharmaceutical Products in Lebanon
- **Annex XIII –** Vaccine Arrival Pathway
- **Annex XIV –** Media Plan
- **Annex XV –** FAQs-Arabic
- **Annex XVI –** AEFI Reporting Form- Arabic & English
- **Annex XVII –** All Variables-Vaccine Platform
- **Annex XVIII –** Vaccination Cards
- **Annex XIX –** Registration Platform Overview