REPUBLIC OF LEBANON **MINISTRY OF PUBLIC HEALTH**

PRIMARY HEALTHCARE DEPARTMENT

LEBANON HEALTH RESILIENCE PROJECT

ENVIRONMENTAL AND SOCIAL

SAFEGUARDS MANAGEMENT FRAMEWORK

(Update to the Addendum to ESMF for the Inclusion of

Component 4:

Strengthen capacity to respond to COVID-19 <u>and</u> <u>vaccination deployment</u>)

BEIRUT

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Prepared by: Ministry of Public Health (MoPH)

Abbreviations and Acronyms

AEC	Arcenciel
AEFI	Adverse Event Following Immunization
AIIR	Airborne Infection Isolation Rooms
ASHRAE	American Society of Heating, Refrigerating and Air Conditioning Engineers
AUB	American University of Beirut
BSN	Bachelor of Science in Nursing
CBRN	Chemical Biological Radio Nuclear Program
CDR	Council for Development and Reconstruction
CEO	Chief Executive Officer
CNCC	COVID-19 National Coordination Committee
COVID-19	Coronavirus Disease
EDL	Electricité Du Liban (Electricity of Lebanon)
EHS	Environmental, Health and Safety
EIA	Environmental Impact Assessment
ESIA	Environmental and Social Impact Assessment
EPI	Extended Program on Immunization
ERT	E Research Technology
ESM	Environmental and Social Management
ESMF	Environmental and Social Management Framework = Environmental and Social Safeguard
	Framework
ESMP	Environmental and Social Management Plan
ESSF	Environmental and Social Safeguard Framework = Environmental and Social Management
	Framework
EVM	Effective Vaccine Management
FEFO	First to Expire First Out
GCFF	Global Concessional Financing Facility
GOL	Government Of Lebanon
GRM	Grievance Redress Mechanism
GSF	General Security Forces
HC	Health care
HCP	Health Care Practitioner
HCWMP	Health Care Waste Management Plan
HDF	Hotel Dieu de France (Hospital)
IBRD	International Bank for Reconstruction and Development
	Intensive care Unit
	Identification Document
	Infertion Drevention and Control
	Islamic Development Bank
ISE	Internal Security Forces
IT	Information Technology
LAU	Lebanese American University
	Lebanon Health Resilience Project
LNPVC	Lebanese National Pharmacovigilance Center
LT	Low Temperature
LU	Lebanese University
MERA	Mobile Expanded Programme for Immunization Registry Application
MoE	Ministry of Environment
MoEHE	Ministry of Education and Higher Education
MoFA	Ministry of Foreign Affairs
MoIM	Ministry of Interior and Municipalities
MoPH	Ministry of Public Health
MSF	Medecins Sans Frontieres
NCVC	National COVID-19 Vaccine Committee
NCVDP	National COVID-19 Vaccination Deployment Plan
NGO	Non-Governmental Organization
NVAP	National Vaccination Action Plan
OHS	Occupational Health and Safety
OP	Operational Policy
PCR	Polymerase Chain Reaction
PDO	Project Development Objective
РНСС	Primary Health Care Centers

PMT	Project Management Team
PMU	Project Management Unit
POE	Point Of Entry
PPE	Personal Protective equipment
RF	Results Framework
Q&A	Questions and Answers
RCCE	Risk Communication and Community Engagement
RHUH	Rafik Hariri University Hospital
SAFE	Sustainable Alternative For the Environment
SARS	Severe Acute Respiratory Syndrome
SEA/H	Sexual Exploitation and Abuse / (Sexual) Harassment
SMS	Short Message Services
SSF	State Security Forces
ТРМА	Third Party Monitoring Agency
ULT	Ultra-Low Temperature
UHC	Universal Health Coverage
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 in the Near East
UPS	Uninterruptible Power Supply
USJ	University Saint Joseph
UVGI	Ultraviolet Germicidal Irradiation
WB	World Bank
WHO	World Health Organization
WMP	Waste Management Plan
WWTP	Waste Water Treatment Plant

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Executive Summary

1 Restructuring of the Lebanese Health Resilience Project

An outbreak of COVID-19 caused by the 2019 novel coronavirus (SARS-CoV-2) has been spreading rapidly and globally since December 2019. Lebanon is also affected by the COVID-19 outbreak, which poses a threat to its heath system. The first cases of COVID-19 were reported in Lebanon on February 21, 2020. In response, the Government of Lebanon (GOL) has prepared a COVID-19 Health Sector Response Plan and developed a National Multi-Sectoral Plan. Progress has been made in risk communication to the population, Port of Entry (POE) screening, the setting up of one testing center and of one treatment center. However, the unmet needs are immense.

Currently, the Country is witnessing an unprecedented surge in COVID-19 cases with record-breaking daily cases reported around 5,500 daily cases. As of January 29, 2020, the country has a total of 296,282 confirmed cases and 2,680 deaths. Test positivity rate for the last 14 days is high at 22.4 percent (compared to the World Health Organization (WHO) recommended rate of 5 percent) (¹). This surge, coupled with a high level of infections among health workers (2,409 cases), has been overstretching the health sector's capacity. Currently, 85 percent of COVID-19 regular beds and 95 percent of COVID-19 ICU beds are occupied.

The outbreak is coming at a time when Lebanon's economy is already going through the worst crisis in recent history and the Government of Lebanon (GOL) has limited resources to respond and when the country is trying to recover from August 4, 2020 blast at Beirut Port. COVID-19 vaccination is therefore essential to protecting lives and enabling Lebanon to reopen the economy with confidence and recover. Lebanon has initiated preparedness activities for COVID-19 vaccine introduction. A COVID-19 National Coordinating Committee (CNCC) was established on November 6, 2020 for the successful planning, coordination and implementation of activities.

The Lebanon Health Resilience Project (LHRP) (US\$120 million) was approved by the Board of Executive Directors at the World Bank (WB) on June 26, 2017, became effective on November 14, 2018, and will close on June 30, 2023. The original Project Development Objective (PDO) is to *increase access to quality healthcare services to poor Lebanese and displaced Syrians in Lebanon*. The project was restructured on March 12, 2020 to reallocate US\$40 million from Components 1, 2 and 3 for COVID-19 response. The PDO was revised as "*to increase access to quality healthcare services to poor Lebanese and displaced Syrians in Lebanon and to strengthen the Government's capacity to respond to COVID-19*". A new component was added "Component 4: Strengthen capacity to respond to COVID-19". The Project was restructured for the second time allowing LHRP to support the purchase and deployment of COVID-19. On January 21, 2021, The WB approved a re-allocation of US\$34 million under Component 4 of the LHRP to support vaccines for Lebanon.

An Environmental and Social Management Framework (ESMF) was prepared for the LHRP, consulted on, disclosed and cleared by the WB in May 2019 (²). This parent ESMF can be found on the following <u>link</u>. Further to the first restructuring, the WB team requested an update of the ESMF in the form of an addendum that tackles the additional environmental, health and safety measures that need to be considered to cover the environmental and social risks under Component 4. An addendum to the parent ESMF was prepared for the restructured Project, virtually consulted on, cleared and disclosed by the WB in July 2020 on the following. Under the second restructuring through Component 4, the WB requested a revision of the addendum to the ESMF to cover COVID-19 vaccines, to reflect the additional social and environmental risks, impacts and mitigation measures associated with the vaccination deployment.

¹ https://www.moph.gov.lb/en/Media/view/43750/1/monitoring-of-covid-19-

² The ESMF was disclosed as Environmental and Social Safeguard Framework (ESSF). In this document both terms ESMF and ESSF refer to the same report disclosed on May 2019 on the WB website.

2 Description of Component 4

The new component includes:

- i. **Case detection and surveillance.** This will include support for:
 - a. Procuring essential commodities for case detection and surveillance such as Polymerase Chain Reaction (PCR) machines, sample collection kits, test kits, and other equipment and supplies for COVID-19 testing and surveillance;
 - b. Capacity building in testing and surveillance; and
 - c. Strengthening IT system for surveillance.
- ii. **Case management and protection of health workers and response personnel.** This will support the strengthening of selected health facilities and establishment and equipping of quarantine and treatment centers, so that they can manage COVID-19 cases, including:
 - a. Procuring beds, furniture, ventilators, pulse oximeters, laryngoscopes, oxygen generators, other equipment and supplies for COVID-19 case management;
 - b. Capacity building and training;
 - c. Procuring Personal Protective Equipment (PPE), disinfectants and other commodities for infection prevention and control (IPC) as well as healthcare waste management;
 - d. Contracting supplementary health workers for COVID-19 treatment centers;
 - e. Paying for fees related to COVID-19 services according to a fee schedule and eligible criteria to be developed and agreed with the World Bank; and,
 - f. Capacity building in COVID-19 case management and in Infection Prevention and Control (IPC).
- iii. **Multi-sectoral response.** This will finance goods, services, training and operational costs to support multi-sectoral activities such as:
 - a. The operations of command rooms at the central and regional levels,
 - b. Implementation of risk commutation and community engagement campaigns,
 - c. Implementation of containment strategies, including port-of-entry interventions, and Operation of rapid response teams.

The new component will also cover the National COVID-19 Vaccination Deployment Plan (NCVDP) through the second restructuring. The Revised addendum to the ESMF can be accessed through this <u>link</u>.

3 Baseline Information for COVID-19

On March 10, 2020, the MoPH prepared "Coronavirus Disease 2019 (COVID-2019) National Health Strategic Preparedness and Response Plan. This plan establishes a national plan of action to scale up preparedness and response capacities in Lebanon for prevention, early detection, and rapid response to coronavirus disease 2019. The plan can be summarized as follows:

- First Line: The MoPH adopts Rafik Hariri University Hospital (RHUH) as a primary reference hospital during the outbreak of the new corona. RHUH includes: 120 beds and 11 respirators at Phase 1 and 350 beds at Phase2.
- Second Line: Regional Public Hospitals. For the first phase: 12 hospitals will be involved including 343 beds (among which 120 at RHUH). For the second phase 1,197 beds will be available.
- Third Line: Seventeen Public hospitals and Private Hospitals Classified T1 will be added (860 additional beds in public hospitals).

On March 19, 2020, the Ministry of Public Health (MoPH) published on its website the "Health sector readiness in Lebanon to respond to the Coronavirus" ³. It states that a specialized committee was formed in cooperation with Rafik Hariri University Hospital to assess the needs for medical supplies for one-month period for 12 public hospitals that will receive COVID-19 patients in the first stages of the virus spread. These needs were divided into (i) Personal Protective Equipment (PPEs) and consumables and (ii) Medical equipment needed for the Intensive Care Units (ICUs).

The MoPH has also several initiatives some of them in coordination with other institutions to inform the population of the current situation of COVID-2019 and raise awareness. Such institutions include the Ministry of Information, UN agencies, NGOs, Scientific Communities, Syndicates etc.

Currently, Lebanon is classified under "large-scale community transmission of COVID-19" and has initiated preparedness activities for COVID-19 vaccine introduction. The work of all the parties involved in the COVID-19 vaccination plan resulted in the preparation of the National COVID-19 Vaccination Deployment Plan (NCVDP). This plan was publicly disclosed in a presentation held by the Minister of Public Health at the Grand Serail on January 28, 2021⁴. It provides the information listed below:

- Types of vaccines
- General vaccination instructions emphasizing that all people aged above 18 will ultimately be able to get vaccinated if they wish to, as getting the vaccine will be optional. However, this vaccination will follow the priority of the vaccination deployment. The priority groups for vaccination by stage
- The priority groups for COVID-19 vaccination
- The eligibility criteria
- The pre-registration and vaccination scheduling
- Follow up on adverse events
- Criteria required for the selection of the vaccination centers
- Personnel needed at each vaccination center
- Vaccination process and time needed
- The Infection Prevention and Control needed at a vaccination center
- The vaccination internal monitoring
- The external communication plan
- The community engagement and accountability

The Baseline Information relevant to Pfizer COVID-19 Vaccination Plan includes:

• Cold Chain Requirements: Pfizer-BioNTech COVID-19 vaccine requires storage in Ultra-Low Temperature (ULT) freezers. During storage, exposure to room light should be minimized and exposure to direct sunlight and UV light should be avoided. The Pfizer vaccine shall be shipped in ULT freezing storage container. It must be thawed for 30 minutes. Once thawed, it has a 2-hour window to dilute and once diluted it shall be used within 6 hours. If the vaccination center is not equipped with an ULT freezer, the vaccine shall arrive in refrigerated cars and must be used within 5 days. When removed from the fridge, it has 2-hour window to dilute and shall be used within 6 hours. The collection and management of cold chain temperature records will be the responsibility of PMU in MoPH in coordinating with the administrations of the selected hospitals for vaccine roll out. The PMU in MoPH will follow the good international industry practices for WHO and the U.S. Department of Health and Human Services' Centers for Disease

³ Health sector readiness in Lebanon to respond to the Coronavirus dated March 19, 2020 available on <u>www.moph.gov.lb</u> (in Arabic)

⁴ <u>https://www.moph.gov.lb/userfiles/files/Prevention/nCoV-%202019/Minister%20Presentation-Final-Jan%2028.pdf</u>

Control and Prevention (CDC) which provides the latest information about COVID-19 and the global outbreak: www. cdc.gov/coronavirus/2019-ncov. This activity will also be monitored by the third-party monitoring (TPM) which is the International Federation of Red Cross and Red Crescent Societies IFRC that will be contracted to play the mentoring part.

- ULT Availability in Lebanon: Between 2015 and 2017, WHO has supported the MoPH in procuring 15 ULT freezers (reaching -80°C) for 12 hospitals in Lebanon (1 public and 1 private hospital in each province). Additionally, 3 private hospitals have been identified to have ULT freezers, totalizing 15 hospitals equipped with adequate ULT cold chain in Lebanon. Recently, UNICEF has conducted the assessment of the existing ULT at hospitals that will potentially be assigned as vaccination centers. As a result of these assessments, UNICEF confirmed the functionality of 13 freezers⁵.
- **Terms of vaccines arrival:** Cartons of Pfizer-BioNTech COVID-19 vaccine multiple dose vials will reach Beirut Airport and will be cleared by a local handling agent in thermal containers with dry ice. They will be directly transported and distributed equally to the vaccination hospitals that have ULT freezers. Additional ULT freezers will be procured if needed. The hospitals equipped with ULT freezers will also serve as vaccination points in order to minimize the need for transporting the vaccine to other locations and hence the risk of damage to the vaccines if taken out of the ULT.

Around 2 million doses of Pfizer-BioNTech COVID-19 doses were reserved by the Lebanese Government. The schedule of arrival of these doses is as follow:

Timeline	No. of Pfizer-BioNTech COVID-19
Q1 2021	249,000
Q2 2021	350,000
Q3 2021	800,175
Q4 2021	699,750
Total	2,098,925

The arrival of the first 5 batches of the vaccine is as follows:

•	Mid-February:	28,080 doses	
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• "	Third week	of February:	31,590 doses
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- First week of March: 41,120 doses
- Second Week of March: 32,760 doses
- Third Week of March: 36,270 doses

Every recipient needs 2 shots (2 doses) with a 3-week period before the first shot and the second one. Consequently, around one (1) million recipients will benefit from the vaccination.

The deep freezers will not be used at the early stages of the Pfizer Vaccine deployments (Q1) as the number of doses will be limited to 249,000. The first batch of vaccines will be stored at RHUH and distributed by cold chain to the vaccination centers where they will be consumed in five days as per protocol. Once larger amounts of vaccine begin deploying starting the second quarter (Q2), the ULT available in the vaccination centers, will start being utilized. Furthermore, to ensure that the vaccine is not wasted or to limit the risk of 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.

⁵ Assessment made by Engineer Makram Barakat assigned by UNICEF

All the equipment and materials needed for the vaccination will also be distributed to the vaccination centers. They include: (i) Syringes, (ii) Diluents, (iii) Safety boxes, (iv) Alcohol swabs, (v) Hand hygiene, (vi) Adrenaline/epinephrine and (vii) PPEs.

- Selected vaccination centers as per the NCVDP are listed as follows:
 - **Beirut (5 no)**: Rafik Hariri University Hospital (RHUH) Governmental, American University of Beirut Medical Center (AUBMC), Hotel Dieu de France (HDF), Saint George (Roum),, Al Makassed Hospital,
 - South Lebanon (3 no.): Saida Governmental, Nabatieh Governmental (Nabih Berry), Tebnine Governmental
 - North Lebanon (2 no.): Tripoli Governmental Hospital, Halba Governmental (Dr. Rassi)
 - Mount Lebanon (6 no.): Baabda University Governmental, Al Bouar Governmental, Daher Bashek Governmental, Ain W Zein Hospital, Al Rasoul Al Aazam Hospital, Zahraa Hospital, .
 - **Bekaa (2 no.):** Baalbeck Governmental Hospital, Zahleh Governmental (Elias El Harawi), and Dar El Amal University Hospital.

The above-listed vaccination centers will be incorporated in the first phase of the National COVID19 Vaccination Deployment Plan (NCVDP). They will increase gradually throughout the vaccination process as per the NCVDP.. The latter is a living document which is continually subject to modification and will be amended and adapted as the context demands. The NCVDP can be found on the MoPH website (moph.gov.lb), and can be accessed through the following <u>link</u>.

- Process of vaccination and qualification of vaccinator: Teams of physician, trained vaccinator nurse, registered nurse and administrative clerk/data operator will be supporting vaccination activities in each of the hospitals. Prior to administering the vaccine, administrative clerk/data entry will thoroughly explain the risks and benefits of the Pfizer-BioNTech COVID-19 vaccine and the recipient will have to either sign a hard copy consent form to be uploaded to the database or electronically sign the consent form if applicable. 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. The Lebanese Red cross will be ready with more than 30 vehicles (cars and ambulances) to either transport the individuals to the nearest vaccination centers if they are unable to do so or alternatively to carry out the vaccinations at their locations.
- Standard Operating Procedures (SOP) and Training: There are Standard Operating Procedures (SOP) for each center. They entail operating procedures for cleaning, infection control, garbage collection, and so on. Mock trainings are being conducted (with the help of Pfizer) to teach the vaccinators on administrating the vaccine, and to study the time consumed in each vaccination and on the application of these SOPs. These training started on January 20, 2021.

4 Institutional Framework for Environmental and Social Management

The Institutions listed in the parent ESMF mainly (i) The Ministry of Public Health (MoPH), (ii) The Ministry of Environment (MoE), (iii) The Ministry of Interior and Municipalities (MoIM), and the UN Agencies (WHO, UNICEF and UNHCR) and their relevant responsibilities still apply. This section of the present report describes the additional responsibilities of the institutions mentioned in the parent ESMF and of the new institutions that will be involved in the implementation of Component 4 and the Pfizer Vaccination under said Component. The additional responsibilities will be on (i) **the MoPH**, (ii) **the Ministry of Information (MoI)** that will handle the communication strategy, (iii) **the Ministry of**

Interior and Municipalities (MoIM) through the Internal Security Forces (ISF), the General Security Forces (GSF) and the State Security Forces (SSF) that will 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. The security forces will also contribute in organizing the citizens entrance and exit if necessary and the Municipalities will be involved in selecting the elderly eligible to vaccination, and iv) and the **UN Agencies (WB, WHO, UNICEF and UNHCR)** that will mainly provide technical support to the MoPH and coordinate awareness raising activities.

5 Stakeholders Consultations relevant to Component 4

In accordance with WB policies, stakeholder's consultation was conducted during the preparation of the ESMF for the parent project and was requested for Component 4 of the restructured LHRP. In line with the national restriction on people's movement and the available resources for carrying out stakeholder engagement in the context of COVID-19 and the WB's "Technical Note: Public Consultations and Stakeholder Engagement in WB-supported operations when there are constraints on conducting public meetings" (March 20, 2020), the project avoided public gatherings and the consultations on Component 4 were done virtually as per the following steps:

- 1. The draft of the addendum to the ESMF for restructured LHRP was distributed in a digital form to stakeholders on May 11, 2020 through the National Infectious Disease Committee at MoPH. The addendum to the ESMF was also distributed on May 28, 2020 to the national COVID 19 committee at the Presidency of the Council of Ministers that includes many Ministries and Institutions. The stakeholders were informed about the Grievance Redress Mechanism (GRM) and they were given 10 days to email back their response. The following email address aberry@gmail.com and elham.em.moph@gmail.com and the following phone number 01-843769 were provided to the stakeholders in order for them to give their feedback and suggestions if they wish to do so.
- 2. Also, virtual meetings were held on March 19, 2020 and June 8, 2020 with MoPH Key staff and the WB Safeguard Team.
- 3. The addendum to the ESMF was revised in accordance with the consultations and will be disclosed on the MoPH website. After COVID-19 restrictions are lifted, face to face consultations will be conducted and the addendum to ESMF will be updated and then disclosed again. Consultations will include vulnerable groups of potential beneficiaries (such as female and elderly refugees, persons with disabilities or underlying medical conditions).

Another round of inclusive consultations took place also specifically on the COVID-19 vaccination. It was conducted in a transparent and systematic manner to ensure clear and widespread communication of the logistics of the deployment, the eligibility criteria for the priority persons, and the associated environmental and social risks and impacts and mitigation measures of the government's vaccination deployment plan. The consultation included vulnerable groups and/or representatives of vulnerable groups of potential beneficiaries (such as female and elderly refugees, persons with disabilities or underlying medical conditions, women groups), representatives of environmental NGOs, health workers, academia and all other stakeholders and beneficiaries. In order to fulfill the WB requirements, and as per the national restrictions, public gatherings were avoided.

Consultations were done virtually as per the following steps:

- 1. Virtual meetings were held on January 18, 2021 and January 21, 2021 with MoPH Key staff and the WB Safeguard Team to discuss main issues to be tackled in the revision to the addendum to the ESMF.
- 2. A meeting was held with Dr. Abdul Rahman Bizri on January 20, 2021 to discuss the work of the NCVC and the main sections of the updated addendum to the ESMF.

A Stakeholders' consultation session was also organized as per the following steps:

- 1. An invitation was sent to stakeholders on January 29, 2021; a copy of the agenda and executive summary of the update to the ESMF addendum were also shared with the stakeholders in advance of the consultation session to provide an outline of the environmental and social impacts and mitigation measures for the COVID-19 vaccine deployment.
- 2. The updated addendum to the parent ESMF was discussed on February 5, 2021 in a virtual meeting. The stakeholders were informed about the Grievance Redress Mechanism (GRM). The following email address aberry@gmail.com, elham.em.moph@gmail. and info@moph.gov.lb and the following phone number 01- 830300 ext (440) and (274) were provided to the stakeholders in order for them to give their feedback and suggestions if they wish to do so.
- 3. A total of 19 participants attended the consultation session held on February 5, 2021 out of which there were 11 women attendees including the WB and MoPH staff. The list of participants is included in Table 12 below.

Participants	Comments raised and answers provided by MoPH
ARCENCIEL (Environmental NGO)	Mr. Mario Goraieb, representative of Arcenciel, shared his concern that nine hospitals do not have contracts with Arcenciel and asked if these hospitals shall be designated as vaccination centers. Mr. Goraieb will be sharing a list with MoPH containing all healthcare facilities contracted with Arcenciel to ensure that all facilities chosen as vaccination sites have established a proper Health Care Waste Management Plan (HCWMP). Then UNICEF will be contracting Arcenciel for waste management.
Lebanese Union of People with Disablities	Mr. Mohammad Loutfi, Representative of Lebanese Union of People with Disabilities, expressed his interest in being part of the consultations and in providing any support needed to include people with disabilities in the vaccination and taking part in the successful deployment of the vaccine. They also raised the issue that all vaccination centers were not well equipped to receive people with disabilities and wanted to make sure staff will be well trained to deal with people with disabilities. MoPH confirmed that all the requests are taken into consideration and that the Red cross will be handling the vaccination at home or transporting them in case the person is not able to move to the vaccination centers.
WHO	Dr. Nohal Al Homs assured all attendees that they will be coordinating with MoPH on the issue of disability and provide any support needed for this issue. They also agree that Arcenciel has a long history of medical waste management in the Country in terms of collection and disposal and asked about the management of the health care waste inside the vaccination centers. MoPH confirmed that any vaccination center should have a HCMP approved by Arcenciel and the PMU before being assigned as vaccination center. WHO asked also if there will be a monitoring committee or a third-party monitoring entity and if they will have environmental specialists. MoPH confirmed that a TPMA will be handling all the vaccination process including the environmental and social safeguards and that the Ministry of Environment (MoE) is a major stakeholder and partner in the COVID-19 vaccination committee. MoPH will share the NCVDP with WHO and all stakeholders.
UNICEF	Dr. Genevieve Begkoyian, UNICEF representative inquired about whether it was the right choice to choose hospitals as vaccination centers given the possibility that there might be infectious areas since Covid patients are getting admitted into the hospitals. The MoPH assured UNICEF that they have provided the hospitals with Standard Operating Procedures so that all infection prevention measures are respected at all times to ensure the safety of healthcare providers and vaccine recipients in hospitals. In addition to the IPC measures that should be strictly applied during vaccinations. UNICEF has provided their services in covering the technical consultations, maintenance, and monitoring of the cold chain. UNICEF

	also raised the issue of the potential for SEA/SH and if the healthcare workers will be trained to deal with the reporting of SEA/H, MoPH confirmed that the training is a mitigation that is recommended in the ESMF. UNICEF also asked if IPCs are part of the framework and MoPH confirmed that they are. Farah Mazloum, UNICEF representative, stressed on the importance of the reporting on sexual abuse and harassment. MoPH explained that the mitigation measures are clearly reflected in the revision to the addendum to the ESMF document.
The Order of Nurses and	Dr. Myrna Abi Abdalla Doumit, Order of Nurses representative, and Assistant Dean of School of Nursing in the Lebanese American University asked if the
Assistant Dean of School of Nursing in the Lebanese American University (LAU)	nurses will be compensated for the additional hours, they will be working on the vaccination deployment. MoPH replied that they will not be paid by the LHRP but by the vaccination centers where they are employed. LHRP will not allocate payment for the nurses. The Order of Nurses representative also stated that the nursing workforce is not very enthused about the vaccination deployment due to news being circulated on broadcasting networks regarding people with or against vaccines and further asked if the committee will be using media and a communications campaign to speak the peoples' language to explain to them the importance of vaccination since there are inaccurate ideas being circulated into the communities. MoPH confirmed that there will be a proactive communication campaign tackling the need for vaccination and that it will be supported by UNICEF. MoPH further explained that they are currently working with the Ministry of Information in this regard. WHO confirmed that they are also working on this issue together with colleagues from UNHCR. MoPH stated that this issue applies also to the need to communicate with doctors since results of a survey recently carried out in December 2020, showed that more than 50% of healthcare workers are refusing to get vaccinated. There will be a need to work on a communication and media campaign to educate and inform people that the COVID19 vaccine is the only way to get rid of this pandemic – the MoPH is working on complete plan that will be released very soon.
UNICEF	Asked what are the next steps and what is needed. MoPH explained that the ESMF will be disclosed soon and that MoPH will be contacting UNICEF and WHO and organizing technical meetings with them to follow up on the NCVDP.

After COVID-19 restrictions are lifted, face to face consultations will be conducted with all relevant stakeholders including internal security forces. The addendum to the ESMF will be updated and disclosed accordingly.

6 Environmental and Social Analysis of Component 4

All measures provided in the main Project ESMP and in the addendum ESMF still apply. Given the nature of the COVID-19 disease, exposure to infection and diseases should be given special attention. IPC strategies should be enhanced to prevent or limit transmission inside and outside of the healthcare facility. They shall comprise:

Using environmental and engineering control such as:

- Establishment and equipping quarantine and treatment centers (Preparation of existing spaces for receiving individuals with suspected/confirmed COVID-19. It does not include large civil works but only minor works and scaling up the facility, mainly physical partitions and airconditioning works). MoPH confirms that actions have already been thoughtfully undertaken in the different hospitals that will receive COVID-19 patients.
- Fire Safety (in accordance with WBG EHS guidelines, and as per MoPH), all the hospitals that will receive funds from LHRP have fire detectors, alarm systems and fire-fighting equipment

adequately placed and sized. This as a pre-requisite for the acquisition of a construction and other relevant permits.

• Wastewater Discharges. There is no evidence to date that the COVID-19 virus has been transmitted via sewerage systems with or without wastewater treatment. According to MoPH all the HC institutions that will receive funds from LHRP are connected to a municipal waste water network as a pre-requisite condition to get their construction license. Regarding Waste Water Treatment Plants (WWTPs) workers, there is no evidence to suggest that additional, COVID 19-specific protection is needed. Wastewater treatment plant workers should follow routine practices to prevent exposure to wastewater, including using the engineering and administrative controls, safe work practices, and PPE normally required for work tasks when handling untreated wastewater. Nonetheless, there would be some liquid waste (kits, reagents, chemical waste, and other hazardous by-products that could be harmful to human health). This should be handled, managed and processed carefully as hazardous waste and should not be discharged with domestic waste water.

Applying standard and special precautions in OHS

As per the ESMF prepared for the LHRP before its restructuring, MoPH needs to make sure any Health Care facility has an ESMP including a Health Care Waste Management Plan (HCWMP). The HCWMP includes a section on Personnel Protection needs. Given the nature of COVID-19, in addition to the general section on Personnel Protection needs, the HCWMP should comprise a section on use of proper PPE when health workers are exposed to a patient with confirmed/suspected COVID-19 or other sources of COVID-19. In addition, in line with WHO Interim Guidance (February 12, 2020) on "Laboratory Biosafety Guidance related to the novel coronavirus (2019-nCoV)", and other guidelines, the parent project Environmental and Social Management Framework (ESMF) will be updated by adding to it WHO standards on COVID-19 response. The plan includes 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, and road safety.

Safe Waste Management

Generally, management of waste that is suspected or known to contain or be contaminated with COVID-19 does not require special precautions beyond those already used to protect workers from the hazards they encounter during their routine job tasks in solid waste. According to MoPH, all the hospitals that will receive funds under the WB Project have already contracted one of the certified institutions that handle medical waste in Lebanon. Both institutions (Arcenciel and the Municipality of Abbassiyeh/SAFE) confirmed in previous and recent communications that they were capable of handling additional loads.

Implementing administrative controls

MoPH started implementing measures and imposing on HC facilities to implement administrative controls for the prevention and control of transmission of COVID-19 infections such as (i) provision of adequate training for HCW, (ii) ensuring an adequate patient-to staff ratio, (iii)establishing a surveillance process for acute respiratory infections potentially caused by COVID-19 among HCW, (iv) ensuring that HCWs and the public understand the importance of promptly seeking medical care and (v) monitoring HCW compliance with standard precautions and providing mechanisms for improvement as needed.

Emergency Preparedness and Response plan

In line with WHO guidelines⁶ the MoPH prepared the Coronavirus Disease 2019 (COVID-2019) National Health Strategic Preparedness and Response Plan that was published on the MoPH's website on March 13, 2020.⁷This document was developed to establish a national plan of action to scale up preparedness and response capacities in Lebanon for prevention, early detection, and rapid response to

⁶ WHO, Critical preparedness, readiness and response actions for COVID-19, Interim guidance, 7 March 2020. ⁷ Available on

https://www.moph.gov.lb/userfiles/files/News/Leb%20nCoV%20Strategic%20Response%20Plan%20MARCH% 202020-converted.pdf

coronavirus disease 2019 (COVID-2019) as required under the International Health Regulations (IHR 2005) using the WHO global 2019 Novel Coronavirus Strategic Preparedness and Response Plan as the foundation. This plan includes an Infection Prevention and Control section.

Preventing Sexual Exploitation and Abuse and Harassment

The Project should focus on putting in place the following, minimum set of measures to prevent Sexual Exploitation and Abuse and (sexual) Harassment (SEA/H)⁸ such as (i) Staff in PMT signing Codes of Conduct, (ii) Disseminate messages clearly prohibiting SEA/SH during the provision of health care, (iii) Make information available to health service providers on where Gender Based Violence (GBV) psychosocial support and emergency medical services can be accessed, (iv) Promote two-way communication between health authorities and communities, and (v) Development of additional rapid guidance on how to deal with SEA/H complaints in operations with existing GRMs or using hotlines and train the operators accordingly.

All measures provided in the parent ESMF and in the above section shall be applied. Additional mitigation measures that might be required in order to avoid negative impacts caused by COVID-19 Vaccination under Component 4 are detailed below:

Risks on Health Workers

As stated above, the ESMF for the LHRP sets that any PHCC or Hospital, to be eligible to receive funds from LHRP, should have an ESMP including a Health Care Waste Management Plan (HCWMP). This is a condition that is made part of the contract between the health institution and the MoPH before any disbursement of funds. The occupational health and safety standards as recommended by WHO for the vaccination teams in direct contact with vaccine recipients shall also be applied.

Risks due to the unsafe management of medical waste

Generally, management of waste in the vaccination center is not suspected to contain or be contaminated with COVID-19 and does not require special precautions beyond those already used to protect workers from the hazards they encounter during their routine job tasks in medical solid waste. Workers and employers should manage solid waste generated from vaccination as they would manage other hazard medical waste as detailed in section 10 "The Health Care Waste Management Plan" of the parent ESMF. According to the NCVDP, it is estimated that each vaccination center will conduct around 400 vaccinations per day. Arcenciel⁹ confirmed its capacity to collect and handle the additional quantities that will be generated by the vaccination centers.

Risks due to the poor maintenance of the cold chain

In order to mitigate this risk of losing vaccines due to deficiency in the cold chain, PMU in MoPH in coordination with administrations of selected hospitals for vaccine roll out and under supervision of IFRC and UNICEF will be handling the proper functioning of the cold chain including monitoring the freezers temperature, out-of-range storage or out-of-range transport temperatures ensuring the good international industry practices are being followed. As mentioned in baseline information relevant to Pfizer COVID-19 vaccination plan section, PMU in MoPH will follow the good international industry practices for WHO and the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) which provides the latest information about COVID-19 and the global outbreak: www. cdc.gov/coronavirus/2019-ncov. This activity will also be monitored by the third-party monitoring (TPM) which is the International Federation of Red Cross and Red Crescent Societies IFRC that will be contracted to play the mentoring part.

The following actions/corrective procedures shall be ensured:

⁸ WB, Technical Note on SEA/H for HNP COVID Response Operations

⁹ Communication with Mr. Mario Ghoreib Manager at Arcenciel on January 27, 2021.

- Follow up and assurance of the conditions that must be met in the cold chain before storing the vaccine. The cold chain equipment must be calibrated, clean, and operating with high efficiency and need to be fully functional at least 48 hours before the expected vaccine arrival date.
- Ensure that cold chain temperatures are monitored periodically and daily; where possible, by electronic data loggers. Temperature monitoring devices and a mechanism for continuous temperature monitoring throughout the supply chain from receipt, during storage and delivery to the vaccination point;
- Perform effective and routine maintenance of the ULT and Low Temperature (LT) equipment
- Identify the location and availability of dry ice for emergency purposes or in case there is a need for transporting the vaccine;
- Ensure the presence of an additional back-up generator in case of power cut or UPS in order to maintain the temperature for a period of not less than 24 hours until the electrical current is restored or repaired.
- Estimate the storage capacity of each unit of cold chain equipment and matching it to the expected quantity to be received.

Risks due to the poor management of the vaccine stock

In order to mitigate the risk of losing the vaccines due to bad stock management, the MOPH PMU in coordinating with the selected hospitals administrations will work to ensure the following:

- Ensure all vaccines are carried in specialized vaccine carriers with temperatures according to the manufacturers' instruction and transported only by authorized refrigerated vehicles specially equipped for this purpose.
- Conduct a physical examination of the received vaccines for quality control purposes, ensuring the absence of damages, a leakage and presence of a sticker with basic information (such as the type of vaccine, expiry date, manufacturing batch number) and other quality control parameters.
- Make sure the vaccine is stored in the appropriate cold chain condition and according to the appropriate temperature, as soon as it is received.
- Arrange the vaccines inside the cold chains according to First to Expire First Out (FEFO). Put the vaccines in the correct vaccine refrigerator without delay with the shortest dated foremost to ensure adequate stock rotation.
- Make sure Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) vials remain upright at all times.
- Report the volumes, doses and ancillary items received and used on an information system to facilitate managing, tracking and reporting on the vaccine stocks and consumption effectively and follow up on expiry dates.
- Perform a daily count post vaccination
- Prepare a clear vaccination schedule and back up to avoid extended periods of storage at the vaccination point;
- Estimating the need to request additional vaccine doses.
- Develop a procedure for spillages on skin/eyes and provide handwashing facilities and eyewash kits
- Develop a procedure for spillage on surfaces and provide gloves, paper towels and all material needed as per the local chemical disinfection policy.

Job creation and economic benefits

The deployment of the vaccine may create very minimal job opportunities such as the recruitment of central and peripheral coordinators and additional income to the public servants. The long-term economic benefits result from the fact that the vaccination will ultimately help the economy recover.

Social Risks

Social risks and impacts under the vaccination deployment include the following (i) Potential Unequal access to vaccines to citizens and vulnerable groups including but not limited to the disabled, elderly and refugees, (ii) Perception of unfair distribution and exclusion, (iii) Potential rising social tensions, (iv) Gender inequalities and potential SEA/H, v) Impacts of the use of National Security Forces for the management of the entrances and exits of the vaccination centers; (vi) poor communication of the

eligibility criteria and potential rising tensions; and (vii) unintended exclusion of vulnerable groups (disabled, elderly, and refugees) in the pre-registration process due to barriers or limited access to IT tools.

The potential social risks can be mitigated by (i) the proper implementation of the proposed NCVDP, (ii) a comprehensive monitoring system, (iii) a well-established and functional GRM with capacitated staff;(iv) an effective and widespread communication strategy on the non-discriminatory nature of the vaccination deployment and the targeted priority populations; (v) a GRM sensitive to SEA/H; (vi) signing of codes of conduct by all project actors; (vii) application of mitigation measures as per the World Bank's Technical Note on the use of military forces to assist in COVID19 operations (March 25, 2020); (viii) The designated hotline at 1787 which will provide support in pre-registration for vaccination and support with filling the digital form for registration thus mitigating unintended exclusion of vulnerable groups in the process due to limited access to IT tools. In addition, close coordination of MoPH with the NGOs for the disabled, elderly, poor and refugees to ensure access and assistance to the pre-registration process.

Implementation of the ESMF/ESMF

The implementation of the ESMF remains unchanged in all its sections: (i) Exclusion list, (ii) Prescreening, (iii) Procedures to be followed by PHCCs, (iv) Procedures for hospitals that have an approved EIA, (v) procedures for hospitals that did not previously submit an EIA to MoE and (vi) capacity building program.

Due to the current situation of confinement, the consultancy firms that are eligible to do environmental studies and laboratories are currently closed. Even public servants at the MoE are advised to stay at home to prevent getting contaminated by the Corona virus. In view of the urgency of the Project, the PMU shall ensure that all Health Care facilities benefiting from the Project have proven capacities in managing E&S issues. In this regard, the eligible facilities should have at minimum an ESMP including a HCWMP and commit to start the procedures set in the original ESMF within 3 months after signature of contract, and the eligible facilities to conduct vaccination should have at minimum an ESMP including a HCWMP.

7 Monitoring and Evaluation System

The monitoring plan provided in the original ESMF still applies, and additional layers of monitoring the vaccination deployment will be implemented.

A monitoring plan will be put in place to monitor the proper use of the vaccination, the fair access to vaccine and to observe the side effects of the vaccine. People will be taught on how to report on side effects; they can either report on the mobile application, through the COVID-19 vaccines call center, or by contacting the vaccination center where they got vaccinated. The progress of vaccination should also be monitored to study factors such as the nature of people that are getting vaccinated.

A Third-Party Monitoring Agency (TPMA) will be monitoring the implementation of the vaccination plan including the monitoring of the adequate functioning of the GRM, the referral pathways of the GRM in the event of any SEA/H complaints, and the implementation of the Environmental and Social mitigation measures related to the vaccination plan. The TPMA will ensure timely reporting in the event of any non-compliance of the implementation of the restructuring component E&S related instrument to put immediate corrective measures into place.

8 Grievance Redress Mechanism

As mentioned in the ESMF, an effective Grievance Redress Mechanism (GRM) is in place at MoPH covering PHHCs and Hospitals.

At the start of the pandemic, a call center with the designated hotline 1214 was put at the service to cover the COVID-19 related issues such as people starting to show symptoms and need to be assessed and referred to hospitals, questions and complaints. The designated number 76- 595 699 was put in place when the first cases of COVID-19 spread and has been replaced on April 2, 2020, to 01-594 459. The capacity of the hotline has been extended to receive and respond to additional calls. This line is being operated by the MoPH epidemiological surveillance unit & volunteers in 2 shifts. The number of operators was increased from 5 to 14. A daily report is being kept for the calls being received at COVID-19 line. Names and numbers of the callers are taken and registered. However, anonymous grievances can be raised and addressed. The Project also records the complaints received related to the Project in general such as environmental concerns. The GRM includes also an appeal process for unresolved grievances that was established before the Project restructuring to the request of the WB.

The respondents are regularly trained on how to handle the calls. Algorithms were developed according to the case definition. Caller reporting forms were put in place they include: Information about Investigator, date time of call, symptoms, risk factors, date of onset. For those asking for the results of tests done in RHUH, they were referred to the call center at RHUH 01-832-020. A daily report is generated by the call center detailing the names of the callers and the reason of the call as shown in the following figure.

The average no of calls received per day before the COVID-19 spread was 120. Since the outbreak, the number of calls increased considerably to reach 136,639 by the end of January 2021. Note that the 1214 hotline is suspended currently for maintenance purposes and was replaced by the hotline 1787 with extensions 1 and 2 and the direct telephone number 01-594459.

On another note, the department of preventive medicine at the MoPH follows up on patient with COVID-19 symptoms and assesses their compliance to home quarantine. The department of preventive medicine performs a follow up with the suspected on daily basis for 14 days after the date of suspicion and coordinates with the Red Cross for the transportation of suspected, probable or confirmed cases. The number of operators performing this task is 5. An average of 650 calls are made on daily basis.

A new hotline (1787) with extensions 1 and 2 was put in place recently to respond to COVID-19 related queries. For the COVID19 vaccination deployment, the MoPH is currently using the same hotline number 1787 with extension no. 1. However, the MoPH is considering dedicating a new hotline specifically designated for the vaccine deployment and is currently in negotiations with a local NGO for this task. Once that hotline becomes operational, the MoPH will widely disseminate the new hotline and related uptake channels to reach all citizens and vulnerable groups. Until such time, the 1787 hotline will be used. It will be operating around sixteen hours a day, six days a week. At any shift, at least five operators will be active. An additional number of operators will be needed (around 15) and additional IT equipment. The COVID19 hotline responds to the following queries:

- Get information on COVID-19
- Request hospitalization
- Pre-registration for vaccination and help with filling the digital form for registration in order to mitigate unintended exclusion of vulnerable groups in the process due to limited access to IT tools
- Report side effects of the vaccine
- Report grievances that can also be anonymous. The GRM shall include the following: (i) referral pathways in the event of any SEA/H related complaints; and (ii) an appeal process for unresolved grievances that was established before the Project restructuring to the request of the WB. Whenever there is an unresolved grievance, such as someone thinking they should be vaccinated earlier, the patient can contact the vaccine center who will convey the message to the committee to act upon in a timely manner.

Additional uptake channels include the direct contact number at 01-594459-, or registering grievances through the MoPH website site (moph.gov.lb) or the ministry's mobile application which is in Arabic.

The GRM was clearly communicated during the virtual stakeholders' engagement held on 5 February 2021 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, complaints from the elderly or other vulnerable groups and grievances regarding the conduct of security personnel. For SEA/SH related complaints, referral pathways will ensure coordination with the relevant NGOs like ABAAD, and KAFA, for example, which are the key local NGOs handling SEA/SH grievances in Lebanon The GRM will also have in place an appeal process in the event of unresolved grievances whereby a complainant who is unsatisfied with the response will have the option to escalate their grievance to MoPH senior management. Grievances will be handled efficiently, immediately where possible, or within a timeline of 3-5 days.

Doctors, nurses and vaccinators will also have the option to file their grievances through the MoPH internal procedures and primarily through the "diwan" or "registrar" where all grievances will be officially recorded and addressed by the responsible staff at the MoPH. Another uptake channel for internal complaints is through the grievance boxes allocated throughout the MoPH. In addition, the grievance boxes allocated at the selected vaccination centers / hospitals under the national vaccination plan will be another uptake channel for doctors, nurses and vaccinators to register their grievances which will accordingly be handled by the relevant hospital staff. Grievances will be handled efficiently in a specified timeline and not exceeding 5 days.

The GRM will be clearly documented with close follow up by the responsible persons. The PMU will hire a GRM officer who will follow up and monitor the GRM in a GRM log.

Cost Estimate

No additional cost is to be incurred to the ESMF as a result of the Project restructuring, the cost provided in the ESMF still applies.

1- Restructuring of the Lebanese Health Resilience Project

1.1 Context

An outbreak of COVID-19 caused by the 2019 novel coronavirus (SARS-CoV-2) has been spreading rapidly and globally since December 2019. Lebanon is also affected by the COVID-19 outbreak, which poses a threat to its heath system. The first cases of COVID-19 were reported in Lebanon on February 21, 2020.

The outbreak was expected to grow exponentially, affecting not just the health system but also the economy and security. In response, the Government of Lebanon (GOL) has prepared a **COVID-19 Health Sector Response Plan and developed a National Multi-Sectoral Plan (See Annex A).** Progress has been made in risk communication to the population, Port of Entry (POE) screening, the setting up of one testing center and of one treatment center. However, the unmet needs are immense. With only one hospital the Rafik Hariri University Hospital (RHUH) prepared to treat cases, Lebanon is under-equipped to respond to such a public health emergency.

Currently, the Country is witnessing an unprecedented surge in COVID-19 cases with record-breaking daily cases reported around 5,500 daily cases. As of January 29, 2021, the country has a total of 296,282 confirmed cases and 2,680 deaths. Test positivity rate for the last 14 days is high at 22.4 percent (compared to the World Health Organization (WHO) recommended rate of 5 percent) (¹⁰). This surge, coupled with a high level of infections among health workers (2,409 cases), has been overstretching the health sector's capacity. Currently, 85 percent of COVID-19 regular beds and 95 percent of COVID-19 ICU beds are occupied.

The outbreak is coming at a time when Lebanon's economy is already going through the worst crisis in recent history and the Government of Lebanon (GOL) has limited resources to respond and when the country is trying to recover from August 4, 2020 blast at Beirut Port. COVID-19 vaccination is therefore essential to protecting lives and enabling Lebanon to reopen the economy with confidence and recover.

The Lebanon Health Resilience Project (LHRP) (US\$120 million) was approved by the Board of Executive Directors at the World Bank (WB) on June 26, 2017, became effective on November 14, 2018, and will close on June 30, 2023. The project is financed by a US\$95.8 million non-concessional portion from the International Bank for Reconstruction and Development (IBRD) and a US\$24.2 million concessional portion from the Global Concessional Financing Facility (GCFF). The original Project Development Objective (PDO) is to *increase access to quality healthcare services to poor Lebanese and displaced Syrians in Lebanon*. The original project design comprised: (i) Component 1: Scale up the scope and capacity of the Primary Health Care Center Universal Health Coverage (PHCC UHC) program (US\$76.5 million); (ii) Component 2: Provision of health care services in public hospitals (US\$36.4 million); and (iii) Component 3: Strengthen project management and monitoring (US\$7.1 million).

The project was restructured on March 12, 2020 to reallocate US\$40 million from Components 1, 2 and 3 for COVID-19 response. The PDO was revised as "to increase access to quality healthcare services to poor Lebanese and displaced Syrians in Lebanon and to strengthen the Government's capacity to respond to COVID-19". A new component was added "Component 4: Strengthen capacity to respond to COVID-19". The Results Framework (RF) was amended to include new indicators for Component 4 and to adjust the targets for indicators related to the other three components. After the first restructuring, resource allocation among the components is as follows: (i) Component 1: US\$51.2 million; (ii) Component 2: US\$23.52 million; (iii) Component 3: US\$5 million; and (iv) Component 4: US\$40 million.

¹⁰ https://www.moph.gov.lb/en/Media/view/43750/1/monitoring-of-covid-19-

Changes in Components 1, 2, 3 and 4 will be as per the following table.

	Original Budget Allocation (Million USD)	Budget Allocation after the Restructuring (Million USD)	Original Number of Target Groups	Revised Number of Target Groups after Restructuring (% of the original)
Component 1	76.5	51.24	-Contracted PHCCs:	-Contracted PHCCs: 170
Component 2	36.4	23.52	204	(83.3%)
Component 3	6.86	5.00	-Lebanese	-Lebanese Beneficiaries:
Component 4	0	40.00	Beneficiaries: 340,000 -Syrian Beneficiaries:	250,000 (73.5%) -Syrian Beneficiaries: 250,000
Front-end Fee	0.24	0.24	375,000	(66.6%)

Table 1: Restructured Project Components

The second Restructuring Paper gets the approval of the Board of Executive Directors to restructure the US\$120 LHRP. The restructuring consists of: (i) reallocating US\$18 million from Component 1 ("Scale up the scope and capacity of the PHC UHC) program") to Component 4 ("Strengthen capacity to respond to COVID-19"); (ii) using US\$34 million under Component 4 to finance COVID-19 vaccine purchase and deployment; and (iii) adding result indicators associated with the support for COVID-19 vaccine procurement and deployment.

Lebanon has initiated preparedness activities for COVID-19 vaccine introduction. A COVID-19 National Coordinating Committee (CNCC) was established on November 6, 2020 for the successful planning, coordination and implementation of activities. In April 2020, the WHO, the European Commission and France had launched the COVAX, a tool to facilitate access to COVID-19 vaccines. The MoPH has reserved vaccines for 20% of the population residing in Lebanon through the COVAX facility and for around 15% of the population through an official bilateral agreement with Pfizer. The GOL has reached out to the WB to support its agreement with Pfizer under component 4 of the LHRP and assist in funding the vaccine budget. On January 21, 2021, The WB approved a re-allocation of US\$34 million under Component 4 of the LHRP to support vaccines for Lebanon.

1.2 Objectives

An Environmental and Social Management Framework (ESMF) was prepared for the LHRP, consulted on, disclosed and cleared by the WB in May 2019 (¹¹). This parent ESMF can be found on the following link: https://www.moph.gov.lb/userfiles/files/Programs%26Projects/LHRP%20-%20ESMF.pdf

Further to the first restructuring, the WB team requested an update of the ESMF in the form of an addendum that tackles the additional environmental, health and safety measures that need to be considered to cover the environmental and social risks under Component 4. Given that COVID-19 is a new disease, additional mitigation measures will need to be included in the ESMF related to (i) health and safety measures, (ii) waste management related to COVID-19 medical wastes, (ii) fire safety, (iv) wastewater management, (v) occupational health and safety aspects related to exposure to infection and diseases, and (vi) emergency preparedness and response plan and exposure control plan and infection control policies and procedures in line with World Health Organization guidelines and WBG Environmental, Health and Safety guidelines. The Grievance Redress Mechanism shall also be strengthened to include a designated line for COVID-19 intake and processing. In addition, Component

¹¹ The ESMF was disclosed as Environmental and Social Safeguard Framework (ESSF). In this document both terms ESMF and ESSF refer to the same report disclosed on May 2019 on the WB website.

4 will be implemented by UN Agency(ies) who will follow World Bank Safeguards Policies. An addendum to the parent ESMF was prepared for the restructured Project, virtually consulted on, cleared and disclosed by the WB in July 2020 on the following links: <u>link</u> and <u>link</u>.

The WB team requested an update of the addendum to the ESMF under component 4 that tackles the Pfizer Vaccination Plan and relevant additional social, environmental, health and safety measures that need to be considered to cover the environmental and social risks associated with the vaccination and the respective mitigation measures. This update of the addendum to the ESMF is structured as follows with updates underlined:

- Chapter 1: Restructuring of the Lebanese Health Resilience Project <u>(Updated to reflect the COVID-19 Vaccination Plan)</u>
- Chapter 2: Description of Component 4 (Updated to reflect the COVID-19 Vaccination Plan)
- Chapter 3: Baseline Information for COVID-19 (Updated to reflect the baseline for the COVID-19 Vaccination Plan)
- Chapter 4: Institutional Framework for Environmental and Social Management (Updated to add new Institutions involved in the COVID-19 Vaccination Plan and new responsibilities on some institutions)
- Chapter 5: Stakeholders Consultations (Updated to add the feedback from the recent stakeholder consultations undertaken with respect to the environmental and social risks, impacts and mitigation measures on the COVID-19 Vaccination Plan)
- Chapter 6: Environmental and Social Analysis (Updated to add the new risks and related mitigations pertinent to the COVID-19 Vaccination Plan)
- Chapter 7: Implementation of the ESMF (No major changes)
- Chapter 8: Monitoring and Evaluation System (Minor changes related to new layers of monitoring for COVID-19 Vaccination Plan)
- Chapter 9: Grievance Redress Mechanism (Updated to add the GRM specifically related to the COVID-19 Vaccination Plan)
- Chapter 10: Cost Estimate (<u>No major changes</u>)
- Annexes (Added Annexes related to COVID-19 Vaccination Plan)

2- Description of Component 4

2.1 Description of Component 4 - strengthen capacity to respond to COVID19

Component 4 of LHRP allows for immediate support to the GOL to enhance the country preparedness, to finance the procurement of medical goods and equipment, and to build capacities of health workers and front-line responders.

The new component includes:

- iv. Case detection and surveillance. This will include support for:
 - a. Procuring essential commodities for case detection and surveillance such as Polymerase Chain Reaction (PCR) machines, sample collection kits, test kits, and other equipment and supplies for COVID-19 testing and surveillance;
 - b. Capacity building in testing and surveillance; and
 - c. Strengthening IT system for surveillance.
- v. **Case management and protection of health workers and response personnel.** This will support the strengthening of selected health facilities and establishment and equipping of quarantine and treatment centers, so that they can manage COVID-19 cases, including:
 - a. Procuring beds, furniture, ventilators, pulse oximeters, laryngoscopes, oxygen generators, other equipment and supplies for COVID-19 case management;
 - b. Capacity building and training;
 - c. Procuring Personal Protective Equipment (PPE), disinfectants and other commodities for infection prevention and control (IPC) as well as healthcare waste management;
 - d. Contracting supplementary health workers for COVID-19 treatment centers;
 - e. Paying for fees related to COVID-19 services according to a fee schedule and eligible criteria to be developed and agreed with the World Bank; and,
 - f. Capacity building in COVID-19 case management and in Infection Prevention and Control (IPC).
- vi. **Multi-sectoral response.** This will finance goods, services, training and operational costs to support multi-sectoral activities such as:
 - a. The operations of command rooms at the central and regional levels,
 - b. Implementation of risk commutation and community engagement campaigns,

c. Implementation of containment strategies, including port-of-entry interventions, and Operation of rapid response teams.

2.2 Component 4 - Description of the COVID-19 Vaccination Plan

The control of COVID-19 pandemic with the COVID-19 vaccine remains the main opportunity to Lebanon to limit its heavy consequences on health, health systems and the economy. Lebanon has initiated preparedness activities for COVID-19 vaccine introduction.

2.2.1 The Country Readiness and Regulation

On November 16 2020, WHO issued a document 'Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines'¹² directed at national authorities who are responsible for managing deployment, implementation and monitoring of COVID-19 vaccines, as well as partners who provide the required support. Key considerations for any country preparing for COVID-19 vaccine deployment and distribution include (i) Introduction, (ii) Regulatory preparedness, (iii) Planning and Coordination, (iv) Costing and Funding, (v) Identification of Target Populations (vi) Vaccination Delivery Strategies, (vii) Preparation of Supply Chain and Management of Healthcare Waste, (viii) Human resources Management and Training, (ix) Vaccine Acceptance and Uptake, (x) Vaccine Safety Monitoring, management of adverse events following immunization and injection safety , (xi) Immunization Monitoring System, (xii) COVID-19 Surveillance and (xi) Evaluation of COVID-19 Vaccine Introduction.

2.2.2 The National COVID-19 Vaccination Committee

According to the MoPH, the NCVC was formed in November 6, 2020 by the Minister of Public Health (MoPH). It was convened with the objectives of: (i) Prepare a mechanism for approval, purchase, registration, receipt and distribution of the vaccine, (ii) Monitor vaccine side effects, (iii) Monitor the cold chain and other issues related to maintaining the quality of the vaccine, (iv) Identify and prioritize target groups and (v) Ensure that the vaccine reaches the target groups in a practical and equitable manner.

The NCVC is headed by Dr. Abdul Rahman Al Bizri and includes members from the following entities: (i) MoPH (Head of Departments, Units and Program Managers and Consultants to the Minister), (ii) WHO, (iii) UNICEF, (iv) UNRWA, (v) UNHCR, (vi) The WB, (vii) Orders of Physicians, (viii) Order of Nurses, (ix) Order of Dentists, (x) Military Medicine, (xi) Lebanese Internal Security Forces, (xii) Lebanese General Security, (xiii) Lebanese State Security, (xiv) NGO Arcenciel, (xv) Lebanese Red Cross, (xvi) Lebanese Society of Bacterial Diseases and Experts in (xvii) Ethics Science, (xviii) Medical Engineering and (xix) Infection Control.

Seven national technical sub-committees have been appointed by NCVC to focus on the main pillars of the WHO/UNICEF/WB preparedness tool known as Vaccine Introduction Readiness Assessment Tool .IRAT)/VRAF 2.0¹³. These pillars are; i) Planning and coordination, ii) Budgeting, iii) Regulatory, iv) Prioritization, Targeting, and COVID-19 Surveillance, v) Service Delivery, vi) Training and Supervision, vii) Monitoring and Evaluation, viii) Vaccine, Cold Chain, Logistics and Infrastructure, vii) Safety Surveillance, and Demand Generation and Communication. The NCVC prepared a National Vaccination Plan (NVAC) and assigned tasks to each sub-committee.

The NCVC met several times between November, 2020 and January 12, 2021 and each of its subcommittees held at least 2-3 meetings to discuss issues relevant to their scope of expertise and assigned duties. Several experts were invited to join meetings when needed. The NCVC and seven Technical Working Groups are preparing the National COVID-19 Vaccine Deployment Plan (NCVDP) which covers all people residing in Lebanon (including Lebanese citizens, Palestinian refugees and registered and non-registered Syrians). The Pfizer Vaccine Plan is a subset of NCVDP.

¹² Refer to <u>https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine_deployment-2020.1</u>

¹³ Refer to <u>https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine-introduction-RA-Tool-2020.1</u>

2.2.3 The National Vaccination Action Plan (NVAP)

The National Vaccination Action Plan is summarized in the following Table¹⁴.

¹⁴ WB, LHRP Restructuring Paper 002.

Table 2: COVID-19 Vaccination Action Plan

Readiness Domain	Actions
Planning and Coordination	• National COVID-19 Vaccine Committee and the Technical Working Groups prepare sub-action plan for the Pfizer vaccine deployment (*)
	· National COVID-19 Vaccine Committee and the Technical Working Groups prepare the comprehensive National COVID-19 Vaccine Deployment Plan (NCVDP)[1]
Regulations	\cdot Mechanisms for indemnification against product liability claims and payment of no-fault compensation (*)
	\cdot Regulatory pathways for: (i) data protection and data governance to ensure appropriate use of vaccination data; (ii) consent to vaccinations, the process for agreeing to or refusing to be vaccinated, and measures to protect those that refuse to be vaccinated (*)
Prioritization and Targeting	\cdot Online system for pre-registration of eligible priority groups identified in the Pfizer plan (*)
Service Delivery	\cdot All standard operating procedures (SOPs) for vaccination storage, distribution and delivery developed and disseminated (*)
	\cdot Vaccination sites identified and prepared based on geographic location, cold chain, logistics, and enhanced Infection Prevention and Control (IPC) procedures
Training and Supervision	\cdot Health Managers, cold chain technicians, vaccinators and supervisors trained and equipped with necessary knowledge and skills
Monitoring and Evaluation	\cdot Management Information System (MIS) established to monitor vaccine coverage and follow-up
	\cdot Multiple channels for grievance reporting (including a hotline, a mobile application, and the MOPH website set up (*)
Cold Chain, Logistics and Infrastructure	\cdot Procurement plan for ancillary supplies and Personal Protective Equipment (PPEs) developed
	· Effective Vaccine Management (EVM) assessment and supply chain sizing tool completed, and procurement initiated in view of receipt of COVAX vaccine by mid-2021
Traceability/ vaccine safety surveillance	• An information system is developed to trace: (i) different types of vaccine and (ii) the people that have been vaccinated. It can (i) send SMS to patients on date and location for vaccination, (ii) send reminder SMS for the second dose, (iii) issue online vaccination certification, (iv) report adverse events – pharmacovigilance
Demand generation and Communication	\cdot Existing call center (adding new hotline) expanded to support COVID-19 vaccine related grievances and address public queries.
	• Public communication campaigned launch to provide information on eligibility, vaccination sites, timing, vaccine safety and efficacy etc.

Note: Actions marked with (*) need to be completed before vaccine roll-out. Others can be completed within the first 6 months after deployment.

3- Baseline Information for COVID-19

This chapter presents the description of the existing baseline conditions relevant to Component 4 only. Another baseline information can be found in the original ESMF.

3.1 Baseline Information for Pfizer COVID-19 Vaccination Plan

The first case of COVID-19 was reported in Lebanon on February 21, 2020. Until March 1, 2020: A total of 231 people were tested at RHUH, with results being 221 negatives and 10 positives.

On March 10, 2020, the MoPH prepared the "Coronavirus Disease 2019 (COVID-2019) National Health Strategic Preparedness and Response Plan" as required under the International Health Regulations and using the WHO global 2019 Novel Coronavirus Strategic Preparedness and Response Plan as foundation¹⁵. This plan establishes a national plan of action to scale up preparedness and response capacities in Lebanon for prevention, early detection, and rapid response to coronavirus disease 2019 (COVID-2019).

As per the above-mentioned plan and based on the available epidemiological data at the date of the preparation of the said plan, the following is estimated: for a population of 6 million, approximately 600 thousand persons (10%) will contract symptomatic infection, over a period of 2-3 months. Of these cases, 90,000 (15%) will seek healthcare, out of which 18,000 (20%) would require hospital admission and 2,700 (3%) would be admitted to the intensive care unit. The death toll is estimated at a maximum of 1,800, 2% of those seeking healthcare. A pandemic that lasts eight weeks and has an attack rate of 10% will require at its peaks (4th and 5th week), to use of 61% of the ICUs over all the Lebanese territory and around 36% of the hospital beds.¹⁶

The main objective of the National Health Strategic Preparedness and Response Plan was the attempt to contain the epidemic, through the implementation of the following measures:

- Monitoring land, sea and air borders, through heat detector and questioning of arrivals and travelers
- Banning travel to infected places
- Conducting a laboratory examination of each suspect, exclusively in Rafik Hariri University Hospital laboratory, or in the laboratories accredited by the MoPH, namely: The American University of Beirut, The Saint George Hospital, The Rizk Hospital/Lebanese American University, The Rodolphe Merieux Laboratory at the Saint Joseph University/Hotel Dieu Hospital)
- Putting all positive cases by examination not showing any symptom in home confinement, and following up with them daily by the MoPH to check for symptoms
- Admitting all positive cases with symptoms to Rafik Hariri University Hospital, corona ward
- Conducting an investigation of all cases in contact with positive cases
- Implementing the epidemic prevention methods in all health centers and hospitals
- Activating non-health institutions and devices to support the MoPH, especially in the application of Public health measures:
 - Municipalities to monitor domestic isolation

¹⁵ The Coronavirus Disease 2019 (COVID-2019) National Health Strategic Preparedness and Response Plan available on <u>https://www.moph.gov.lb/en/Pages/127/27070/coronavirus-disease-health-strategic-preparedness-and-response-plan</u> -

¹⁶ Idem 14

- Ministry of Interior and Municipalities, Public Security, Port Administration and the Army to apply airport control and land crossings.
- Ministry of Information to contribute to raising awareness
- The civil and private sector to spread awareness
- Ministry of Finance, High Relief Council to secure the necessary funds
- Conducting an assessment of the capacity of government hospitals to accommodate cases
- Equipping government hospitals with necessary medical equipment and materials (respirators, monitoring devices, protective equipment for health workers, ...)
- Allocation of funds to relevant government hospitals to increase the number of health workers, particularly nurses
- Allow university hospitals (which scored Level 2 in the Assessment of External Biosafety Quality) to do the PCR tests for Corona within the price maximum determined by the MoPH¹⁷. (See Annex B for extracts from WHO Laboratory Biosafety Manual)
- Ask private university hospitals to support relevant public hospitals for Corona related issues in the field of training health personnel and the application of disease prevention methods
- Activate the emergency plan for the private hospitals that are preparing themselves for stage four "Countries experiencing larger outbreaks of local transmission (Community transmission)"

On March 19, 2020, MoPH published on its website the "Health sector readiness in Lebanon to respond to the Coronavirus" ¹⁸ document to explain further the MoPH Plan and set its general outline that is based on the following lines:

3.1.1 First Line: The MoPH adopts Rafik Hariri University Hospital

The MoPH adopts Rafik Hariri University Hospital (RHUH) as a primary reference hospital during the outbreak of the new corona. RHUH includes:

- a. Independent Emergency Department
- b. 11 rooms for intensive care
- c. 64 rooms capable of accommodating light to medium cases
- d. 56 rooms to accommodate light cases
- e. Some rooms can accommodate two people in some cases
- f. No of beds for COVID-19 Patients (Phase 1): 120 beds and 11 respirators
- g. No of beds for COVID-19 Patients (Phase 2): 350 beds

¹⁷ Laboratory facilities are designated as (i) basic – Biosafety Level 1, (ii) basic – Biosafety Level 2, containment – (ii) Biosafety Level 3, and (iv) maximum containment – Biosafety Level 4. Biosafety level designations are based on a composite of the design features, construction, containment facilities, equipment, practices and operational procedures required for working with agents from the various risk groups

¹⁸ Health sector readiness in Lebanon to respond to the Coronavirus dated March 19, 2020 available on <u>www.moph.gov.lb</u> (in Arabic)

3.1.2 Second Line: Regional Public Hospitals

Eleven (11) additional public hospitals will be adopted by the MoPH. These hospitals were selected based mainly on their location as such, one hospital was selected in each geographical area.

The regional Public Hospitals that were selected as second line are listed in the following Table ¹⁹.

¹⁹ Idem 17

SN	Governmental Hospital	Readiness	No of beds for COVID-19 Patients (Phase 1)	No of beds for COVID-19 Patients (Phase 2)
1	Tripoli	Qualified to receive suspected cases with an equipped external screening room Receives cases that do not require intensive care (16 beds)	16 beds 7 respirators in ICU	170 beds
		Needs PCR testing Unit for COVID-19		
2	Elias Hrawi-	Use the independent emergency department and receive	19 beds	49 beds
	Zahle	cases that do not require intensive care	3 respirators for	
		Needs PCR testing Unit for COVID-19	COVID-19	
3	Nabih Berri	Use the independent emergency department for	22 beds	127 beds
	University-	emergency areas with isolation department and intensive	5 respirators	
	Nabatiyeh	care department		
		Needs PCR testing Unit for COVID-19	_	
4	Hermel	Use the independent emergency department to receive	20 beds	58 beds
		emergency cases with the department of intensive care	3 respirators	
		Needs PCR testing Unit for COVID-19	_	
5	Baalbek	Use of the independent emergency department	22 beds	103 beds
		Receives cases that do not require intensive care on the	6 respirators	
		first floor		
		The ICU includes 6 beds ready to receive patients	_	
6	Saida	Receives cases that do not need intensive care	8 beds	80 beds
		There is an independent emergency room	4 respirators	
		The ICU includes 4 beds ready to receive patients	_	
7	Beint Jbeil	There is an independent emergency room	25 rooms	60 beds
		Receives cases that do not need intensive care	6 respirators	
		The ICU includes 6 beds ready to receive patients	_	
8	Machghara	There are independent emergency rooms (5 rooms and 2	40 beds	40 beds
		outside the hospital)	4 respirators	
		Receives cases that do not need intensive care beds)	_	
		Intensive care (4 beds)	_	
9	Bcharreh	There is one independent emergency department	22 beds	36 beds
		Receives cases that do not require intensive care	2 respirators	
		The ICU includes 2 beds	_	
10	Halba	There is an independent emergency department	9 beds	84 beds
		Receives cases that do not require intensive care	3 respirators	
		The ICU includes 3 beds	_	
11	Ftouh	To use an independent emergency department and set up	20 beds	40 beds
	Kesserwan - Al	an external screening room	3 respirators	
	Bouar	Receives cases that do not require intensive care on the		
		first floor (12 rooms)		
		TOTAL	223	847

Table 3: Regional	Public Hos	pitals selected	d as second	l line ((20)

²⁰ Idem 17

In summary:

- For the first phase: RHUH and 11 hospitals will be involved including 343 beds currently available for COVID-19 patient (120 at RHUH and 223 in Regional Public hospitals)
- For the second phase 1,197 beds will be available (350 at RHUH and 847 in Regional hospitals)

All the selected hospitals were accredited by the MoPH in 2011 ²¹. The accreditation includes chapters on the Practice, Patient safety, the Building, Engineering maintenance, Environmental services, fire safety, Human Resources, Infection Control, OHS and Waste Management.

3.1.3 Third Line: Other Public Hospitals and Private Hospitals Classified as highest Tariff (T1)

Seventeen (17) public hospitals can additionally be involved. These hospitals can be used when the capacity of the public hospitals, selected at the first and second stages described above, is exceeded. The hospitals selected for the third line are distributed throughout the Lebanese territory and listed in the following Table.

SN	Governmental Hospital	Total No. of beds
1	Qana	8
2	Baabda	62
3	Minieh	40
4	Sibline	90
5	Jezzine	21
6	Kherbet Qanafar	25
7	Marjaoun	45
8	Hasbaya	55
9	Ehden	10
10	Dahr el Bashek	73
11	Tebnine	86
12	Mais el Jabal	61
13	Orange Naso	72
14	Rashaya	80
15	Tannourine	62
16	Sour	30
17	Al Shohar Al Gharbi	40
TOTAL		860

Table 4: Public Hospitals selected as third line (22)

It is clear that RHUH, the regional public hospitals selected as second line and other public hospitals selected as third line totalize 2,057 beds. Therefore, the support of the private hospitals classified as T1 may be needed, because the potential peak demand in beds may reach 18,000 beds.

²¹ Personal communication with Dr. Abboud on March 19, 2020

²² Idem 17

The Classification of Hospitals as T1 takes into account the accreditation and patient satisfaction, that are a reflection of quality, accounting for 40% and 10% respectively of the total contracting score. Other factors are a reflection of performance, and together account for 50% of the total contracting score (Refer to Annex C for details).

The funding of the COVID-2019 National Health Strategic Preparedness and Response Plan relies on several sources:

- The WB Loan 40 million dollars of which have been allocated for Corona cases (restructuring of LHRP). This loan will be used to cover the settlement or procurement of (i) Materials for about 28 million (ii) Salaries of health team's nurses and doctors, (iii) Hospital bills for patients for about 2 million and (iv) Training for about 1 million. The procurement process under this loan will be through WHO and UNICEF. The main purpose is to secure the materials that may become rare and unavailable.
- The High Relief Council will purchase needs to fight COVID19 for an amount of \$10 million. This amount will be compensated from the WB Loan mentioned above.
- A fund at UNICEF that will be partially used to fulfill the needs to fight COVID-19. The MoPH and UNICEF will work on the restructuring of the fund.
- The MoPH will secure approximately \$3 million that are available in the Ministry's account at the Central Bank and that were transferred in previous years from a WB loan. The disbursement of this fund will follow the WB disbursement procedures.
- The budget of the MoPH through solicitation of offers.
- The budget for each hospital.

A specialized committee was formed in cooperation with Rafik Hariri University Hospital to assess the needs for medical supplies for one-month period for each of public hospital that are listed under stage 2.

The needs were identified for one month and divided into materials to be worn by the health workers (PPEs) when treating cases and medical equipment needed for the ICUs. A dynamic mechanism was developed to identify needs periodically to meet needs and when there is any shortage as shown in the following table.

Table 5: List of PPEs and consumables needed for one month for 1 hos	pital (23)
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#	Description	Unit	Number
Α	N95: Particulate respirator compliant with NIOSH N95 or EN 149 FFFP2 and fluid resistant (1/2 medium, 1/2 Large)	Piece	5,000
В	3 ply surgical face mask, compliant with EN 14683 type IIR or ASTM F2100 level2 or level 3 or equivalent	Box of 50	2,000
C	Disposable gown: single use, long sleeves, fiber made non-woven, thumb loop, tape tab for neck closure, water and liquids proof, compliant with the EN 13795 high performance level, or AAMI level 3 performance	Piece	60,000
D	Goggles / eye protection compliant with EU standard directive 86/686/EEC, EN 166/2002 or ANSI/ISEA Z87.1-2010 or equivalent	Piece	65,000
E	Disposable coverall: compliant with EN 943-1:2002 such TYVEK or equivalent (1/3L, 1/3XL, 1/3XXL)	Piece	30,000
F2	Latex gloves free powder	Box of 100	4,000
Н	Hand sanitizer 1liter	Piece	5,000
0	Cover shoes for tyvek coverall or equivalent	Pair	1,000
S	Cadaver bags (Double cover)	Piece	300
Z10	Alcoholic, Hand Rub-(Sterilium) 500 ml / A liter	Piece	5,000
Z13	Towel Roll	Piece	5,000
Z27	Hydro soluble bags - Rolls	piece	500

A procurement committee was established in order to prepare tenders and launch them quickly on the MoPH website and under the supervision of the WB. Procurement documents were launched on March 28, 2020 for the procurement of 70 respirators for the use of other public hospitals and 10 PRC for the use of Public hospitals under stage 2.

In parallel, the MoPH has asked the 53 private hospitals, that are classified T1 to be prepared to receive COVID-2019 patients in case the capacity of the public hospitals is exceeded. These are hospitals distributed throughout the entire Lebanese territory.

3.1.4 Other Initiatives by MoPH

The MoPH had several initiatives some of which in coordination with other institutions of the Public sector to inform the population of the current situation of COVID-2019 and raise awareness. Such initiatives are listed below:

- Information and statistics systems
 - An information system has been developed to collect information related to the diagnosis and treatment of COVID-19 cases from all hospitals

²³ Idem 17
- A schedule has also been set up to collect information periodically at the national level, with everything related to COVID-19 in order to determine any potential deficiency: available medical equipment, health workers, number of patients entering the hospitals, etc.
- Awareness campaigns and a communication plan
 - The MoPH launched a campaign entitled "With the awareness we face Corona" that aimed at providing citizens with the necessary information and guidance to prevent the emerging COVID-19 and to correct false information in circulation. For this end, the Ministry launched a special hashtag for the campaign on all social media
 - The MoPH produced 8 short educational films, 3 for children and 5 for adults on all topics related to Corona: methods of prevention, method of washing hands, symptoms, household confinement, tips for health workers and tips for travelers. All of this material was sent to television stations to broadcast them extensively
- Partnership with communication channels
 - In cooperation with the Ministry of Telecommunications, SMS are being sent to all citizens with awareness messages
 - The Ministry of Administrative Reform undertook an initiative to circulate all the educational material issued by the MoPH to all the administration employees through an online learning site
 - The MoPH is working in partnership with international social media platforms to promote advertisements and educational material that were developed by MoPH at no cost (Facebook-Twitter-Google-YouTube-WhatsApp)
- MoPH's cell phone application. The Ministry's cell phone application was developed to include a special section on Corona that will aim at:
 - o Publishing all data and instructions related to CoVID-19
 - Geographical distribution of hospitals and the publication of information on the number of vacant beds allocated for Corona patients and the means of communication with these hospitals
 - o Integration with informational systems related to corona patients
- Corona self-diagnosis application on cell phone
 - A self-diagnosis of the symptoms of corona in order to relieve the load on the Ministry's hotline and to alleviate citizen's anxiety was also launched
- Additional sections were created on the MoPH's website to cover information and advice related to the emerging COVID-19
 - A special section was created to publish all epidemiological monitoring data in addition to data and reports for citizens, health professionals and travelers.
- A Health Advice section was also created to publish educational materials and awareness on prevention from COVID-19.
- The MoPH hotline 1214:
 - Was made available 24 hours a day 7 days a week
 - The number of employees was increased from 5 to 14
 - The number of calls received on the hotline from February 21 through March 18, 2020 was 21,830
 - The number of calls answered on the hotline from February 21 through March 18, 2020 was 8,641

- A comprehensive national plan was developed and implemented by the National Program for Psychological Health at the MoPH in partnership with WHO, UNICEF and all interested parties. Its objectives are to:
 - o Address stigma and discrimination against infected persons and health workers
 - o Promote mental health and prevent stress related to the current situation
 - Provide psychological support to people in quarantine in the hospital or at home
 - o Provide guidance to support children and the elderly in dealing with psychological stress
 - Training and supporting health workers in self-care and managing patients' psychological crises
 - Strengthening the work of the National Hotline for Psychological Support and Suicide Prevention 1564 -Embrace Lifeline

As of March 28, 2020, the total number of registered persons infected by COVID-19 was 412 as of April 23, 2020, the number reached 688 and as of June 13, 2020, the total number of cases was 1422 ²⁴, Lebanon was classified under "Countries experiencing cases clusters in time, geographic location and/or common exposure (Clusters of cases)" as per WHO transmission scenarios for COVID-19.3.5

3.2 National COVID-19 Vaccination Deployment Plan (NVDP)²⁵

Currently, Lebanon is classified under "large-scale community transmission of COVID-19" and has initiated preparedness activities for COVID-19 vaccine introduction. The works of all the parties involved in the COVID-19 Vaccination plan resulted in the preparation of the National COVID-19 Vaccination Deployment Plan (NCVDP) that was disclosed in a presentation held by the Minister of Public Health at the Grand Serail on January 28, 2021. This plan is summarized below.

3.2.1 Types of Vaccines

The three types of vaccines are being considered for import into Lebanon include: (i) Vaccines that use mRNA technology, such as the BNT162b2 Mrna vaccine, known as "Pfizer-Biontech", (ii) Vaccines that use the viral vector technology, namely ChAdOx1 nCoV-19 Known as the "AstraZeneca-Oxford" vaccine and (iii) Subunit vaccines, represented by the Chinese Sinopharm vaccine. Pfizer will be the vaccine type that will be funded by the WB and not all the vaccines that are included in the NCDVP.

Another possible vaccine is the "Moderna" vaccine, which uses messenger RNA technology as well as the Russian "Sputnik V" vaccine and the "Johnson & Johnson" vaccine, which use virus vector technology Recombinant adenomyosis (rdAv).

3.2.2 General Vaccination Instructions

All people aged above 18 will ultimately be able to get vaccinated if they wish to, as getting the vaccine will be optional. However, this vaccination will follow the priority of the vaccination deployment. Below is a list of some relevant general information regarding the NCDVP.

• All people aged 18 and over who wish to be vaccinated will be able to get the vaccine at the appropriate stage.

²⁴ https://www.moph.gov.lb/en/Media/view/27196/1/daily-report-on-covid-19-

²⁵ Referring to the presentation held by the Minister of Public Health during the launch of the Vaccination Plan at the Grand Serail on January 28, 2021. Accessible online through

https://www.moph.gov.lb/userfiles/files/Prevention/nCoV-%202019/Vaccination%20plan.pdf

- All people aged 16-17 years' old who wish to get the vaccine will be vaccinated after obtaining the consent of their guardians.
- Vaccinations are not mandatory and they will be given to people who are eligible and wanting to receive them. People should be helped to make an informed decision about vaccination by explaining the need for vaccines and their benefits as well as side complications and contraindications.
- The vaccine is free for people who receive it through the Lebanese Ministry of Health.
- All persons residing in Lebanon who are eligible to receive the vaccine will be included in the vaccination campaign regardless of their nationality.
- Any purchase of vaccines from private parties will be in coordination with the MoPH and these will be added to the vaccinated numbers in the national campaign. The Ministry assigned a committee to study and analyze the potential new vaccines that might be imported by private companies. Discussion regarding this issue are still ongoing.
- Any acceptance of a donation of vaccines must be done in coordination with the MoPH. The vaccines are to be added to the count of the vaccinated persons within the national campaign.

3.2.3 The priority groups for vaccination by stage

As per the NCVDP, the priority groups in COVID-19 vaccination campaigns were identified according to the following criteria and are listed in the Table below:

- The risk of exposure to the virus and infection
- The risk of serious complications when catching the infection
- The categories that are essential to maintaining a good response to the COVID-19 pandemic such as the health care system and those needed for the good functioning of society and its natural cycle.

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

Stages 1 and 2 represent the first 35 percent of the total population (both citizens and non-citizens) to be vaccinated in 2021. The remaining stages 3 and 4 (the second 35 percent of the population) are expected to be completed end of 2021 and might be completed by 2022. Vaccination to priority populations (table 3) 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 economic cycle in the country.

Table 6: Estin	hated P	riority	Populati	ons for CC	JVID-19	vacci	nation	in Lebano	n26	
	Æ					n			01	

Phase	Target population	Population size[1]	Share of population*
	High risk health workers	55,000	0.8%
	Aged 65 and older	600,143	9.2%
	Those below age $65 (55 - 64 \text{ years})$ but with comorbidities	237,183	3.6%
	All those between ages 55-64 not covered earlier,	237,183	3.6%
First 35%[2]	16-54 years with co-morbidities [3],	1,150,671	17.7%
	health workers not covered earlier	5,000	0.1%
	Individuals essential for preserving the essential function of the society, persons and staff in elderly shelters, prisons	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 \geq 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

Sequential prioritization of healthcare workers:

- Frontline Healthcare workers (ER personnel, ICU...)
- Medical & Nursing Students & Postgraduate students if involved in frontline healthcare
- HCW performing aerosol-generating procedures (e.g., intubation, cough induction procedures, bronchoscopies, some dental procedures and exams)
- Environmental health workers 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, Pneumo...)
- Midwives working outside hospitals
- Physiotherapists
- Community pharmacists
- Dentists
- PHC staff

²⁶ Idem 24

^[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 remaining 35% includes Phases 3 and 4.

Category 1	Category 2	Category 3
High-Risk	Intermediate-Risk	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	Speech Therapy & Ergotherapists	
centers		
Covid 19 vaccination staff	Psychologists	

 Table 7: Healthcare workers categorization by risk of exposure

Table 8: Nursing Vaccine Prioritization

Very high risk	High risk	Medium risk	Low risk
Emergency room	Coronary care + telemetry	Endoscopy unit	Nursing faculties
	units		and technical
			schools
ICU (COVID + regular)	Medical surgical and pediatric	Operating room	Insurance
			companies
NICU + PICU	Dialysis	Recovery room	Medical companies
Inhalation therapy	Home care nursing		Administration
Cardiac surgical unit	Long stay hospitals		
Regular COVID ward	Nurseries & schools		
Oncology + Palliative care	Primary care centers		
COVID 19Vaccination 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 $\geq 40 \text{ Kg/m2}$)
- 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. Food and Drug Administration (FDA) have issued an Emergency Use Authorization (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.

Reaching out to incarcerated individuals

A special sub-committee will be formed to 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 to the national committee its activities and seek support from the committee to be able execute the tasks entitled.

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 do the above given on a clear agenda, at least a day in advance, a clear list of the individual's names and telephones to contact them and transport them to the nearest vaccine center according to the locations to be provided and according to priority criteria.

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.

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 be 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.

3.2.4 The eligibility criteria

The eligibility criteria are based on the following:

- Priority groups for vaccination by stage Scheme: risk and age-based approach as detailed in previous section 3.5.3 and Table 4
- Patient should provide his name and register an appointment online on the following <u>link</u>²⁷. Upon arrival, he/she must submit his ID and the system-based ID from the registration form.
- Patients will be excluded if they are under the age of 16, if they presented a severe allergic reaction after a previous dose of the vaccine or to any ingredient of this vaccine.
- Special criteria will apply for breastfeeding and pregnant women and for patient s who present severe immunosuppression.

3.2.5 The Pre-Registration and vaccination scheduling28

Online pre-registration for the COVID-19 vaccine will be a prerequisite for the selection of vaccine recipients on following link: <u>https://covax.moph.gov.lb/impactmobile/vaccine/non-medical</u>, and it will help determine demand for vaccination and ultimately the selection of recipients based on the prioritization scheme. When more than one vaccine will be available in Lebanon, an option to choose vaccine will be added for people to choose.

Pre-registration can be done by the person who wants to be vaccinated, and in case Internet 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, PHCs 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 the norm. For registration platform, to ensure that there will be not 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.

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 1) directly register through their institutions/orders/sectors or 2) self-register through the app or 3) pre-register through a call center.

²⁷ https://covax.moph.gov/lb/impactmobile/vaccine

²⁸ National Deployment and vaccination Plan for COVID-19

3.2.6 Follow up on adverse events

The patient will be monitored for adverse events for 15 minutes following vaccination. During this time, a community healthcare worker will provide the patient with the vaccination card, which includes the system-generated identification number and educate the patient on the side effects of the vaccine and Adverse Events Following Immunization (AEFI) reporting strategy. The system will alert patients to access the application or the website for a daily, brief safety check-in within 15 days to report AEFI. Refer to Annex H: Form on Adverse Event Following Immunization Reporting Form for COVID-19 Vaccine(s).

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:

- 1. Observation following vaccination at vaccination centers
- 2. Self-reporting of recipients of the vaccine to ask about any side effects and complications following the vaccination
- 3. 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

The EPI department have already developed an AEFI reporting form as part of the EPI program under MERA and a zero reporting form will be individually filled out by the recipients. In parallel, a <u>COVID-19</u> <u>AEFI reporting form (Annex H</u>) 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.

Table 9: 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 XIII)
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	https://www.who.int/vaccine_safety /software-assistance-guiding-hq-

	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.)	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/

After three weeks, and depending on availability of the vaccine, the MERA (or new system) will notify the patients with the date, time and location for the second dose of vaccination.

3.2.7 Criteria for the selection of the vaccination centers

The following criteria and points are taken into consideration with regards to the selection of vaccination centers:

- Centers must be distributed in different regions in accordance with population distribution,
- The address of the center must be known and accessible,
- The center should be adaptable to weather change and equipped with cooling and heating
- There should be appropriate entrances and exits,
- There should be possibility to respect the rules of social distancing between people standing in lines waiting for their turn,
- There should be a car park,
- The center should ensure sufficient space and rooms for vaccination (more than 1 room),
- The center should allocate a place to register names and preparing the necessary documents,
- The center should establish a clinic to treat allergic reactions,
- The waiting rooms in the center should be able to observe the rules of social distancing,
- The center should be equipped with washbowls for the purpose of frequent hands washing,
- The center shall have a room to monitor people after vaccination,
- The center should be equipped with cooling devices (very low temperature, fridges, fridges, etc.),
- The center should be equipped with power supply and alternative support sources (UPS + generators),
- There should be power supply and electrical outlets in vaccination rooms and offices,
- The center should be equipped with computers and internet connection,
- The center should provide infection prevention and control equipment and personal protective equipment
- The center should have a proper medical waste management system including a cold room to store medical waste.

3.2.8 Personnel needed for each vaccination center

Any vaccination center shall have at minimum the following personnel:

- Technical personnel able to operate refrigeration equipment and maintain very low temperatures,
- People who are good at handling and transporting vaccines,
- Cleaners,
- Sufficient number of health care workers should be employed in these centers:
 - a. Eight (8) nurses trained health workers to administer vaccines and monitor side effects
 - b. Two (2) secretaries trained in organizing appointments to receive vaccinations and preparing the necessary documents (List of persons who received the vaccine, the cards, the follow-up ...)
 - c. Two (2) non-medical staff
 - d. At least one (1) doctor in each center
 - e. Administrative Officer (1) for administrative operations

The number of centers designated for vaccination will between 30 to 35 centers and the number will potentially increase. The places of vaccination that were approved for now are large government hospitals and university hospitals in the capital and regions. They will be distributed evenly all over the country.

3.2.9 Vaccination process and Time needed

Four Hundred (400) persons can be vaccinated daily in each vaccination center during 8 to 10 hours of work, on average 40 persons/hour. The process follows the sequence: Registration, waiting room, vaccination room, monitoring room, exit, instructions room. The whole process should take around 35 minutes.

3.2.10 Infection Prevention and Control

Adherence to infection prevention and control (IPC) guidelines is a key milestone 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.

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

- Ensuring that vaccination personnel are COVID-19-free: All personnel involved in vaccination should theoretically be screened for COVID-19 whether by repetitive Polymerase chain reaction (PCR) tests or through clinical screening (daily temperature check and symptoms check). Any personnel with a 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.
- 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.

- 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.
- Chairs and desks in direct contact with vaccine recipients should be disinfected after each use.
- An IPC section will be included in the intra-vaccination monitoring form to monitor the adherence of personnel to the required measures.
- 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 Arcenciel will support the waste management of all materials.

3.2.11 Vaccination Internal Monitoring

One supervisor will be recruited for the monitoring of the vaccination at provincial level. Monitoring will be conducted electronically using smart phones or tablets to ensure proper management and implementation of the vaccination, alignment with IPC measures and timely identification of gaps for immediate action.

3.2.12 External Communication Plan 29

Starting December 2020, MoPH started implementing an External Communication Plan. The objectives of the communication plan are to (i) Increase the trust of the population in the ability of a safe and effective vaccine to reduce disease burden, (ii) Refute the rumors and misleading information challenging the safety and effectiveness of the vaccine and (iii) Inform the population about the vaccination deployment plan including target groups, vaccination centers and vaccination timing. The communication plan will be shadowing the NCVDP as detailed below.

Phase 0: Starting December 2020

- Establish a rumor tracking system: 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 and Key advocacy messages adapted to different target groups: Involve the MoI & Risk Communication and Community Engagement (RCCE) External Communications taskforce as key partners
- Develop the crisis communication plan including:
 - Assign a team for crisis communication and a single point of contact from the eResearch Technology (ERT). ERT is a global data and technology company that minimizes uncertainty and risk in clinical trials. ERT should handle media and public statements.
 - Conduct a risk and scenario analysis.

²⁹ Idem 26

- Develop primary messages and strategic narratives for the potential scenarios including statements and internal communications.
- Develop tailored messaging for different channels such as official websites, trusted journalists, etc. and different target groups.
- Develop a media strategy: Proactive, Transparent and Accountable.

<u> Phase 1: Q1 2021</u>

- 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.

<u> Phase 2: Q2 – Q3 2021</u>

- 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 and youth advocates to increase confidence in vaccines and ensure a better understanding of the national plan

3.2.13 Community Engagement and Accountability30

MoPH is planning to conduct an Effective Community Engagement and accountability strategy to better engage the community in order to achieve long-term and sustainable outcomes based on the right of the community members to be informed, consulted, involved and empowered. Details of the community engagement plan are detailed below.

Phase 0: December-February

- Social data collection to be conducted by multiple actors and relevant ministries with respective channels and platforms. This must include behavioral 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
- Technical guidance and Questions/Answers (Q&A) is provided by the Government on vaccine characteristics, procedures, side effect, priority groups and access to vaccination
- Role of PFIZER is defined in Task Force to timely address medical and technical issues/misinformation/rumors
- Face to face community engagement can be conducted based on COVID-19 national procedures/lockdown; otherwise, virtual and inclusive community engagements will be conducted.

³⁰ Idem 26

Phase 1: Mid-February to June 2021

- Phase I Community Engagement by area: RCCE members design micro plans to launch and implement diversified community engagement activities based on social data, key messages and training.
- Train MoPH COVID-19 call center staff and frontline health workers 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 design micro plans to launch and implement diversified community engagement activities based on social data, key messages and training.
- Put in place a monitoring system to track community level refusal
- Conduct refresher trainings for priority target groups based on social and refusal data.

3.3 Baseline Information for Pfizer COVID-19 Vaccination Plan

This chapter presents the description of the existing baseline conditions relevant to Pfizer COVID-19 Vaccination Plan only. Other baseline information can be found in the parent ESMF or in the previous section of the present report.

3.3.1 Cold Chain Requirements

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 staffs 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 it arrives in Lebanon through Rafic Hariri International Airport, to their storage, distribution and vaccination administration.

Pfizer-BioNTech COVID-19 vaccine requires storage in Ultra-Low Temperature (ULT) freezers. During storage, exposure to room light should be minimized and exposure to direct sunlight and UV light should be avoided. The Pfizer vaccine shall be shipped in ULT freezing storage container. It must be thawed for 30 minutes. Once thawed, it has a 2-hour window to dilute and once diluted it shall be used within 6 hours. If the vaccination center is not equipped with an ULT freezer, the vaccine shall arrive in refrigerated cars and must be used within 5 days. When removed from the fridge, it has 2-hour window to dilute and shall be used within 6 hours.

In order to mitigate this risk of losing vaccines due to deficiency in the cold chain, PMU in MoPH in coordination with administrations of selected hospitals for vaccine roll out and under supervision of IFRC and UNICEF will be handling the proper functioning of the cold chain including monitoring the freezers temperature, out-of-range storage or out-of-range transport temperatures and ensuring the good international industry practices are being followed. PMU in MoPH will follow the good international industry practices for WHO and the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) which provides the latest information about COVID-19 and the global outbreak: www. cdc.gov/coronavirus/2019-ncov. This activity will also be monitored by the third-party monitoring (TPM) which is the International Federation of Red Cross and Red Crescent Societies IFRC that will be contracted to play the mentoring part.

3.3.2 ULT Availability in Lebanon

Between 2015 and 2017, WHO has supported the MoPH in procuring 15 ULT freezers (reaching -80°C) for 12 hospitals in Lebanon (1 public and 1 private hospital in each province). Additionally, 3 private hospitals have been identified to have ULT freezers, totalizing 15 hospitals equipped with adequate ULT cold chain in Lebanon.

Recently, UNICEF has conducted the assessment of the existing ULT at hospitals that will potentially be assigned as vaccination centers. As a result of these assessments, UNICEF confirmed the functionality of 13 freezers31 (Refer to table below) and will be assuring maintenance of all the ULT freezers prior to vaccine arrival. Based on the same source, the maintenance of the freezers stopped in 2017. However, maintenance can be done immediately at a limited cost. Regarding the spare parts that might be required, according to the same source, they are available in the local market or can be fixed locally without the need for import. The maintenance checks and resulting works can be done in 36 hours. None of the installed freezers is being monitored remotely but can be easily equipped with Wi-Fi and cameras for this end. Any vaccination center should have an alternative source of Power supply to Electricite du Liban (EDL) such as a private generator or a subscription to a collective generator. The possibility of the use of Uninterruptible Power Supply (UPS) units are also under study. A UPS can ensure a 6-hour back up time for a freezer in case of power failure.

3.3.3 Terms of vaccine distribution

Cartons of Pfizer-BioNTech COVID-19 vaccine multiple dose vials will reach Beirut Airport and will be cleared by a local handling agent in thermal containers with dry ice. They will be directly transported and distributed equally to the vaccination hospitals that have ULT freezers. Additional ULT freezers will be procured if needed. The hospitals equipped with ULT freezers will also serve as vaccination points in order to minimize the need for transporting the vaccine to other locations and hence the risk of damage to the vaccines if taken out of the ULT.

Around 2 million doses of Pfizer-BioNTech COVID-19 doses were reserved by the Lebanese Government. The schedule of arrival these doses is as per the following Table.

Timeline	No. of Pfizer-BioNTech COVID-19
Q1 2021	249,000
Q2 2021	350,000
Q3 2021	800,175
Q4 2021	699,750
Total	2.098,925

Table 10: Schedule of arrival and number of vaccines by quarter ³²

The arrival of the first 5 batches of the vaccine is as follows:

- Mid-February: 28,080 doses
- Third week of February: 31,590 doses
- First week of March: 41,120 doses
- Second Week of March: 32,760 doses
- Third Week of March: 36,270 doses

³¹ Assessment made by Engineer Makram Barakat, assigned by UNICEF

³² Idem 24

Each person needs 2 shots (2 doses) with a 3-week period before the first shot and the second one. Consequently, around one (1) million recipients will benefit from the vaccination.

It is worth mentioning that the deep freezers will not be used at the early stages of the Pfizer Vaccine deployments (Q1) as the number of does will be limited to (249,000 doses). The first batch of vaccines will be stored RHUH and distributed by cold chain to the vaccination centers where they will be consumed in five days as per protocol. Once larger amounts of vaccine start deploying starting the second quarter (Q2), the ULT available in the vaccination centers, will start being utilized. Furthermore, to ensure that the vaccine is not wasted or to limit the risk of 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.

All the equipment and materials needed for the vaccination will also be distributed to the vaccination centers. They include: (i) Syringes, (ii) Diluents, (iii) Safety boxes, (iv) Alcohol swabs, (v) Hand hygiene, (vi) Adrenaline/epinephrine and (vii) PPEs.

Proposed Hospitals assigned as vaccination centers are listed in Table 10 below.

Table 11: Proposed vaccination centers and status of their freezers³³

No.	Mohafazat	Hospital	Status of the Existing ULT Freezer	
1	Beirut	RHUH Governmental	Working in good condition	
2		Hotel Dieu de France	Unknown	
3		Saint-George (Roum)	Unknown	
4		AUBMC	Working in good condition	
5		Al Makassed Hospital		
			Working in good condition	
1	South Labanon	Saida Covernmental	Working in good condition	
2	South Lebanon	Nabatiah Covernmental Hospital (Nabih	Working in good condition	
2		Rabatien Governmental Hospital (Nabin	working in good condition	
3		Tebnin Governmental Hospital		
1	North Lebanon	Tripoli Governmental Hospital	Working in good condition	
2		Halba Governmental Hospital (Abdalla Al	0 0	
		Rassy)		
1	Mount Lebanon	Baabda University Governmental		
2		Al Bouar Governmental		
3		Daher Bashek Governmental	Working in good condition	
		Zahraa Hospital		
4		Ain W Zein	Working in good condition	
5		Al Rasoul El Azam		
1	Bekaa	Zahleh Governmental (Elias Hrawi)	Working in good condition	
2	_	Baalback Governmental meh Hospital		
	The above-listed vaccination centers will be incorporated in the first phase of			

be above-listed vaccination centers will be incorporated in the first phase of the National COVID19 Vaccination Deployment Plan (NCVDP). They will increase gradually throughout the vaccination process as per the NCVDP. The latter is a living document which is subject to modification and will be amended and adapted as the context demands. The NCVDP can be found on the MoPH website (moph.gov.lb), and can be accessed through the following <u>link</u>.3.3.4 Process of Vaccination

Surge teams of physician, trained vaccinator nurse, registered nurse and administrative clerk/data operator will be supporting vaccination activities in each of the hospitals. The vaccinator will be a Bachelor of Science in Nursing (BSN) meeting the following criteria:

- Basic Life Support in American Heart Association (AH) certified centers (2 yearly re certification)
- o Anaphylaxis Training & Anaphylaxis Refresher (every two years)
- o Immunization Study Day at least once
- o Immunization updates (Half day two yearly min)

Prior to administering the vaccine, administrative clerk/data entry will thoroughly explain the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine and the recipient will have to either sign a hard copy consent form to be uploaded to the database or electronically sign the consent form if applicable.

³³ Idem 24

Following dilution, each vial contains 6 doses. Vaccination of 1 individual is estimated to take 10 minutes 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.

3.3.5 Standard Operating Procedures (SOP) and Training

There are Standard Operating Procedures (SOP) for each center. They entail operating procedures for cleaning, infection control, garbage collection, and so on. In the meantime, mock trainings are being conducted (with the help of Pfizer) to teach the vaccinators on administrating the vaccine, and to study the time consumed in each vaccination. (Refer to Annex E for COVID-10 Vaccine Training Report).

Standard Operating Procedure for COVID-19 Immunization developed by the Primary Healthcare Department at the MoPH for Pfizer COVID-19 Vaccines are provided in Annex F).

4- Institutional Framework for Environmental and Social Management

The Institutions listed in the parent ESMF mainly (i) The Ministry of Public Health (MoPH), (ii) The Ministry of Environment (MoE), (iii) the Ministry of Interior and Municipalities (MoIM), and the UN Agencies (WHO, UNICEF and UNHCR) and their relevant responsibilities still apply.

This section of the present report describes the additional responsibilities of the institutions mentioned in the parent ESMF and of the new institutions that will be involved in the implementation of Component 4 and the Pfizer Vaccination under said Component.

Ministry of Public Health (MoPH)

The MoPH supervises and monitors all the activities under Component 4. MoPH will:

- Monitor the good implementation of Component 4
- Carry out procurement agreements with UN agencies
- Contract additional health workers and build their capacities
- Prepare for regulatory approval, market authorization and post-market surveillance of COVID-19 products (e.g. laboratory diagnostics, therapeutics, vaccines), when available
- Implement a plan for monitoring health personnel exposed to confirmed COVID-19 cases for respiratory illness and for reporting healthcare-associated infections
- Dedicate communication staff to raise awareness on the risk of contamination and community engagement and to disseminate national case definitions for surveillance to the public and private health sectors and communicate changes when needed.
- Implement surveillance strategies to monitor and report disease trends, disease severity and impacts on health and other systems
- Maintain, monitor, and develop the call center that was established at MoPH

The MoPH supervises and monitors all the activities under Pfizer Vaccination:

- Coordinate and follow up with the NVCC and the proper implementation of the NCVDP
- Monitor the good implementation of the vaccination
- Carry out procurement agreements with UN agencies and the WB
- Assign health workers and build their capacities in vaccination, contract new staff if needed
- Maintain, monitor, and develop a grievance redress mechanisms and hotline dedicated to COVID-19 vaccine at MoPH

The Ministry of Information (MoI)

The Ministry of Information (MoI) plays a crucial role in being part of the COVID-19 Vaccination committee. The MoI is working in close coordination with the NCVC committee and the MoPH to handle the communication activities. The MoI is being assisted by UNICEF to put a communication strategy.

The Ministry of Interior and Municipalities (MoIM)

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. The Internal Security Forces (ISF), the General Security Forces (GSF) and the State Security Forces (SSF), in coordination with the Ministry of Public Health (MoPH), will also be responsible for assuring the safety of personnel and patients and provide security at the facilities where vaccines will be deployed as and when required. They will also contribute in organizing the citizens entrance and exit if necessary. The Municipalities will be involved in selecting the elderly eligible to vaccination.

UN Agencies (WB, WHO, UNICEF, UNRWA and UNHCR)

Considering the limitations in the supply chain of required medical goods, the global involvement of relevant UN Agencies (i.e.) in the procurement and distribution of these goods, the procurement plan will be agreed upon between the MoPH and the UN Agencies. They will also:

- Provide technical support to the MoPH
- Coordinate awareness raising activities
- Help assessing the requirements of the cold chain

WORLD BANK

• The WB, under its current Lebanon Health Resilience Project, is expected to finance COVID-19 vaccines procurement and deployment.

WHO will be providing:

- Technical support for vaccine introduction and deployment, including strategies, vaccine safety issues, development guidelines, conducting of training on AEFI surveillance for COVID-19 vaccine-related issue, and other issues of vaccine pharmacovigilance
- Support in procurement (syringes, swabs, safety boxes) and 6 new ULT freezers

UNICEF will be:

- 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, maintenance and monitoring
- Procurement of consumable items required for the vaccination process
- Contracting with Arcenciel 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.

UNRWA will be:

- Supporting MOPH for the delivery of COVID-19 vaccines to displaced and refugee population
- Providing the services of 44 nurses to be trained and be deployed in vaccination centers if needed.
- Helping fundraise to get additional vaccine doses for refugees in Lebanon

UNHCR will be:

- Supporting MOPH for the delivery of COVID-19 vaccines to displaced and refugee population
- Help fundraise to get additional vaccine doses for refugees in Lebanon

Stakeholders Consultations relevant to Component 4

5.1 Objectives and limitations

In accordance with WB policies, stakeholder's consultation was conducted during the preparation of the ESMF for the parent project and was requested for the COVID-19 Vaccination Plan under Component 4 of the restructured LHRP.

Since February 29, 2020 till date, the MoIM took several measures in the intention to slow the spread of the disease by limiting people's movement and exposure to crowded environments where the disease can easily be spread from one carrier to many other people nearby. On January 14, 2021 the MoIM imposed a strict full lockdown in Lebanon till January 25, 2021. The lockdown was extended to February 8, 2021. These measures also limit the Project's ability to use traditional methods of public consultations and stakeholder engagement.

In line with the above mentioned national restriction and the available resources for carrying out stakeholder engagement in the context of COVID-19 and the WB's **"Technical Note: Public Consultations and Stakeholder Engagement in WB-supported operations when there are constraints on conducting public meetings"** (March 20, 2020), the project will avoid public gatherings and minimize physical interaction between people. (Refer to Annex G).

5.2 Stakeholders Consultation Process

5.2.1 Stakeholder Consultations Conducted During First Restructuring

In order to fulfill the WB requirements, and as per the national restrictions, public gathering was avoided and consultations were done virtually as per the following steps:

- The draft of the addendum to the ESMF for restructured LHRP was distributed in a digital form 1. to stakeholders on May 11, 2020 through the National Infectious Disease Committee at MoPH that includes representatives from academic institutions in Lebanon such as the American University of Beirut (AUB) and its associated Medical Center, the Lebanese American University (LAU) and its associated Rizk Hospital, the Lebanese University (LU), Saint Joseph University and its associated HDF Hospital, the Lebanese Order of Physicians, the Lebanese Pediatric Society and to the World Health Organisation (WHO). The addendum to the ESMF was also distributed on May 28, 2020 to the national COVID 19 committee at the Presidency of the Council of Ministers that includes many Ministries and Institutions, to the representative of MoE at the Chemical Biological Radio Nuclear Program (CBRN Program) and to licensed institutions managing medical waste treatment facilities (Arcenciel and Abbassiyeh Municipality/SAFE). The stakeholders were informed about the Grievance Redress Mechanism (GRM) and they were given 10 days to email back their response. The following email address aberry@gmail.com and elham.em.moph@gmail.com the following phone number 01- 843769 were provided to the stakeholders in order for them to give their feedback and suggestions if they wish to do so.
- 2. Also, virtual meetings were held on March 19, 2020 and June 8, 2020 with MoPH Key staff and the WB Safeguard Team.
- 3. Feedback was received only from the representative of MoE at the Chemical Biological Radio Nuclear Program (CBRN Program).

After COVID-19 restrictions are lifted, face to face consultations will be conducted and the addendum to ESMF will be updated and then disclosed again.

Date	Stakeholder	Contacted Person	
May 11	National Infectious	Dr Walid Ammar (Director General of the MoPH)	
	Disease Committee	Dr Rasha Hamra (Head of Health Education Department at MoPH)	
		Ms Hilda Harb (Head of Statistics Department at MoPH)	
		Dr Iman Shankiti (WHO Representative to Lebanon) <shankitii@who.int>,</shankitii@who.int>	
		Dr Alissar Rady (Senior Officer at WHO) <radya@who.int></radya@who.int>	
May 28	National COVID-19 Committee	Dr. Jacques Mokhbat (Chairman of Internal Medicine Department at LAU) <jacques.mokhbat@gmail.com>,</jacques.mokhbat@gmail.com>	
		Dr.Abdul Rahman Bizri (AUB) <ab00@aub.edu.lb>,</ab00@aub.edu.lb>	
		Dr. Wafaa Jurayi (AUB) <drijreige@hotmail.com>,</drijreige@hotmail.com>	
		Dr. Nada Melhem (AUB) <melhemn@aub.edu.lb>,</melhemn@aub.edu.lb>	
		Dr. joseph rachkidi <rachkidi@yahoo.fr>,</rachkidi@yahoo.fr>	
Dr.Nada Ghosn (MoPH, LU, Bala <esumohleb@gmail.com>, Dr. Pierre AbiHanna (RHUH) be</esumohleb@gmail.com>		Dr.Nada Ghosn (MoPH, LU, Balamand University) <esumohleb@gmail.com>,</esumohleb@gmail.com>	
		Dr. Pierre AbiHanna (RHUH) <boutrosh@hotmail.com>,</boutrosh@hotmail.com>	
		Nadine Yared (AUB) <nay04@mail.aub.edu>,</nay04@mail.aub.edu>	
		Dr. Jacques choucair (USJ/HDF) <jacqueschoucair@hotmail.com>,</jacqueschoucair@hotmail.com>	
Representative of MoE at CBRN National			
	Committee	Ms. Viviane Sassine (for unofficial review) <v.sassine@moe.gov.lb></v.sassine@moe.gov.lb>	
	Arcenciel	M. Robin Richa (CEO) < <u>robin.richa@arcenciel.org</u> >	
	Municipality of Abbasiyeh/SAFE	Ms. Leyla Farhat (Head of Projects) <head.projects1@miragewm.com></head.projects1@miragewm.com>	

Table 12: Stakeholders Consulted

The main comments provided:

Comments were received from Ms. Viviane Sassine only. They can be summarized as follows:

- 1. The discharge of hospital effluents directly in the municipal sewer network without any prior treatment is not accepted. However, MoPH responded that a prior treatment of the hospital effluents is desirable but such an intervention is beyond the scope of the Project in terms of time and budget.
- 2. It has been confirmed the proposed treatment methods by the waste operators serving the Project beneficiary hospitals are using treatment methods complying with the requirements of Decree 1338/2004.
- 3. There were comments on the waste management and they were addressed in the ESMF addendum.
- 4. There were some editorial comments that have been taken into consideration in the ESMF addendum.

5.2.2 Stakeholder Consultations Conducted During Second Restructuring – Vaccination Plan

Another round of consultation took place also specifically on the COVID-19 vaccination. It was conducted in a transparent, inclusive, and systematic manner to ensure clear and widespread communication of the logistics of the deployment and the eligibility criteria for the priority persons and the COVID-19 vaccine deployment associated environmental and social risks, impacts and mitigation measures. Consultation included vulnerable groups of potential beneficiaries (such as female and elderly refugees, persons with disabilities or underlying medical conditions). In order to fulfill the WB requirements, and as per the national restrictions, public gathering was avoided and a virtual consultation session was held instead following the guidance of the World Bank's technical note on conducting consultations during times of constraints like COVID-19. Key messages included the following:

- Voluntary basis (no coercion) of the deployment program
- Inclusive and non-discriminatory nature of the deployment program
- Mobilization of the security forces to provide security at the facilities where vaccines will be deployed
- Phasing of the deployment and location of the vaccination facilities
- The potential environmental and health risks
- 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 anonymity and confidentiality where required
- The availability of the GRM to capture community feedback on COVID19 vaccination

Consultations were conducted virtually as per the following steps:

- 4. Virtual meetings were held on January 18, 2021 and January 21, 2021 with MoPH Key staff and the WB Safeguard Team to discuss main issues to be tackled in the revision to the addendum to the ESMF.
- 5. A meeting was held with Dr. Abdul Rahman Bizri on January 20, 2021 to discuss the work of the NCVC and the main sections of the revised addendum to the ESMF.

A wider stakeholders consultation session was also organized as per the following steps:

- 4. An invitation was sent to stakeholders on January 29, 2021 followed by the executive summary of the updated addendum to the parent ESMF tackling COVID-19 Vaccine and the agenda of the consultation session.
- 5. The updated addendum to the parent ESMF was discussed on February 5, 2021 in a virtual meeting. The stakeholders were informed about the vaccine deployment associated environmental and social impacts and mitigation measures and the project Grievance Redress Mechanism (GRM). The following email address aberry@gmail.com, elham.em.moph@gmail. and info@moph.gov.lb and the following phone number 01- 830300 ext. (440) and (274) were provided to the stakeholders in order for them to give their feedback and suggestions if they wish to do so. .
- 6. A total of 19 participants attended the consultation session held on February 5, 2021 out of which there were 11 were women attendees including the WB and MoPH staff. The list of participants is included in Table 12 and a screenshot of the attendees can be found in Figure 1.

The following questions and comments were raised:

Table 13: Comments raised during the stakeholder consultation on 5 February 2021

Participants	Comments raised and answers provided by MoPH
ARCENCIEL (Environmental NGO)	Mr. Mario Goraieb, representative of Arcenciel, shared his concern that nine hospitals do not have contracts with Arcenciel and asked if these hospitals shall be designated as vaccination centers. Mr. Goraieb will be sharing a list with MoPH containing all healthcare facilities contracted with Arcenciel to ensure that all facilities chosen as vaccination sites have established a proper Health Care Waste Management Plan (HCWMP). Then UNICEF will be contracting Arcenciel for waste management.
Lebanese Union of People with Disabilities	Mr. Mohammad Loutfi, Representative of Lebanese Union of People with Disabilities, expressed his interest in being part of the consultations and in providing any support needed to include people with disabilities in the vaccination and taking part in the successful deployment of the vaccine. They also raised the issue that all vaccination centers were not well equipped to receive people with disabilities and wanted to make sure staff will be well trained to deal with people with disabilities. MoPH confirmed that all the requests are taken into consideration and that the Red cross will be handling the vaccination at home or transporting them in case the person is not able to move to the vaccination centers.
WHO	Dr. Nohal Al Homsi assured all attendees that they will be coordinating with MoPH on the issue of disability and provide any support needed for this issue. They also agree that Arcenciel has a long history of medical waste management in the Country in terms of collection and disposal and asked about the management of the health care waste inside the vaccination centers. MoPH confirmed that any vaccination center should have a HCMP approved by Arcenciel and the PMU before being assigned as vaccination center. WHO asked also if there will be a monitoring committee or a third party monitoring entity and they will have environmental specialists. MoPH confirmed that a TPMA will be handling all the vaccination process including the environmental and social safeguards and that the Ministry of Environment (MoE) is a major stakeholder and partner in the COVID-19 vaccination committee. MoPH will share the NCVDP with WHO and all stakeholders.
UNICEF	Dr. Genevieve Begkoyian, UNICEF representative inquired about whether it was the right choice to choose hospitals as vaccination centers given the possibility that there might be infectious areas since Covid patients are getting admitted into the hospitals. The MoPH assured UNICEF that they have provided the hospitals with Standard Operating Procedures so that all infection prevention measures are respected at all times to ensure the safety of healthcare providers and vaccine recipients in hospitals. In addition to the IPC measures that should be strictly applied during vaccinations. UNICEF has provided their services in covering the technical consultations, maintenance, and monitoring of the cold chain. UNICEF also raised the issue of the potential for SEA/SH and if the healthcare workers will be trained to deal with the reporting of SEA/H,. MoPH confirmed that the training is a mitigation that is recommended in the ESMF. UNICEF also asked if IPCs are part of the framework and MoPH confirmed that they are. Farah Mazloum, UNICEF representative, stressed on the importance of the reporting on sexual abuse and harassment. MoPH explained that the mitigation measures are clearly reflected in the revision to the addendum to the ESMF document.
The Order of Nurses and Assistant Dean of School of Nursing in the Lebanese American University (LAU)	Dr. Myrna Abi Abdalla Doumit, Order of Nurses representative, and Assistant Dean of School of Nursing in the Lebanese American University, asked if the nurses will be compensated for the additional hours they will be working on the vaccination deployment. MoPH replied that they will not be paid by the LHRP but by the vaccination centers where they are employed. LHRP will not allocate payment for the nurses. The Order of Nurses representative also stated that the nursing workforce is not very enthused about the vaccination deployment due to news being circulated on broadcasting networks regarding people with or against vaccines and further asked if the committee will be using media and a communications campaign to speak the peoples' language to explain to them the importance of vaccination since there are inaccurate ideas being circulated into the communities. MoPH confirmed that there will be a proactive communication campaign tackling the need for vaccination and that it will be supported by UNICEF. MoPH further explained that the Ministry is currently working with the Ministry of Information in this regard. WHO confirmed that they are also working on this issue together with colleagues

	from UNHCR. MoPH stated that this issue applies also to the need to communicate with doctors since results of a survey recently carried out in December 2020, showed that more than 50% of healthcare workers are refusing to get vaccinated. There will be a need to work on a communication and media campaign to educate and inform people that the COVID19 vaccine is the only way to get rid of this pandemic – the MoPH is working on complete plan that will be released very soon
UNICEF	Asked what are the next steps and what is needed. MoPH explained that the ESMF will be disclosed soon and that MoPH will be contacting UNICEF and WHO and organizing technical meetings with them to follow up on the NCVDP.

Below is a list of the stakeholders consulted on the vaccination deployment.

Table 14: Stakeholders Consulted specifically on the vaccination deployment

Stakeholder	Contact Person	Email address
WHO (Lebanon office)	Nohal Al Homsi,	alhomsin@who.int
UNICEF	Yasmine Ibrahim (Health Officer)	yasibrahim@unicef.org
UNICEF	Dr Genevieve Begkoyian	gbegkoyian@unicef.org
UNICEF	Farah Mazloum	fmazloum@unicef.org
UNICEF	Musonda Kasonde	mkasonde@unicef.org
UNHCR	Asaad Kadhum	Kadhum(a)unhcr.org
Order of Nurses and Academia	Myrna Abi Abdallah Doumit	myrna.doumit@gmail.com
Arcenciel – Medical Waste	Mario Goraieb	mario.goraieb@arcenciel.org
Abaad (Gender; SEA/SH)	Mohamad Mansour LHDF	mohamad.mansour@abaadmena.org
LUPD (Lebanese Union of Persons with Physical Disabilities)	Mohammed Ali Loutfy	loutfy.lphu@gmail.com
Arab Watch Coalition	Ouafa Haddioui	ouafa@arabwatchcoalition.org
Arab Watch Coalition	Achraf Berra	achraf@arabwatchcoalition.org
MoPH	Dr. Atika Berry	aberrymd@gmail.com
MoPH	Elham El Mais	elham.em.moph@gmail.com
MoPH	Edmond Abboud	abbouded@gmail.com
World Bank	Rim Atoui	ratoui@worldbank.org
World Bank	Noushig Kaloustian	nkaloustian@worldbank.org
Word Bank	Ahmed Hassoon Ali Al Saedi	aalsaedi@worldbank.org
World Bank	Linda Khalil	lindaslim@hotmail.com

Municipalities, Orders of Physicians, UNRWA (Refugees), Order of Dentists, Order of Pharmacists, Military Medicine, Lebanese Internal Security Forces, Lebanese General Security, Lebanese State Security, Lebanese Red Cross, Lebanese Society of Bacterial Diseases, Ministry of Environment, Justice Without Frontiers (Gender, Sexual Exploitation and Abuse and Harassment), MSF (Médecins sans Frontières), Beit el Baraka (Elderly), Ajialouna (Elderly), Kibarouna (Elderly), SOS (Children), SESOBEL (People with disabilities), Kafa (Gender)were invited but did not attend. World Bank staff were present as silent observers.

After COVID-19 restrictions are lifted, face to face consultations will be conducted with all relevant stakeholders including internal security forces. The addendum to the ESMF will be updated and disclosed accordingly.

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Figure 1. Virtual Stakeholder Consultation on WebEx

6- Environmental and Social Analysis of Component 4

All measures provided in the parent ESMF for the LHRP project apply. The following section outlines the additional environmental and social risks associated with Component 4 and recommends the respective mitigation measures (addendum) that might be required to avoid negative impacts on the social and environmental aspects caused by Component 4. Given the nature of this corona virus, exposure to infection and diseases should be given special attention. For this end, section 10 "Health Care Waste Management Plan" of the ESMF should reflect the WHO interim guidance on Infection Prevention and Control during health care when novel coronavirus (nCOV) infection is suspected (January 25, 2020). IPC strategies should be enhanced to prevent or limit transmission inside and outside of the healthcare.

6.1 Using environmental and engineering control

These controls cover the basic infrastructure of the health care facility. The aim being to ensure the HC facility is using effective and sufficient measures to prevent and control infection within its premises and the environment.

6.1.1 Establishment and equipping quarantine and treatment centers

The facility should ensure triage for assessing all patients at admission allowing early recognition of possible COVID-19 infection and immediate isolation of patients with suspected COVID-19 infection in an area separate from other patients (source control). This activity entails preparation of existing spaces for receiving individuals with suspected/confirmed COVID-19. It does not include large civil works but only minor works and scaling up the facility. Engineering controls includes the installation of physical barriers or partitions in triage areas to guide patients, curtains separating patients in semi-private areas. A separation of at least 1 meter should be maintained between all patients³⁴. This activity should also consider Airborne Infection Isolation Rooms (AIIRs) with proper ventilation or if AIIRs are not available, isolation of the patient in a private room and equipping of room for aerosol-generating procedures with proper ventilation.

Isolation tents or other portable containment structures may serve as alternative patientplacement facilities when AIIRs are not available and/or examination room space is limited. However, the responsible person/entity must ensure that the room air exhausts directly to the outside, or passes through proper filters, if recirculated.³⁵. For general ward rooms with natural ventilation, adequate ventilation is considered to be 60 l/s per patient. For aerosol-generating procedures, natural ventilation with air flow shall be at least 160 l/s per patient. Negative pressure rooms should have at least 12 air changes per hour and a controlled direction of air flow when using mechanical ventilation.³⁶

Engineers can support emergency planning by understanding the design, operations, and maintenance adequacy of buildings for which they are responsible and helping emergency planners mitigate vulnerabilities or develop interventions. For instance, there may be means to increase dilution ventilation, increase relative humidity, or quickly apply upper room Ultraviolet Germicidal Irradiation (UVGI) in an emergency room, and crowded rooms. In other situations, reducing ventilation or creating pressure differentials may be the appropriate strategy. ³⁷

³⁴ WHO, Infection prevention and control during health care when novel coronavirus (nCOV) infection is suspected, Interim guidance (25 January 2020)

³⁵ Operational Safety and Health Administration - https://www.osha.gov/SLTC/mers/control_prevention.html ³⁶ Idem 18

³⁷ ASHRAE Position Document on Airborne Infectious Diseases, Approved by ASHRAE Board of Directors Reaffirmed by Technology Council February 5, 2020 - Expires August 5, 2020 - available online - www.ashrae.org

As directed by the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), when a new outbreak occurs and is caused by a microorganism that spreads by the airborne route, fast action affecting building operations will be needed. Accordingly, MoPH directed hospitals that have central air conditioning to undergo a separation procedure and this activity is being implemented. Other hospitals that have independent air conditioning for Corona units have negative pressure rooms equipped with HEPA filters³⁸. MoPH confirms that actions have already been thoughtfully undertaken in all the hospitals that will receive COVID-19 patients in collaboration with infection control professionals and based on knowledge of the system and its operation and the nature and source of the threat from MoPH budget ³⁹. If a facility would need to introduce the measures under this section, the associated environmental and social risks and correspondent mitigation measures are detailed in the original ESMF for the LHRP before its restructuring, in Section 8 entitled "Environmental and Social Analysis of the proposed Project".

6.1.2 Fire Safety

In accordance with WBG EHS guidelines, the hospitals should be equipped with fire detectors, alarm systems, and fire-fighting equipment. The equipment should be maintained in good working order and be readily accessible. It should also be adequate for the dimensions and use of the premises, equipment installed, physical and chemical properties of substances present, and the maximum number of people present. The hospital shall be provided with manual firefighting equipment that is easily accessible and simple to use. Fire and emergency alarm systems shall be installed and shall be both audible and visible.

According to the MoPH, all the hospitals that will receive funds from LHRP have fire detectors, alarm systems and fire-fighting equipment adequately placed and sized. This as a pre-requisite for the acquisition of construction and other relevant permits.⁴⁰

6.1.3 Wastewater Discharges

There is no evidence to date that the COVID-19 virus has been transmitted via sewerage systems with or without wastewater treatment ⁴¹.

According to MoPH all the HC institutions that will receive funds from LHRP are connected to a municipal wastewater network as a pre-requisite condition to get their construction permit⁴². As part of an integrated public health policy, wastewater carried in sewerage systems should be treated in well-designed and well-managed centralized wastewater treatment plants. Each stage of treatment (as well as retention time and dilution) results in a further reduction of the potential risk.

Regarding WWTPs workers, there is no evidence to suggest that additional, COVID 19-specific protections are needed. Furthermore, there is no evidence that sewage or wastewater treatment workers contracted severe acute respiratory syndrome (SARS), which is caused by another type of coronavirus that caused a large outbreak of acute respiratory illness in 2003 ⁴³. Wastewater treatment plant operations, should continue to follow routine practices that prevent exposure to

³⁸ Personal Communication with Dr. Attika Berry (MoPH) on March 27, 2020

³⁹ Idem 36

⁴⁰ Idem 36

⁴¹ WHO-UNICEF, Water, sanitation, hygiene and waste management for the COVID-19 virus, Technical brief, dated March 3, 2020

⁴² Idem 36

⁴³ Idem 39

wastewater, including using the engineering and administrative controls, safe work practices, and PPE normally required for work tasks when handling untreated wastewater.⁴⁴

6.2 Applying standard and special precautions in OHS

The ESMF for the LHRP sets that any PHCC or Hospital, to be eligible to receive funds from LHRP, should have an ESMP including a Health Care Waste Management Plan (HCWMP). This is a condition that is made part of the contract between the health institution and the MoPH before any disbursement of funds. The HCWMP includes a section on Personnel Protection ensuring the personnel is well informed, wears protective equipment, waste workers are duly immunized, establishing a training for personnel protection and a plan for the provision of protective equipment.

Given the nature of COVID-19, in addition to the Personnel Protection established in the Health Care Waste Management Plan, MoPH needs to make sure the ESMP including the HCWMP comprises a section on use of proper PPE when health workers are exposed to a patient with confirmed/suspected COVID-19 or other sources of COVID-19. The HC facility shall be implementing additional precautions for suspected cases such as contact and droplet and airborne precautions for aerosol-generating procedures, in accordance with WHO guidelines.

It is recommended that this section states clearly that when novel coronavirus (nCOV) infection is suspected, healthcare workers shall wear:

- Gowns: single use, long sleeves, fiber made non-woven, thumb loop, tape tab for neck closure, water and liquids proof, compliant with the EN 13795 high performance level, or AAMI level 3 performance or equivalent. If there are shortages of gowns, they should be prioritized for aerosol-generating procedures, care activities where splashes and sprays are anticipated, and high-contact patient care activities that provide opportunities for transfer of pathogens to the hands and clothing of HCP.
- Disposable respirators compliant with NIOSH N95 or EN 149 FFFP2 and fluid resistant or better respirators. Based on local and regional situational analysis of PPE supplies, facemasks are an acceptable alternative when the supply chain of respirators cannot meet the demand. Those masks should be 3 ply surgical face mask, compliant with EN 14683 type IIR or ASTM F2100 level 2 or level 3 or equivalent. Then, during this time, available respirators (which filter inspired air, offer respiratory protection) should be prioritized for procedures that are likely to generate respiratory aerosols, which would pose the highest exposure risk to Health Care Practitioner (HCP).
- Eye/face protection (e.g., goggles, face shield) that protect the wearer from splashes and sprays compliant with EU standard directive 86/686/EEC, EN 166/2002 or ANSI/ISEA Z87.1-2010 or equivalent
- Latex Gloves, powder free, hypo allergic, tear resistant, sterile and for single use.

In some particular cases, there might be a need for:

- Disposable coverall. Those should be compliant with EN 943-1:2002 such TYVEK or equivalent
- Cover shoes for TYVEK coverall or equivalent (closed, impermeable, length to below knee, washable and disinfected if reusable

Note that all these PPEs will be procured under the WB Loan.45

6.3 Safe Waste Management

Generally, management of waste that is suspected or known to contain or be contaminated with COVID-19 does not require special precautions beyond those already used to protect workers from the hazards they encounter during their routine job tasks in solid waste. Workers and employers should manage solid

⁴⁴ Ref.: Centers for Disease Control and Prevention -https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html

⁴⁵ Personal Communication with Dr. Attika Berry (MoPH) on March 27, 2020

waste contaminated with COVID-19 as they would other regulated medical waste as detailed in section 10 "The Health Care Waste Management Plan" of the ESMF. Hospitals shall use typical engineering and administrative controls, safe work practices, and PPE, such as puncture-resistant gloves and face/eye protection, to prevent worker's exposure to medical waste, including sharps and other items that can cause injuries or exposures to infectious materials ⁴⁶.

According to the MoPH, all the hospitals that will receive funds under the WB Project have already a Health care Waste Management Plan and have contracted one of the companies that handles medical waste in Lebanon (Abbasiyeh Municipality/SAFE or Arcenciel)⁴⁷. Both institutions confirmed in previous communications that they were capable of handling additional loads.

Arcenciel (that handles 85% of the medical waste treatment in Lebanon) has equipped one of its medical waste treatment centers with a microwave machine instead of autoclaving. This technology permits a continuous flow, reducing the need for storage and requires less operators. Currently, Arcenciel has the capacity of handling 23 t/day of infectious medical waste. During March 2020, the total quantity of COVID-19 related infectious waste received was 20.5 t, averaging 1.2 t/day, the bulk of 17 t being from RHUH. Furthermore, due to the current spread of the corona virus, all other non-urgent operation were put on hold, consequently, on average, the total daily quantity of infectious waste received remained almost constant comparing to previous months⁴⁸. Arcenciel has also increased its fleet by 2 trucks.

6.4 Implementing administrative controls

MoPH started implementing measures and imposing on HC facilities to implement administrative controls for the prevention and control of transmission of COVID-19 infections such as (i) provision of adequate training for HCW, (ii) ensuring an adequate patient-to staff ratio, (iii)establishing a surveillance process for acute respiratory infections potentially caused by COVID-19 among HCW, (iv) ensuring that HCWs and the public understand the importance of promptly seeking medical care and (v) monitoring HCW compliance with standard precautions and providing mechanisms for improvement as needed.

6.5 Emergency Preparedness and Response plan

In line with WHO guidelines⁴⁹ the MoPH prepared the Coronavirus Disease 2019 (COVID-2019) National Health Strategic Preparedness and Response Plan that was published on the MoPH's website on March 13, 2020.⁵⁰

This document was developed to establish a national plan of action to scale up preparedness and response capacities in Lebanon for prevention, early detection, and rapid response to coronavirus disease 2019 (COVID-2019) as required under the International Health Regulations (IHR 2005) using the WHO global 2019 Novel Coronavirus Strategic Preparedness and Response Plan as the foundation. This plan includes an Infection Prevention and Control section. (See Annex A).

6.6 Preventing Sexual Exploitation and Abuse and Harassment

The Project should focus on putting in place the following, minimum set of measures to prevent Sexual Exploitation and Abuse and (sexual) Harassment (SEA/H)⁵¹ to be reflected in the ESMF.

⁴⁶ United States Department of Labor Occupational Safety and Health

Adminstrationhttps://www.osha.gov/SLTC/covid-19/controlprevention.html #solidwaste

⁴⁷ Personal Communication with Dr. Attika Berry (MoPH) on March 27, 2020

⁴⁸ Personal Communication with Mario Ghoraeib (Head of the Environmental Program at Arcenciel) on April 3, 2020.

⁴⁹ WHO, Critical preparedness, readiness and response actions for COVID-19, Interim guidance, 7 March 2020.
⁵⁰ Available on

https://www.moph.gov.lb/userfiles/files/News/Leb%20nCoV%20Strategic%20Response%20Plan%20MARCH% 202020-converted.pdf

- Staff in PMT will sign Codes of Conduct.
- Publicly post or otherwise disseminate messages clearly prohibiting SEA/SH during the provision of health care, whether healthcare providers are perpetrators or survivors.
- Make information available to health service providers on where Gender Based Violence (GBV) psychosocial support and emergency medical services can be accessed (within the health system).
- Promote two-way communication between health authorities and communities that would allow information on instances of SEA/H to surface and inform strengthening of SEA/H measures as needed.
- This could include the development of additional rapid guidance on how to deal with SEA/H complaints in operations with existing GRMs or using hotlines.

All measures provided in the parent ESMF and in the above section shall be applied. The following section analyses the additional environmental, health and social risks and related mitigation measures that might be required in order to avoid negative impacts caused by COVID-19 Vaccination under Component 4.

6.7 Preventing Risks to Health Workers

As stated above, the ESMF for the LHRP sets that any PHCC or Hospital, to be eligible to receive funds from LHRP, should have an ESMP including a Health Care Waste Management Plan (HCWMP). This is a condition that is made part of the contract between the health institution and the MoPH before any disbursement of funds.

The occupational health and safety standards as recommended by WHO for the vaccination teams in direct contact with vaccine recipients will be applied. The following disinfectants and PPEs are required. It is to be noted that the required PPE will depend on the position and duties of team members:

- Two (2) hand sanitizers should be available at the vaccination site daily: 1 for personnel use and 1 for vaccine recipient use.
- One (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).

6.8 Preventing Risks due to the unsafe management of medical waste

Generally, management of waste in the vaccination center is not suspected to contain or be contaminated with COVID-19 and does not require special precautions beyond those already used to protect workers from the hazards they encounter during their routine job tasks in medical solid waste. Workers and employers should manage solid waste generated from vaccination as they would manage other hazard medical waste as detailed in section 10 "The Health Care Waste Management Plan" of the parent ESMF.

⁵¹ WB, Technical Note on SEA/H for HNP COVID Response Operations

Arcenciel an NGO that handles the medical wastes for most of the Health Care Centers and Hospitals in Lebanon and who has an active contract with around 80% of healthcare facilities in Lebanon. According to the NCVDP, it is estimated that each vaccination center will conduct around 400 vaccinations per day. Arcenciel⁵² confirmed its capacity to collect and handle the additional quantities that will be generated by the vaccination centers.

6.9 Preventing Risks due to the poor maintenance of the cold chain

In order to mitigate this risk of losing vaccines due to deficiency in the cold chain, PMU in MoPH in coordination with administrations of selected hospitals for vaccine roll out and under supervision of IFRC and UNICEF will be handling the proper functioning of the cold chain including monitoring the freezers temperature, out-of-range storage or out-of-range transport temperatures and ensuring the good international industry practices are being followed. PMU in MoPH will follow the good international industry practices for WHO and the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) which provides the latest information about COVID-19 and the global outbreak: www. cdc.gov/coronavirus/2019-ncov. This activity will also be monitored by the third-party monitoring (TPM) which is the International Federation of Red Cross and Red Crescent Societies IFRC that will be contracted to play the mentoring part. The following actions/corrective procedures shall be ensured:

- Follow up and assurance of the conditions that must be met in the cold chain before storing the vaccine. The cold chain equipment must be calibrated, clean, and operating with high efficiency and need to be fully functional at least 48 hours before the expected vaccine arrival date. Ensure that cold chain temperatures are monitored periodically and daily; where possible, by electronic data loggers. Temperature monitoring devices and a mechanism for continuous temperature monitoring throughout the supply chain from receipt, during storage and delivery to the vaccination point;
- Perform effective and routine maintenance of the ULT and Low Temperature (LT) equipment
- Identify the location and availability of dry ice for emergency purposes or in case there is a need for transporting the vaccine;
- Ensure the presence of an additional back-up generator in case of power cut or UPS in order to maintain the temperature for a period of not less than 24 hours until the electrical current is restored or repaired.
- Estimate the storage capacity of each unit of cold chain equipment and matching it to the expected quantity to be received.
- All above actions should be done by hospitals administrations under supervision of MoPH PMU, IFRC and UNICEF.

6.10 Preventing Risks due to the poor management of the vaccine stock

In order to mitigate the risk of losing the vaccines due to bad stock management, the MOPH PMU in coordinating with the selected hospitals administrations will work to ensure the followings:

- Ensure all vaccines are carried in specialized vaccine carriers with temperatures according to the manufacturers' instruction and transported only by authorized refrigerated vehicles specially equipped for this purpose that in line with WHO guidelines and Pfizer COVID-19 vaccine preservations instructions.
- Conduct a physical examination of the received vaccines for quality control purposes, ensuring the absence of damages, a leakage and presence of a sticker with basic information (such as the type of vaccine, expiry date, manufacturing batch number) and other quality control parameters.
- Make sure the vaccine is stored in the appropriate cold chain condition and according to the appropriate temperature, as soon as it is received.

⁵² Communication with Mr. Mario Ghoreib Manager at Arcenciel on January 27, 2021.

- Arrange the vaccines inside the cold chains according to First to Expire First Out (FEFO). Put the vaccines in the correct vaccine refrigerator without delay with the shortest dated foremost to ensure adequate stock rotation.
- Make sure Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) vials remain upright at all times.
- Report the volumes, doses and ancillary items received and used on an information system to facilitate managing, tracking and reporting on the vaccine stocks and consumption effectively and follow up on expiry dates.
- Perform a daily count post vaccination
- Prepare a clear vaccination schedule and back up to avoid extended periods of storage at the vaccination point;
- Estimating the need to request additional vaccine doses.
- Develop a procedure for spillages on skin/eyes and provide handwashing facilities and eyewash kits
- Develop a procedure for spillage on surfaces and provide gloves, paper towels and all material needed as per the local chemical disinfection policy.

6.11 Job creation and economic benefits

The deployment of the vaccine may create very minimal job opportunities such as the recruitment of central and peripheral coordinators and additional income to the public servants. The long-term economic benefits result from the fact that the vaccination will ultimately help the economy recover.

6.12 Preventing Social Risks and Impacts

6.12.1 Perception of unfair distribution, unequal access and exclusion

The NCVDP provided clear details that every eligible person as per the priority populations will have access to the vaccine, regardless of their economic status. It is the responsibility of GOL to ensure the most disadvantaged communities receive this vaccine asper the NCVDP. The monitoring program will make sure there will be no black market and only pre-registered persons receive the vaccine as per the priorities set in the NCVDP.

The deployment of the vaccine may create social tensions due to lack of information on the eligibility criteria resulting in the potential perception of exclusion. It should be made clear through various and effective and widespread methods of information dissemination that the vaccination plan will be provided on a voluntary basis (no coercion) and will be managed in an inclusive and non-discriminatory manner and includes marginalized populations such as (i) refugees, (ii) immigrant workers and (iii), vulnerable groups (disabled, and elderly and women) and that the plan will not include children for unsuitability and as per the NCVDP. The transparency should be assured through information dissemination 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. The dissemination of information will also cut of the potential black market and side deals. A detailed communication plan was already developed and will be implemented as per the NCVDP to ensure inclusion of certain vulnerable groups including the disabled, the elderly, and refugees.

In addition, the deployment of the vaccine may result in the unintended exclusion of vulnerable groups (disabled, elderly, and refugees) in the pre-registration process due to barriers or limited access to IT tools. To mitigate or avoid such risks, the designed hotline at 1787 will provide support in pre-registration for vaccination and help with filling the digital form for registration which will help mitigate unintended exclusion of vulnerable groups in the process due to limited access to IT tools. In addition, the MoPH will ensure continuous and close coordination with the NGOs for the disabled, elderly, poor and refugees to ensure access and assistance to the pre-registration process. During the virtual stakeholder consultation conducted on 5 February 2021 a representative of the Lebanese Union of Persons with Disabilities

(LUPD) expressed his interest in coordinating closely with the MoPH to ensure widespread dissemination of information regarding the vaccination deployment details to effectively reach all persons with disabilities. The PMU GRM officer who will be hired for the project will also closely follow up on the nature of grievances and ensure corrective measures by the relevant parties where needed.

6.12.2 Potential rising social tensions

Confiscations and re- use, misappropriation, theft, corruption, leakage, people lacking formal IDs and even accidental waste of vaccine may rise in social tensions. A close monitoring and follow up of the NCVDP is needed to prevent rising social tension.

6.12.3 Gender inequalities and potential SEA/H

Gender inequalities and norms can play an important role for access to critical health services such as vaccinations. Moreover, pandemics can create or exacerbate the conditions that especially put women and girls at greater risk of SEA/H. For instance, women and girls may be forced into exchanging sexual favors for access to testing, treatment, vaccines or even supplies. If the NCVDP is well followed during implementation, the risk of gender inequalities and potential SEA/H will be avoided.

6.12.4 Impacts of the use of National Security Forces for the management of the entrances and exits of the vaccination centers

As stated in the present document, Lebanese Internal Security Forces are members of the NCVC. 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, armed forces were assigned in the NCVDP to secure the entrances and exits from the vaccinations to the priority populations. That being said, and as per the World Bank's Technical Note on the use of military forces to assist in COVID19 operations (see Annex H), any potential risks associated with the presence of security forces will be mitigated through the recommendations made in this technical note. Such risks could be associated with the potential diversion of materials, aid and assistance; (ii) potential for SEA/H; (iii) international media comment and reactions; (iv) other related risks. These risks can be mitigated through the project established GRM with SEA/H referral pathways as well as clear communication and awareness campaigns throughout project implementation.

7- Implementation of the ESMF

The implementation of the ESMF remains unchanged in all its sections: (i) Exclusion list, (ii) Prescreening, (iii) Procedures to be followed by PHCCs, (iv) Procedures for hospitals that have an approved EIA, (v) procedures for hospitals that did not previously submit an EIA to MoE and (vi) capacity building program.

Due to the current situation of confinement, the consultancy firms that are eligible to do environmental studies and laboratories are currently closed. Even public servants at the MoE are advised to stay at home to prevent getting contaminated by the Corona virus. In view of the urgency of COVID-19 vaccination. PMU shall ensure that all Health Care facilities benefiting from the Project have proven capacities in managing E&S issues. In this regard, the eligible facilities should have at minimum an ESMP to mitigate, avoid, and minimize the environmental and social risks associated with the project including a HCWMP and commit to start the procedures set in the original ESMF within 3 months after signature of contract, and the eligible facilities to conduct vaccination should have at minimum an ESMP including a HCWMP.

8- Monitoring and Evaluation System

The monitoring plan provided in the original ESMF still applies However, additional layers of monitoring the vaccination deployment will be implemented.

A monitoring plan will be put in place to monitor the proper use of the vaccination, the fair access to vaccine and to observe the side effects of the vaccine. People will be taught on how to report on side effects; they can either report on the mobile application, or by the COVID-19 vaccines call center, or by contacting the vaccination center where they got vaccinated. The progress of vaccination should also be monitored to study factors such as the nature of people that are getting vaccinated.

A Third-Party Monitoring Agency (TPMA) will be monitoring the implementation of the vaccination plan including the monitoring of the adequate functioning of the GRM, the referral pathways of the GRM in the event of any SEA/H complaints, and the implementation of the Environmental and Social mitigation measures related to the vaccination plan. The TPMA will ensure timely reporting in the event of any non-compliance of the implementation of the restructuring component E&S related instrument to put immediate corrective measures into place.

As mentioned in the ESMF, an effective Grievance Redress Mechanism (GRM) is in place at MoPH covering PHHCs and Hospitals.

9.1 GRM established under component 4

The existing call center with the designated hotline 1214 was put at the service to cover the COVID-19 related issues such as people starting to show symptoms and need to be assessed and referred to hospitals, questions and complaints. The designated number 76- 595 699 was put in place when the first cases of COVID-19 spread and has been replaced on April 2, 2020, to 01-594 459. The capacity of the hotline has been extended to receive and respond to additional calls. This line is being operated by the MoPH epidemiological surveillance unit & volunteers in 2 shifts. The number of operators was increased from 5 to 14. A daily report is being kept for the calls being received at COVID-19 line. Names and numbers of the callers are taken and registered. However, anonymous grievances can be raised and addressed. The Project also records the complaints received related to the Project in general such as environmental concerns. The GRM includes also an appeal process for unresolved grievances that was established before the Project restructuring to the request of the WB.

The respondents are regularly trained on how to handle the calls. Algorithms were developed according to the case definition. Caller reporting forms were put in place they include: Information about Investigator, date time of call, symptoms, risk factors, date of onset. For those asking for the results of tests done in RHUH, they were referred to the call center at RHUH 01-832-020. A daily report is generated by the call center detailing the names of the callers and the reason of the call as shown in the following figure.



Figure 2: COVID-19 call center log (MoPH)-

The average no of calls received per day before the COVID-19 spread was 120. Since the outbreak, the number of calls increased considerably to reach 136,639 by the end of January 2021. Note that the 1214 hotline is suspended currently for maintenance purposes and was replaced by the hotline 1787 with extensions 1 and 2 and the telephone number 01-594459. It will be operating around sixteen hours a day,
six days a week. At any shift, at least five operators will be active. It responds to the following queries: An additional number of operators will be needed (around 15) and additional IT equipment.

On another note, the department of preventive medicine at the MoPH follows up on patient with COVID-19 symptoms and assesses their compliance to home quarantine. The department of preventive medicine performs a follow up with the suspected on daily basis for 14 days after the date of suspicion and coordinates with the Red Cross for the transportation of suspected, probable or confirmed cases. The number of operators performing this task is 5. An average of 650 calls are made on daily basis.

9.2 GRM established for the COVID-19 vaccination deployment

A new hotline (1787) with extensions 1 and 2 was put in place recently to respond to COVID-19 related queries. For the COVID19 vaccination deployment, the MoPH is currently using the same hotline number 1787 with extension no. 1. However, the MoPH is considering dedicating a new hotline specifically designated for the vaccine deployment and is currently in negotiations with a local NGO for this task. Once that hotline becomes operational, the MoPH will widely disseminate the new hotline and related uptake channels to reach all citizens and vulnerable groups. Until such time, the 1787 hotline will be used. It will be operating around sixteen hours a day, six days a week. At any shift, at least five operators will be active. An additional number of operators will be needed (around 15) and additional IT equipment. The COVID19 hotline responds to the following queries:

- 1. Get information on COVID-19
- 2. Request hospitalization
- 3. Pre-registration for vaccination and help with filling the digital form for registration
- 4. Report side effects of the vaccine
- 5. Report grievances that can also be anonymous. The GRM includes also an appeal process for unresolved grievances that was established before the Project restructuring to the request of the WB. Whenever there is an unresolved grievance, such as someone thinking they should be vaccinated earlier, the patient can contact the vaccine center who will convey the message to the committee to act upon.

A new NGO will be contracted to operate the hotline. The NGO will provide volunteers that will be trained by WHO according to WHO guidelines and they will handle the pre-registration, inquiries and complaints and the side effects of the vaccine.

Additional uptake channels include the direct contact number at 01-594459-,or registering grievances/complaints through the MoPH website site (moph.gov.lb) or the ministry's mobile application which is in Arabic.

The GRM was clearly communicated during the virtual stakeholders' engagement held on 5 February 2021 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, complaints from the elderly or other vulnerable groups and grievances regarding the conduct of security personnel. For SEA/SH related complaints, referral pathways will ensure coordination with the relevant NGOs like ABAAD, and KAFA, for example, which are the key local NGOs handling SEA/SH grievances in Lebanon The GRM will also have in place an appeal process in the event of unresolved grievances whereby a complainant who is unsatisfied with the response will have the option to escalate their grievance to MoPH senior management. Grievances will be handled efficiently, immediately where possible, or within a timeline of 3-5 days.

Doctors, nurses and vaccinators will also have the option to file their grievances through the MoPH internal procedures and primarily through the "diwan" or "registrar" where all grievances will be officially recorded and addressed by the responsible staff at the MoPH. Another uptake channel for internal complaints is through the grievance boxes allocated throughout the MoPH. In addition, the grievance boxes allocated at the selected vaccination centers / hospitals under the national vaccination plan will be another uptake channel for doctors, nurses and vaccinators to register their grievances which will accordingly be handled by the relevant hospital staff. The principles of confidentiality and anonymity will also be applied to the internal grievances redress mechanism. The principles of confidentiality and anonymity will be handled efficiently and in a specified timeline and not exceeding 5 days.

The GRM will be clearly documented with close follow up by the responsible persons. The PMU will hire a GRM officer who will follow up and monitor the GRM in a GRM log.

10- Cost Estimate

No additional cost is to be incurred to the ESMF as a result of the Project restructuring, the cost provided in the ESMF still applies.

Annexes

- Annex A: Coronavirus Disease 2019 (COVID-2019) Health Strategic Preparedness & Response Plan
- Annex B: Basic Laboratories Biosafety Levels 1 and 2
- Annex C: Hospital Performance Contracting 2014- MoPH Lebanon
- Annex D: Summary of COVID-19 Vaccination Readiness Assessment
- Annex E: COVID-19 Vaccination Training Report by MoPH
- Annex F: Standard Operating Procedure for COVID-19 Immunization prepared by the Primary Healthcare Department at the MoPH
- Annex G: Technical Note: Public Consultations and Stakeholder Engagement in WB-supported operations when there are constraints on conducting public meetings
- Annex H: Technical note: Use of Military Forces to Assist in COVID-19 Operations Suggestions on how to mitigate risks – Version 1- March 25, 2020
- Annex I: Form on Adverse Event Following Immunization Reporting Form for COVID-19 Vaccine(s)

Annex A: COVID-2019 Health Strategic Preparedness and Response Plan



Coronavirus Disease 2019 (COVID-2019) Health Strategic Preparedness and Response Plan

Lebanon

 $10~\mathrm{March}~2020$

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I. Purpose of the Document

This document has been developed to establish a national plan of action to scale up preparedness and response capacities in Lebanon for prevention, early detection, and rapid response to coronavirus disease 2019 (COVID-19) as required under the International Health Regulations (IHR 2005). Using the WHO global 2019 Novel Coronavirus Strategic Preparedness and Response Plan as the foundation, this plan was developed for Lebanon.

II. Background, PHEIC declaration and Situation Analysis

Coronaviruses are zoonotic viruses that circulate amongst animals. Some have been identified in humans, causing illness ranging from mild symptoms to severe illness.

On 31 December 2019, WHO was alerted to several cases of pneumonia of unknown origin in Wuhan City, Hubei Province of China. One week later, on 7 January 2020, Chinese authorities confirmed that they had identified a new virus as the cause of the pneumonia cluster. The new virus is a coronavirus, belonging to the same family of viruses that cause the common cold, as well as viruses that cause Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). This new virus is currently referred to as the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).

Since the first cases were reported, WHO has been working with Chinese authorities and global experts to learn more about the virus, including source of infection, how it spreads, severity, high-risk groups, how best to treat patients, and what countries can do to prepare for and respond to the situation or to the epidemic.

The Emergency Committee on the COVID-19 under the International Health Regulations (IHR 2005) was first convened on 22-23 January, and subsequently reconvened on 30 January 2020. The Director General of WHO declared the COVID-19 outbreak to be a public health emergency of international concern (PHEIC) after the second meeting. The Emergency Committee has provided recommendations to WHO, to the People's Republic of China, to all countries, and to the global community, on measures to control this outbreak. The Committee believes that it is still possible to interrupt virus spread, provided that countries establish strong measures to detect disease early, isolate and treat cases, trace contacts, and promote social distancing measures commensurate with risk.

As of 1 March 2020, the total number of reported confirmed cases of COVID-19 stood at 87,161 cases reported from 60 countries and 2980 associated deaths (CFR 3.4%). Of the total number of confirmed cases, 79,968 were reported from China, 3,736 from Republic of Korea, 1,128 from Italy, and 593 from Iran. The number of confirmed/suspected cases and affected countries continues to rise.

Most cases of COVID-19 are mild in nature, but some have progressed to severe illness and death. Human-to- human transmission has been confirmed in many of the affected countries. There is not enough information about the epidemiological profile of COVID-19 to draw definitive conclusions about the full clinical features of disease, the intensity of the human-to-human transmission, and the original source of the outbreak. However, WHO is working closely with affected countries to compile more epidemiological data to answer the unknown questions.

Given high volumes of domestic and international travel both to and from affected countries and the observed human to human transmission, it is not unexpected that new confirmed cases will continue to appear in other areas and countries. With the information currently available for the novel coronavirus, WHO advises that measures to limit the risk of exportation or importation of the disease should be implemented without unnecessary restrictions of international traffic and trade.

CoVID 19 is transmitted by droplet, from an infected person. It can remain infective up to several days on inert material. The main mode of prevention remains: distancing at least 1.5 meters from an infected person, frequent hand hygiene and cough etiquette practices. Based on the current data, one person infects on average 4 persons, and the mortality is around 3%

a. Situation in the WHO Eastern Mediterranean Region

Regional health system context

Almost two-thirds of the Region's countries are experiencing directly or indirectly complex emergencies, with fragile health systems, weak disease surveillance, poor response capacities, and a sub-optimal level of public health preparedness – all factors making them particularly vulnerable to any emerging infectious diseases. Major religious mass gatherings are taking place in the region which pose unique risks to public health security.

Detecting and responding to emerging infectious diseases have become an important public health priority for Eastern Mediterranean Region. Majority of the countries in the region have adequate influenza and other respiratory disease surveillance system through extended network of sentinel sites. 20 out of the 22 countries in the region have functioning reference laboratories with the ability to detect and confirm seasonal influenza virus, MERS-CoV and other high threat pathogens. Furthermore, all countries in the region have trained national multidisciplinary rapid response teams for timely investigation and response to any public health threat. Countries with complex emergencies in the region have functioning early warning surveillance system with the ability to detect epidemic-prone diseases. Therefore, it's important to leverage the existing respiratory disease surveillance and laboratory capacities for the current surveillance and investigation and response to COVID-19 outbreak.

Regional epidemiological context

The epidemiology of the region is constantly changing. As of march 1 2020, 11 countries in the WHO Eastern Mediterranean Region (EMR) have reported COVID-19 cases. A total of 1,122 laboratory confirmed cases, of which 978 are from Iran, have been reported in the EMR. All death in the region totaling 54, have been reported from Iran.

Due to the global nature of travel, it is expected that further cases of COVID-19 may appear in other countries in the Region. EMRO dashboard can be accessed on: https://app.powerbi.com/view?r=eyJrIjoiN2ExNWI3ZGQtZDk3My00YzE2LWFjYmQtNGMwZjk00 WQ1MjFhIiwid CI6ImY2MTBjMGI3LWJkMjQtNGIzOS04MTBiLTNkYzI4MGFmYjU5MCIsImMiOjh9

Number of countries in the region have taken steps to repatriate their citizens from Wuhan or other cities affected by the outbreak, and those repatriated nationals were isolated for 14 days. WHO/EMRO has developed an interim guidance to countries for evacuation and quarantine of travelers returning from China. Thus far, WHO recommends no restrictions on travel and trade while some countries in the Region decided to take restrictive measures at Points of Entries, including suspension of flight coming from/to China, South Korea, Italy, and Iran. Such restrictive legal enforcements are currently considered and decided by each state.

III. COVID-19 Risk Analysis

a. Overall Risks

As of 28 February, WHO assessed the COVID-19 risk to be very high for China, very high at the regional level, and very high at the global level.

Sitrep: <u>https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200228-sitrep-39-covid-19.pdf?sfvrsn=5bbf3e7d_2</u>

Overall Risk		
China	Regional	Global
Very High	Very High	Very High

This assessment takes into consideration:

• *High likelihood of further spread:* Human-to-human transmission, including transmission within healthcare settings, has been confirmed within Wuhan and cities outside of China. The outbreak continues to grow within China at a rapid rate. In addition, 7193 confirmed cases have been

reported by 59 countries outside China as of 1 March 2020. Local transmission has been confirmed in many countries other than China.

• **Potential impact on human health:** The virus can cause severe illness and death. However, many

uncertainties remain, including the full extent of the current outbreak within China, and the full clinical spectrum of illness.

• *Effectiveness of current preparedness and response measures:* Until now, countries that have reported an imported case have demonstrated efficient and effective disease surveillance and response measures. Many countries that are yet to report a case have also demonstrated effective surveillance measures to date, through rapid testing and isolation of suspected cases. However, of great concern are countries that are less prepared to detect and respond to an imported case.

b. Risk Analysis in Lebanon

Lebanon has been strengthening and maintaining its national capacities required under the International Health Regulations (IHR 2005). Lebanon has conducted the Joint External Evaluation (JEE) and developed national action plans for health security to meet their core capacity requirements under the IHR. The following JEE technical areas were used for measuring capacity; (1) IHR coordination, (2) Infection prevention and control, (3) Laboratory and Biosecurity / Biosafety, (4) Surveillance, (5) Reporting, (6) Preparedness, (7) Emergency Response, (8) Risk Communications, and (9) Points of Entry. All the countries of the region scored between 2/5 and 5/5. Lebanon preparedness and readiness relatively good, scoring 4/5.

Lebanon's geographic location makes it a busy hub for travel to and from all the world. Although it does not have direct flights with China, the initial epicenter for the outbreak, it does have direct fights to most regional countries, and to all Europe. Based on the epidemiologic data, the first case of COVID 19 was imported to Lebanon through travelers coming back from Iran/ Qom, believed to be the epicenter in Iran. The first case was confirmed on 21 February 2020; a Lebanese woman who was aboard a plane coming from Iran. Until March 1, 2020: A total of 231 people were tested at RHUH, with results being 221 negatives and 10 positives. 8 of the COVID-19 cases had travel history to Qom city in Iran, while 2 had direct contact with persons who have been to Iran. Local transmission is confirmed but remains limited to these 2 cases.

Taking into consideration the mode of transmission, the risk of exposure, the readiness of the health system, as well as the likelihood and the severity of the impact of a local outbreak, the risk of local transmission and spanning outbreak in Lebanon is high.

IV. Preparedness and response interventions based on Transmission Scenarios

Through this plan, the MOH will closely work with the relevant authorities and other partners to build strong capacity to prevent, prepare, detect and respond to any potential COVID-19 outbreak. This plan will address the existing capacity gaps related to the prevention, preparedness, detection and response for emerging infectious diseases.

The overall goal of the national preparedness and response plan is to strengthen surveillance and response for COVID-19 infection to early detect any imported case, rapidly contain local transmission and mitigate the health impact of the outbreak in Lebanon.

WHO has defined 4 transmission scenarios for COVID-19:

1. Countries with no cases (No

Cases);

2. Countries with 1 or more cases, imported or locally detected (Sporadic

Cases);

3. Countries experiencing cases clusters in time, geographic location and/or common exposure (Clusters of cases);

4. Countries experiencing larger outbreaks of local transmission (Community

Regional Preparedness and Response Plan for COVID-19 – *final draft version* transmission).

I. Preparedness Measures for Scenario 1

The main measures that were implemented in Lebanon before the 21st of February when no COVID-19 cases were detected yet included:

- Awareness raising activities, development and dissemination of IEC material
- Intensive dissemination of risk communication and community engagement messages
- Screening at POEs of travelers coming from outbreak countries
- Ensuring a functional surveillance system with clear SOPs for case detection and confirmation

II. Outbreak Containment Measures for Scenarios 2 and 3

The transmission scenario that we are currently witnessing remains contained. The cases reported have been imported by exposure from a country with local transmission or through contact with infected household member.

The main measures to be taken include:

- Intensive risk communication and community engagement
- At POE, screening travelers coming from outbreak countries
- Ensuring a functional surveillance system with clear SOPs for case detection and confirmation
- Ensuring patient care and quarantine facilities with clear SOPs for patient referral
- Ensuring adequate reference diagnostic lab capacity, with standard safety and quality SOPs.
- Provision of PPEs at health facility level
- National coordination mechanisms established
- Assessment of capacities and gaps for potential local spread and outbreak explosion

III. Outbreak Mitigation Measures for Scenario 4

In case of an outbreak and based on the current available epidemiological data, the following is estimated: for a population of 6 million, approximately 600 thousand persons (10%) will contract symptomatic infection, over a period of 2-3 months. Of these cases, 90,000 (15%) will seek healthcare, out of which 18,000 (20%) would require hospital admission and 2,700 (3%) would be admitted to the intensive care unit. The death toll is estimated at a maximum of 1,800, 2% of those seeking healthcare. A pandemic that lasts eight weeks and has an attack rate of

10% will require at its peaks (4th and 5th week), to use 61% of the ICUs in all the Lebanese territories and around

36% of the hospital beds.

- Awareness raising activities should continue and be reinforced
- Surveillance activities should be maintained
- Risk communication and community engagement activities should continue
- IPC programs should be rigorously implemented especially in all hospitals and health facilities
- Designation of additional referral hospitals
- Development of new SOPs for patient diagnosis and referral and home care
- Develop protocols for quarantine (self-quarantine, isolation canters etc.)
- Ensure sufficient stock of PPEs with focus on the health care workers
- Support referral laboratories by MOPH and partners with the needed testing kits and PPEs.

V. Areas of work and priority actions i. Partnership and coordination

a. Establishment of the national COVID19 Task Force to mobilize resources and monitor country level activities to facilitate coordination with relevant ministries

- b. Strengthen multi-sectoral coordination, as well as coordination with WHO local office, by sharing updated information and contingency planning
- c. Conduct quick mapping of human resource needs for the implementation of the national plan
- d. Set up and activate Emergency Operation Centers (EOC) at national and sub-national levels to better coordinate the response
- e. Coordination of activities of all health and relevant non-health partners
- f. Establish and maintain the COVID19 national platform for national data collection, provide appropriate support or guidance, and closed-loop communication of answers in timely manner
- g. Coordinate between relevant stakeholders (including the National CD Committee) to support priority research activities in order to close knowledge gaps

ii. Points of Entry and IHR (2005)

- a. Establishment of multi-sector POE contingency plans and establishment of referral protocols from POE to designated health facilities
- b. Provide guidance regarding issues of travel and trade based on current public health advice
- c. Coordinate provision of needed technical support for related IHR capacities
- d. Provide and update overview of global traffic/trends in regard to COVID-19 and the EMR, as well as specific capacities at PoE
- e. Share technical guidance related to IHR capacities
- f. Provide targeted technical support/assessment to specific PoE (Beirut Rafic Hariri International Airport, Sea ports, and Border Crossing Points)
- g. Organize trainings for health and non-health authorities at POEs

iii. Health Information Management

- a. Disseminate standard case definitions, case investigation and follow up for active surveillance of COVID-19 to all surveillance sites (Health Facilities, Lebanese Order of Physicians, Syndicate of Hospitals, Orderof Nursing...)
- b. Collect daily information relevant to COVID-19 through social media, local newspapers, community (event-based surveillance)
- c. Establish active case finding
- d. Ensure that national surveillance system covers laboratories, health facilities in public and private sector, points of entry, and other relevant health providers with a direct line of communication with the national IHR Focal point
- e. Ensure timely notification of confirmed and probable cases to WHO (within 24 hours of identification), as well as reporting of suspected cases of COVID-19 preferably through EMFLU or using WHO interim case reporting form.
- f. Enhance/establish existing acute respiration infection surveillance system, as needed, including indicator-based surveillance, event-based surveillance, and sentinel surveillance
- g. Develop dashboards, repositories and situation reports (as needed)
- h. Provide information required to guide all aspects of the operations including communications, risk and needs assessment, priority setting, planning, information management, health operations and health logistics
- I. Produce and disseminate daily briefing and weekly updates to all levels

iv. Case management

- a. Ensure healthcare service continuity (facilities, personnel, medicines, supplies, medical devices) and surge plans including establishment of a referral system to designated hospitals.
- b. Provide case management technical expertise and guidance to health facilities in Lebanon
- c. Provide trainings on healthcare/ambulatory teams in the management of COVID-19 cases, Infectioncontrol, PPE donning and doffing ...
- d. Facilitate implementation of international/WHO protocols for research/clinical trials at country level if there are opportunities

v. Infection Prevention and Control (IPC)

- a. Provide IPC technical expertise and guidance to Health facilities when needed, particularly regarding triage, early recognition, standard precautions, isolation procedures, and referral mechanisms in line with WHO guidelines
- b. Organize refresher trainings on IPC and capacity building for all health facilities

vi. Rapid Response Teams (RRTs)

- a. Establish multidisciplinary rapid response teams (RRTs) and ensure the RRTs are in place at national and subnational levels
- b. Ensure the mechanism of activation and deployment of national RRTs is in place
- c. Conduct refresher trainings among national RRT teams in case management, specimen collection and transport, contact tracing, decontamination, investigation, social mobilization and safe and dignified burials.
- d. Ensure RRTs are trained and equipped to investigate suspected cases, especially regarding the provision of appropriate investigation protocols and case definitions, systems for contact tracing, and surveillance mechanisms as outlined
- e. Coordinate with WHO local office for collaboration on outbreak investigation and response
- f. Organize field-based simulation exercise to ensure the functionality of RRTs.

vii. Laboratory diagnostics

- a. Establish and sustain laboratory confirmatory capacity for COVID-19 (at RHUH and other designated hospitals at Mohafazat level)
- b. Adapt and disseminate SOPs for specimen collection, management and transportation for COVID-19 diagnostic testing
- c. Strengthen national diagnostic capacity through in-service training and mentoring among lab technicians.
- d. Ensure availability of testing kits and other essential supplies at the national reference laboratory at RHUH and at laboratories of designated hospitals at Mohafazat level.
- e. Build capacity for collection, storage and transportation of samples and establish a process for shipment of specimens to international reference laboratories when needed.
- f. Establish surge plans in to be used in times of increased testing demands

viii. Risk communication and community engagement

- a. Develop and implement national emergency risk communication and community engagement strategies for COVID-19
- b. Identify and designate media spokesperson(s) at the national level and organize regular interviews with traditional and non-traditional media organizations
- c. Ensure timely and credible information is made available to the public, health professionals and other key audiences in appropriate formats through different accessible platforms addressing different audiences including the general public
- d. Disseminate press releases regularly highlighting the latest situation and national response
- e. Hold press briefings to raise media awareness on the latest situation, address media queries and ensure media are aware of correct facts and information.
- f. Reinforce national rumor and misinformation detection and management mechanisms

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- g. Update regularly the covid-19 page of the MOH website
- h. Develop and disseminate Information, education and communication materials in coordination with concerned stakeholders (UN agencies, NGOs, Scientific Communities, Syndicates etc.)

ix. Operations support and logistics

- a. Consolidate requests and share with the PMO's national committee for quantification and prioritization
- b. Survey for IPC and Laboratory Reagent stocks available and identify gaps
- c. Develop a list of items needed for resupply or procurement (National and subnational, POE...)

x. Programme Management

- a. Allocate funds for the execution of the National plan in collaboration with WHO country office
- b. Manage and support financial allocation for all operating costs
- c. Support fast track procurement requests

V. Operationalizing the

plan

Implementation of this plan will require significant and extensive coordination and collaboration which includes but is not limited to national technical meetings, and workshops between health authorities and other partners and ministries.

VI. Monitoring and

evaluation

Monitoring and evaluation of the national preparedness and response will be conducted at regular intervals by the MOH. **Key performance and impact indicators can be used to monitor and evaluate the implementation of the planned activities**, as well as to assess the overall performance of the programme, derive evidence & lessons learnt to correct and adjust the program and operations. A progress report will be generated and shared regularly with the national committee highlighting the progress and level of operational readiness, the strengths, weakness, gaps and recommendations on how to address the challenges.

Monitoring framework			
Туре	Indicator	Target containment scenario	Target mitigation scenario
Point of entry and IHR	Number of POE that have capacity to detect suspected/confirmed cases	3	0
5	Number of POE that have isolation	4	0
Health Information Management	% of HCF where surveillance guidelines are disseminated to healthcare workers including private sector	100%	100%
<u> </u>	Public designated hospitals to treat COVID- 19 cases	1	5
Case management	%Nb of Hospitals where case management were disseminated	100%	100%
Infection Prevention and	% of acute healthcare facilities with triage capacity	50%%	100%
Control	% of acute healthcare facilities with isolation capacity	5%	100%
	Nb trained multidisciplinary rapid response teams at Mohafazat level	4	4
Rapid Response Teams	% of hospitals that have adequate supplies including PPEs	100%	100%
	% of alerts have been verified and investigated within 48 hours	100%	100%
	Nb of laboratory that can provide results within 72 hours	1?	5
Laboratory diagnostics	Number of national reference laboratories with capacity to test COVID-19	1	1
	Number of national laboratories with trained	1	5
	Number of national reference laboratories reporting virological data through EMFLU or FluNet	1	5
Risk communication and community engagement	Presence of health communication plan that was updated according to the new situation	1	1
	frequency of media interviews and press release in different languages	daily	Weekly
Operations support and logistics	Number of hospitals experiencing stock-outs of critical items	0	0
	Number of labs receiving IPC medical supplies and laboratory reagents in response to COVID-	1	5
Programme Management	% of surge deployment resources from the external and internal rosters of experts	0%	TBD

VII. Timeline

Areas of work	Activities	Timeline
1. Partnership and	a. Establishment of a National COVID19 technical committee to mobilize resources and monitor country	Ongoing
Coordination	level	
	activities to facilitate coordination with relevant authorities, ministries and WHO country office	
	b. Strengthen multi-sectoral coordination, by sharing updated information and contingency planning for	
	joint actions	
	c. Coordinate and collaborate with WHO country office to cover gaps in preparedness and response as	
	the	
	outbreak evolves in order to complete and implement the national preparedness and response plan for	
	COVID-19	
	d. Conduct quick mapping of human resource needs for the implementation of the national plan	
	e. Set up and activate Emergency Operation Centers (EOC) at national and sub-national levels to	
	better coordinate the response	
	f. Support and guide the coordination of activities of all health and relevant non-health partners	
	g. Establish and maintain the national platform to provide appropriate support or guidance, and closed-	
	loop	
2. Point of entry	a. Provide technical expertise to inform operations for IHR and PoE issues, including guidance on	Feb - April
(PoE) and IHR	establishing	
	multi-sector PoE contingency plans and establishment of referral protocols from PoE to designated health	
	facilities	
	b. Provide guidance regarding issues of travel and trade based on current public health advice and in	
	alignment with global strategy	
	c. Coordinate provision of needed technical support for related IHR capacities	
	d. Provide and update overview of global traffic/trends in regards to COVID-19, as well as specific	
	capacities at	
	PoE	

Areas of work	Activities	Timeline
3. Surveillance and	a. Disseminate standard case definitions, case investigation and follow up for active surveillance of	Ongoing
reporting systems	COVID-19 to all surveillance sites	
	b. Collect daily information relevant to COVID-19 through social media, local newspapers, community	
	(event-	
	based surveillance)	
	c. Establish active case finding	
	d. Ensure national surveillance systems cover laboratory, private sector, points of entry, and other	
	relevant	
	health providers with direct line of communication with the national IHR Focal point	
	e. Ensure timely notification of confirmed and probable cases to WHO (within 24 hours of	
	identification), as well as reporting of suspected cases of COVID-19 preferably through EMFLU or in	
	using WHO interim case reporting form.	
	f. Enhance/establish existing acute respiration infection surveillance system, as needed, including	
	indicator - based surveillance, event-based surveillance, and sentinel surveillance	
	g. Keep national and subnational country levels informed on the evolution of the outbreak in the region	
	h. Develop dashboards, repositories and situation reports	
	i. Provide information required to guide all aspects of the operations – including communications, risk	
	and needs assessment, priority setting, planning, information management, health operations and health	
	logistics	
	Monitor available research knowledge and product development to inform the operations	
4. Case Management	a. Ensure healthcare service continuity (facilities, personnel, medicines, supplies, medical devices) and	Ongoing
	surge plans including establishment of a referral system	
	b. Provide case management technical expertise and guidance to health facilities	
	c. Provide trainings on healthcare/ambulatory teams in the management of COVID-19	
	cases d. Coordinate with stakeholders (National CD Committee) to address unknown about	
	clinical	
	characterization, challenges in clinical care and collaboration to innovate and problem solve together e.	
	Facilitate implementation of international/WHO protocols for research/clinical trials at country	
5. Infection	a. Provide IPC technical training and guidance to Health facilities when needed, particularly regarding	February- April
Prevention and	vention and triage, early recognition, standard precautions, isolation procedures, and referral mechanisms in line with	
Control (IPC)	WHO guidelines	
	b. Share up-to-date interim WHO IPC guidance documents with HC professionals	
	c. Provide IPC training and capacity building if at national and subnational levels if	
	needed d. Strengthen triage and isolation capacity in referral hospital(s)	

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Areas of work	Activities	Timeline
6. Rapid Response	a. Coordinate with Mohafazat and Caza physicians to activate/reactivate the multidisciplinary rapid	March-May
Teams (RRTs)	response teams (RRTs) and ensure the RRTs are in place at national and subnational levels	
	b. Ensure the mechanism of activation and deployment of national RRTs is in place	
	c. Conduct refresher trainings among national RRT teams in case management, specimen collection	
	and transport, contact tracing, decontamination, investigation, social mobilization and safe and	
	dignified burials.	
	d. Provide technical guidance to ensure RRTs are trained and equipped to investigate suspected cases,	
	especially regarding the provision of appropriate investigation protocols and case definitions, systems for	
	contact tracing, and surveillance mechanisms as outlined	
	e. Coordinate with WHO country office for any international collaboration on outbreak investigation and	
	response	
	f. Organize field-based simulation exercise to ensure the functionality of RRTs.	
7. Laboratory	a. Support reference lab to establish and sustain laboratory confirmatory capacity for COVID-19	Ongoing
diagnostics	b. Adapt and disseminate SOPs for specimen collection, management and transportation for COVID	
	Dragnostic testing	
	c. Provide technical assistance to strengthen national diagnostic capacity through in-service training	
	and mentoring among iab technicians.	
	 Ensure availability of testing Kits and other essential supplies in national reference laboratories. Establish access to a designated international COVID 19 reference laboratories. 	
	f Build capacity for collection, storage and transportation of samples and establish a process for	
	shipment of specimens to international reference laboratories until national capacity can be established	
8 Risk	a Provide support to develop and implement national emergency risk communication and	Ongoing
communication and	community engagement strategies and/or action plans for COVID-19	o ngomg
community	b. Identify and designate media spokesperson(s) at national and subnational levels and organize	
engagement	regular interviews with traditional and non-traditional media organizations	
00	c. Support timely and credible information is made available to the public, health professionals and other	
	key audiences in appropriate formats through different accessible platforms addressing different audiences	
	including vulnerable populations	
	d. Disseminate press releases regularly highlighting the latest situation and national response	
	e. Hold press briefings to raise media awareness on the latest situation, address media queries and	
	ensure media are aware of correct facts and information.	
	f. Reinforce national and subnational rumour and misinformation detection and management mechanisms	s
	g. Update regularly the nCoV info and the MOPH website	

Areas of work	Activities	Timeline
	h. Conduct regional traditional and social media surveillance for listening and understanding	
	perception of target audience and provide technical support to subnational levels	
	i. Develop and disseminate Information, education and communication materials	
9. Operations	National Level	Ongoing
support and logistics		
	a. Consolidate requests and share for quantification and prioritization	
	b. Survey for IPC and Laboratory Reagent stocks available and identify	
	gaps c. Develop a list of items needed for resupply or procurement	
	Subnational	
	a. Receive, inspect, consolidate, kit, and dispatch emergency medical	
	supplies b. Report on available supplies and dispatches completed	
	c. Liaise with the central level to monitor and report on global supply availability and forecast (request	
	for new supplies)	
	d. Monitors and reports on supply chain disruptions or blockages	
10. Programme	a. Support referral hospitals with resource allocation and management	Ongoing
Management	b. Ensure budget monitoring of the allocated funds with WHO country office and the National nCov	
0	technical and ministerial committees	
	c. Manage and support financial allocation for all operating costs	
	d. Support the surge deployment resources from the private sector and public sector rosters of	
	experts e. Support fast track procurement request for national and subnational health facilities	

Surveillance documents and forms in attached zipped folder:

- Case Definition
- Hospital Reporting Form
- Specimen collection
- Laboratory request form
- Call center
- Caller form
- Patient and data flow
- The First Few X (FFX) Cases and contact investigation protocol
- Household transmission investigation protocol

Laboratory documents and forms in attached zipped folder:

- Receiving and processing samples suspected for COVID-19
- Instructions of donning and removing of PPEs using gown
- Instructions on donning and doffing of PPEs using coverall
- Real time RT PCR
- Receiving and processing samples suspected for COVID-19
- Sequence of donning PPE audit checklist
- Sequence of removing PPE audit checklist
- Sequence of removing PPE using coverall audit checklist
- Specimen collection and handling guidelines of suspected novel coronavirus
- Recommendations for sample transportation
- Waste management of contaminated materials
- Reception of samples suspected of novel coronavirus

Regional Preparedness and Response Plan for COVID-19 – final draft version Self Isolation guidelines

English	
Self-Isolation	
Upon your return from an affected country, or in case you had close contact with a suspected or confirmed COVID-19 case, you need to self-isolate 14 days even if you do not have any symptoms	for
From the airport to your house:	
• Wear a facemask before you exit the plane	
• Do not hug and kiss any of your friends or family receiving you at the airport	
• Use a private car to drive home	
One of the plane passengers should drive the car	
• Leave car windows open	
• Go directly to your house or to the place where you will self-isolate	
At your house:	
• Stay home; in your room, your apartment, or your house. Do not go to work, classes, athletic events, or other religious or social gatherings until 14 days a	after
the date of your departure from the affected country.	
 Stay in a well-ventilated foom with a window that can be opened, separate from other people in your nome. Keep the door closed Ask friends, family members or delivery services to carry out errands for you – such as getting groceries, medications or other shopping 	
• Wash your hands. This should be done often and thoroughly with soap and water, for at least 20 seconds, rinse and dry thoroughly. Avoid touching y	our
eyes, nose, and mouth with unwashed hands.	
 Do not invite of allow visitors to enter. If it urgent to speak to someone who is not a member of your household, do this over the phone. It is important that you separate yourself from other people in your home and if you share facilities like toilets and bathrooms, regular cleaning will 	be
 Ensure you use separate towels from other household members, both for drying yourself after bathing or showering and for hand hygiene purposes. 	
• Do not share drinking glasses, towels, eating utensils, bedding, or any other items until you are no longer asked to self-isolate.	
• All waste that has been in contact with the individual, including used tissues, and masks if used, should be put in a plastic rubbish bag and tied when fu The plastic bag should then be placed in a second bin bag and tied.	ıll.

	What is already done	In progress	Partners to MOPH
coordination	-a National Crisis Multi- Ministerial committee is established -National inter- ministerial crisis Task force is established -a standing National Infectious Diseases Committee is activated	-More active engagement of non-health stakeholders (Crisis response funding, self- quarantine monitoring, points of Entry screening)	WHO, UNCT, OCHA, DRM
Points of entry	 Written SOPs for travelers screening Updated travelers screening form Awareness roll ups and brochures PPEs for airport and land crossing health and security staff PM decision regarding measures at Airport Surged additional staff for screening travelers (9 RNs by WHO, 3 MDs volunteers) Repurposed 23 RNs (UNICEF) for land crossings Training Land crossing health and security staff 	-Stock piling of PPEs for all POE -More political commitment for implementation of prevention measures	WHO, UNICEF, ministry of public works, academic institutions, professional orders
surveillance	-Team trained and equipped -Call center activated -Case investigation SOPs updated -Contact tracing and referral SOPs updated -FFX investigation	-Logistics support (drivers for coordination in all Mohafazat of surveillance activities) -Human resources for call center, and patient and contact tracing and investigation -PPEs	WHO, heath societies: Infectious diseases, epidemiology, pulmonary; academic institutions, professional orders and

Interventions Implemented So Far in Lebanon

Diagnosis and treatment	-Reference Lab at RHUH fully and safely	-Securing sufficient quantities of reagents	WHO, heath societies:
	equipped for testing	and primers and lab supplies at reference lab	infectious diseases,
	-4 isolation rooms, 128 beds dedicated,	-Update all hospitals contingency plans	epidemiology,
	additional 64 beds under preparation at RHUH	-Designate and upgrade referral hospitals in	pulmonary; academic
	-Stock of PPEs for one month at	each Mohafazat	institutions,
	RHUH	-Clarify role of private sector in crisis response	professional orders and
	-Guidelines for testing, referral, case management and case management		syndicates
	and IPC disseminated to all health professionals,	-ensure a national contingency stock of	
	and to UN medical team (ESCWA and UNIFIL)	advanced	
	-assessment of 5 public hospitals for potential	PPEs for hospital case management	
Risk communication	-Awareness brochures for general public and	-Media support staff at MOPH for	WHO, UNICEF,
	travelers	daily communication and updates	UNCT, RCO, Media,
	-TV radio and social media interviews		ministry of
	-Daily sitrep by WHO, periodical preparedness	-More community sensitization and	Information, DRM.
	briefs	active engagement	
	-Sensitization meeting to Scientific societies at		
	order of physicians		

Annex B: Basic Laboratories - Biosafety Levels 1 and 2

Extracts from "WHO Laboratory biosafety manual - Third edition- 2004" available online through <u>https://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf</u>

3.Basic laboratories-

Biosafety Levels 1 and 2

For the purposes of this manual, the guidance and recommendations given as minimum requirements pertaining to laboratories of all biosafety levels are directed at microorganisms in Risk Groups 1-4. Although some of the precautions may appear to be unnecessary for some organisms in Risk Group 1, they are desirable for training purposes to promote good (i.e.safe) microbiological techniques (GMT).

Diagnostic and health-care laboratories (public health, clinical or hospital-based) must all be designed for Biosafety Level 2 or above. As no laboratory has complete control over the specimens it receives, laboratory workers may be exposed to organisms in higher risk groups than anticipated. This possibility must be recognized in the development of safety plans and policies. In some countries, accreditation of clinical laboratories is required. Globally, standard precautions (2) should always be adopted and practiced.

The guidelines for basic laboratories – Biosafety Levels 1 and 2 presented here are comprehensive and detailed, as they are fundamental to laboratories of all biosafety levels. The guidelines for containment Laboratories-Biosafety Level3 and maximum containment laboratories- Biosafety Level 4 that follow (Chapters 4 and 5) are modifications of and additions to these guidelines, designed for work with the more dangerous (hazardous) pathogens.

Code of practice

This code is a listing of the most essential laboratory practices and procedures that are basic to GMT. In many laboratories and national laboratory programmes, this code may be used to develop written practices and procedures for safe laboratory operations.

Each laboratory should adopt a safety or operations manual that identifies known and potential hazards, and specifies practices and procedures to eliminate or minimize such hazards. GMT are fundamental to laboratory safety. Specialized laboratory equipment is a supplement to but can never replace appropriate procedures. The most important concepts are listed below.

Access

1. The international biohazard warning symbol and sign (Figure 1) must be displayed on the doors of the rooms where microorganisms of Risk Group 2 or higher risk groups are handled.





BIOHAZARD

ADMITTANCE TO AUTHORIZED PERSONNEL ONLY

Biosafety		Level:
Responsible investigate	0 r:	In
case of emergency call:		
Daytime phone:	Home phone:	

Only authorized persons should be allowed to enter the laboratory working areas.
 Laboratory doors should be kept closed.

- 4. Children should not be authorized or allowed to enter laboratory working areas.
- 5. Access to animal houses should be specially authorized.
- 6. No animals should be admitted other than those involved in the work of the laboratory.

Personal protection

1. Laboratory coveralls, gownsor uniforms must be worn at alltimes for work in the laboratory.

2. Appropriate gloves must be worn for all procedures that may involve direct or accidental contact with blood, body fluids and other potentially infectious materials or infected animals. After use, gloves should be removed aseptically and hands must then be washed.

3. Personnel must wash their hands after handling infectious materials and animals, and before they leave the laboratory working areas.

- 4. Safety glasses, face shields (visors) or other protective devices must be worn when it is necessary to protect the eyes and face from splashes, impacting objects and sources of artificial ultraviolet radiation.
- 5. It is prohibited to wear protective laboratory clothing outside the laboratory, e.g. in canteens, coffee rooms, offices, libraries, staff rooms and toilets.
- 6. Open-toed footwear must not be worn in laboratories.
- 7. Eating, drinking, smoking, applying cosmetics and handling contact lenses is prohibited in the laboratory working areas.
- 8. Storing human foods or drinks anywhere in the laboratory working areas is prohibited.
- 9. Protective laboratory clothing that has been used in the laboratory must not be stored in the same lockers or cupboards as street clothing.

Procedures

- 1. Pipetting by mouth must be strictly forbidden.
- 2. Materials must not be placed in the mouth. Labels must not be licked.
- 3. All technical procedures should be performed in a way that minimizes the formation of aerosols and droplets.
- 4. The use of hypodermic needles and syringes should be limited. They must not be used as substitutes for pipetting devices or for any purpose other than parenteral injection or aspiration of fluids from laboratory animals.
- 5. All spills, accidents and overt or potential exposures to infectious materials must be reported to the laboratory supervisor. A written record of such accidents and incidents should be maintained.
- 6. A written procedure for the clean-up of all spills must be developed and followed.
- 7. Contaminated liquids must be decontaminated (chemically or physically) before discharge to the sanitary sewer. An effluent treatment system may be required, depending on the risk assessment for the agent(s) being handled.
- 8. Written documents that are expected to be removed from the laboratory need to be protected from contamination while in the laboratory.

Laboratory working areas

- 1. The laboratory should be kept neat, dean and free of materials that are not pertinent to the work.
- 2. Work surfaces must be decontaminated after any spill of potentially dangerous material and at the end of the working day.
- 3. All contaminated materials, specimens and cultures must be decontaminated before disposal or cleaning for reuse.
- 4. Packing and transportation must follow applicable national and/or international regulations.
- 5. When windows can be opened, they should be fitted with arthropod-proof screens.

Biosafety management

- 1. It is the responsibility of the laboratory director (the person who has immediate responsibility for the laboratory) to ensure the development and adoption of a biosafety management plan and a safety or operations manual.
- 2. The laboratory supervisor (reporting to the laboratory director) should ensure that regular training in laboratory safety is provided.
- 3. Personnel should be advised of special hazards, and required to read the safety or operations manual and follow standard practices and procedures. The laboratory supervisor should make sure that all personnel understand these. A copy of the safety or operations manual should be available in the laboratory.
- 4. There should be an arthropod and rodent control programme.
- 5. Appropriate medical evaluation, surveillance and treatment should be provided for all personnel in case of need, and adequate medical records should be maintained.

Laboratory design and facilities

In designing a laboratory and assigning certain types of work to it, special attention should be paid to conditions that are known to pose safety problems. These include:

- 1. Formation of aerosols
- 2. Work with large volumes and/or high concentrations of microorganisms
- 3. Overcrowding and too much equipment
- 4. Infestation with rodents and arthropods
- 5. Unauthorized entrance
- 6. Workflow: use of specific samples and reagents.

Examples of laboratory designs for Biosafety Levels 1 and 2 are shown in Figures 2 and 3, respectively.

Design features

- 1. Ample space must be provided for the safe conduct of laboratory work and for cleaning and maintenance.
- 2. Walls, ceilings and floors should be smooth, easy to dean, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be slip-resistant.
- 3. Bench tops should be impervious to water and resistant to disinfectants, acids, alkalis, organic solvents and moderate heat.
- 4. Illumination should be adequate for all activities. Undesirable reflections and glare should be avoided.
- 5. Laboratory furniture should be sturdy. Open spaces between and under benches, cabinets and equipment should be accessible for cleaning.
- 6. Storage space must be adequate to hold supplies for immediate use and thus prevent clutter on bench tops and in aisles. Additional long-term storage space, conveniently located outside the laboratory working areas, should also be provided.



Figure 2. A typical Biosafety Level 1 Laboratory (graphics kindly provided by CUH2A, Princeton, NJ, USA)

- 7. Space and facilities should be provided for the safe handling and storage of solvents, radioactive materials, and compressed and liquefied gases.
- 8. Facilities for storing outer garments and personalitems should be provided outside the laboratory working areas.
- 9. Facilities for eating and drinking and for rest should be provided outside the laboratory working areas.
- 10.Hand-washing basins, with running water if possible, should be provided in each laboratory room, preferably near the exit door.
- 11. Doors should have vision panels, appropriate fire ratings, and preferably be selfclosing.
- 12.At Biosafety Level2, an autoclave or other means of decontamination should be available in appropriate proximity to the laboratory.
- 13.Safety systems should cover fire, electrical emergencies, emergency shower and eyewash facilities.
- 14. First-aidareas or rooms suitably equipped and readily accessible should be available

- 15.In the planning of new facilities, consideration should be given to the provision of mechanical ventilation systems that provide an inward flow of air without recirculation. If there is no mechanical ventilation, windows should be able to be opened and should be fitted with arthropod-proof screens.
- 16. A dependable supply of good quality water is essential. There should be no crossconnections between sources of laboratory and drinking-water supplies. An antibackflow device should be fitted to protect the public water system.
- 17. There should be a reliable and adequate electricity supply and emergency lighting to permit safe exit. A stand-by generator is desirable for the support of essential equipment, such as incubators, biological safety cabinets, freezers, etc., and for the ventilation of animal cages.
- 18. There should be a reliable and adequate supply of gas. Good maintenance of the installation is mandatory.
- 19. Laboratories and animal houses are occasionally the targets of vandals. Physical and fire security must be considered. Strong doors, screened windows and restricted issue of keys are compulsory. Other measures should be considered and applied, as appropriate, to augment security (see Chapter 9).

Laboratory equipment

Together with good procedures and practices, the use of safety equipment will help to reduce risks when dealing with biosafety hazards. This section deals with basic principles related to equipment suitable for laboratories of all biosafety levels. Requirements for laboratory equipment pertinent to higher biosafety levels are dealt with in the relevant chapters.

The laboratory director should, after consultation with the biosafety officer and safety committee (if designated), ensure that adequate equipment is provided and that it is used properly. Equipment should be selected to take account of certain general principles, i.e. it should be:

- 1. Designed to prevent or limit contact between the operator and the infectious material
- 2. Constructed of materials that are impermeable to liquids, resistant to corrosion and meet structural requirements
- 3. Fabricated to be free of burrs, sharp edges and unguarded moving parts
- 4. Designed, constructed and installed to facilitate simple operation and provide for ease of maintenance, cleaning, decontamination and certification testing; glassware and other breakable materials should be avoided, whenever possible.

Detailed performance and construction specifications may need to be consulted to ensure that the equipment possesses the necessary safety features (see also Chapters 10 and 11).



Figure 3.A typical Biosafety Level 2 laboratory (graphics kindly provided by CUH2A, Princeton, NJ USA). Procedures likely to generate aerosols are performed within a biological safety cabinet. Doors are kept closed and are posted with appropriate hazard signs. Potentially contaminated wastes are separated from the general waste stream.

Essential biosafety equipment

- 1. Pipettingaids -to avoid mouth pipetting. Many different designs are available.
- 2. Biological safety cabinets, to be used whenever:
 - infectious materials are handled; such materials may be centrifuged in the open laboratory if sealed centrifuge safety cups are used and if they are loaded and unloaded in a biological safety cabinet
 - there is an increased risk of airborne infection
 - procedures with a high potential for producing aerosols are used; these may include centrifugation, grinding, blending, vigorous shaking or mixing, sonic disruption, opening of containers of infectious materials whose internal pressure may be different from the ambient pressure, intranasal inoculation of animals, and harvesting of infectious tissues from animals and eggs.
- 3. Plastic disposable transfer loops. Alternatively, electric transfer loop incinerators may be used inside the biological safety cabinet to reduce aerosol production.

- 4. Screw-capped tubes and bottles.
- 5. Autoclaves or other appropriate means to decontaminate infectious materials.
- 6. Plastic disposable Pasteur pipettes, whenever available, to avoid glass.
- 7. Equipment such as autoclaves and biological safety cabinets must be validated with appropriate methods before being taken into use. Recertification should take place at regular intervals, according to the manufacturer's instructions (see Chapter 7).

Health and medical surveillance

The employing authority, through the laboratory director, is responsible for ensuring that there is adequate surveillance of the health of laboratory personnel. The objective of such surveillance is to monitor for occupationally acquired diseases. Appropriate activities to achieve these objectives are:

- 1. Provision of active or passive immunization where indicated
- 2. Facilitation of the early detection of laboratory-acquired infections
- 3. Exclusion of highly susceptible individuals (e.g. pregnant women or immune compromised individuals) from highly hazardous laboratory work
- 4. Provision of effective personal protective equipment and procedures.

Guidelines for the surveillance of laboratory workers handling microorganisms at Biosafety Level1

Historical evidence indicates that the microorganisms handled at this level are unlikely to cause human disease or animal disease of veterinary importance. Ideally, however, all laboratory workers should undergo a pre-employment health check at which their medical history is recorded. Prompt reporting of illnesses or laboratory accidents is desirable and all staff members should be made aware of the importance of maintaining GMT.

Guidelines for the surveillance of laboratory workers handling microorganisms at Biosafety Level 2

- 1. A pre-employment or preplacement health check is necessary. The person's medical history should be recorded and a targeted occupational health assessment performed.
- 2. Records of illness and absence should be kept by the laboratory management.
- 3. Women of childbearing age should be made aware of the risk to an unborn child of occupational exposure to certain microorganisms, e.g. rubella virus. The precise steps taken to protect the fetus will vary, depending on the microorganisms to which the women may be exposed.

Training

Human error and poor technique can compromise the best of safeguards to protect the laboratory worker. Thus, a safety-conscious staff, well informed about the recognition and control of laboratory hazards, is key to the prevention of laboratory-

acquired infections, incidents and accidents. For this reason, continuous in-service training in safety measures is essential. An effective safety programmer begins with the laboratory managers, who should ensure that safe laboratory practices and procedures are integrated into the basic training of employees. Training in safety measures should be an integral part of new employees 'introduction to the laboratory. Employees should be introduced to the code of practice and to local guidelines, including the safety or operations manual. Measures to assure that employees have read and understood the guidelines, such as signature pages, should be adopted. Laboratory supervisors play the key role in training their immediate staff in good laboratory techniques. The biosafety officer can assist in training and with the development of training aids and documentation (see also Chapter 21).

Staff training should always include information on safe methods for highly hazardous procedures that are commonly encountered by all laboratory personnel and which involve:

- 1. Inhalation risks (i.e. Aerosol production) when using loops, streaking agar plates, pipetting, making smears, opening cultures, taking blood/serum samples, centrifuging, etc.
- 2. Ingestion risks when handling specimens, smears and cultures
- 3. Risks of percutaneous exposures when using syringes and needles
- 4. Bites and scratches when handling animals
- 5. Handling of blood and other potentially hazardous pathological materials
- 6. Decontamination and disposal of infectious material.

Waste handling

Waste is anything that is to be discarded.

In laboratories, decontamination of wastes and their ultimate disposal are closely interrelated. In terms of daily use, few if any contaminated materials will require actual removal from the laboratory or destruction. Most glassware, instruments and laboratory clothing will be reused or recycled. The overriding principle is that all infectious materials should be decontaminated, autoclaved or incinerated within the laboratory.

The principal questions to be asked before discharge of any objects or materials from laboratories that dealwith potentially infectious microorganisms or animal tissues are:

- 1. Have the objects or materials been effectively decontaminated or disinfected by an approved procedure?
- 2. If not, have they been packaged in an approved manner for immediate on-site incineration or transfer to another facility with incineration capacity?
- 3. Does the disposal of the decontaminated objects or materials involve any additional potential hazards, biological or otherwise, to those who carry out the immediate disposal procedures or who might come into contact with discarded items outside the facility?

Decontamination

Steam autoclaving is the preferred method for all decontamination processes. Materials for decontamination and disposal should be placed in containers, e.g. autoclavable plastic bags, that are colour-coded according to whether the contents are to be autoclaved and/or incinerated. Alternative methods may be envisaged only if they remove and/or kill microorganisms (for more details see Chapter 14).

Handling and disposal procedures for contaminated materials and wastes

An identification and separation system for infectious materials and their containers should be adopted. National and international regulations must be followed. Categories should include:

- 1. Non-contaminated (non-infectious) waste that can be reused or recycled or disposed of as general, "household" waste
- 2. Contaminated (infectious) "sharps"- hypodermic needles, scalpels, knives and broken glass; these should always be collected in puncture-proof containers fitted with covers and treated as infectious
- 3. Contaminated material for decontamination by autoclaving and thereafter washing and reuse or recycling
- 4. Contaminated material for autoclaving and disposal
- 5. Contaminated material for direct incineration.

Sharps

After use, hypodermic needles should not be recapped, clipped or removed from disposable syringes. The complete assembly should be placed in a sharps disposal container. Disposable syringes, used alone or with needles, should be placed in sharps disposal containers and incinerated, with prior autoclaving if required.

Sharps disposal containers must be puncture-proof/-resistant and must not be filled

to capacity. When they are three-quarters full they should be placed in "infectious waste "containers and incinerated, with prior autoclaving if laboratory practice requires it. Sharps disposal containers must not be discarded in landfills.

Contaminated (potentially infectious) materials for autoclaving and reuse

No preclearing should be attempted of any contaminated (potentially infectious) materials to be autoclaved and reused. Any necessary cleaning or repair must be done only after autoclaving or disinfection.

Contaminated (potentially infectious) materials tor disposal

Apart from sharps, which are dealt with above, all contaminated (potentially infectious) materials should be autoclaved in leak-proof containers, e.g. autoclavable, colour-coded plastic bags, before disposal. After autoclaving, the material may be placed in transfer containers for transport to the incinerator. If possible, materials deriving from health- care activities should not be discarded in landfills even after decontamination. If an

incinerator is available on the laboratory site, autoclaving may be omitted: the contaminated waste should be placed in designated containers (e.g. colour-coded bags) and transported directly to the incinerator. Reusable transfer containers should be leak-proof and have tight-fitting covers. They should be disinfected and cleaned before they are returned to the laboratory for further use.

Discard containers, pans or jars, preferably unbreakable (e.g. plastic), should be placed at every work station. When disinfectants are used, waste materials should remain in intimate contact with the disinfectant (i.e. not protected by air bubbles) for the appropriate time, according to the disinfectant used (see Chapter 14). The discard containers should be decontaminated and washed before reuse.

Incineration of contaminated waste must meet with the approval of the public health

and air pollution authorities, as well as that of the laboratory biosafety officer (see section on Incineration in Chapter 14).

Chemical, fire, electrical, radiation and equipment safety

A breakdown in the containment of pathogenic organisms may be the indirect result of chemical, fire, electrical or radiation accidents. It is therefore essential to maintain high standards of safety in these fields in any microbiological laboratory. Statutory rules and regulations for each of these will normally be laid down by the competent national or local authority, whose assistance should be sought if necessary. Chemical, fire, electrical and radiation hazards are considered in greater detail in Part VI of this manual (Chapters 17 and 18).

Additional information regarding safety equipment is presented in Chapter 11.

Annex C: Hospital Performance Contracting 2014- MoPH – Lebanon53

The following factors have been chosen as measures of hospital performance in 2014 ⁵⁴, for use in setting tariffs for services provided by public and private hospitals contracted with the MoPH:

- 1. Accreditation
- 2. Patient satisfaction
- 3. Case-Mix Index (CMI)
- 4. Intensive Care Unit (ICU) admissions
- 5. Proportion of Surgical to Medical admissions
- 6. Deduction rate

The main purpose is to set a fair pricing system that reflects the complexity as well as the quality of services provided. Some indicators are integrated to provide incentives and disincentives for hospitals to promote good practice and discourage overuse and abuse of the system. The first two factors,

accreditation and patient satisfaction, are a reflection of quality, accounting for 40% and 10% respectively of the total contracting score. Factors 3 to 6 are a reflection of performance, and together account for 50% of the total contracting score.

The base data used for indicators of factors 3 to 5 is all regular stay (2-15 days) hospitalizations that took place under the MoPH's coverage in public and private hospitals, between June 2012 and May 2013. This comprises 76% of all admissions in this period, and excludes short-stay (0-1 days; 22%) and long-stay (>15 days; 2%) to enable the calculation of an accurate CMI, a similar practice used in other systems such as the US Centers for Medicare and Medicaid Services (CMS).

1. Accreditation

The results of the 2012 accreditation round of hospitals have been used in developing the contracting score. Accreditation was given a weight of 40% in this score relative to other factors. All hospitals with no reservation result were given an incentive of 5%, by including a multiplier of 1.05, while all hospitals with a simple reservation result had a neutral multiplier of 1.

2. Patient satisfaction

A phone call survey conducted by a professional and independent firm is conducted on a randomly selected sample of 25 patients per hospital. The results of the survey have a weight of 10% of the total contracting score. Therefore, accreditation and patient satisfaction together comprise 50% of the total contracting score.

3. Case-Mix Index (CMI)

Case-Mix Index was first calculated separately for medical and surgical admissions, using discharge diagnosis ICD10 and CPT code respectively. We also excluded mixed admissions that comprise only 4% of hospitalizations, to enable a more accurate CMI calculation. The methodology is similar to that detailed in the article "Ammar W., Khalife J., El-Jardali F., Romanos J., Harb H., Hamadeh G., Dimassi H. (2013). Hospital accreditation, reimbursement and case mix: links and insights for contractual systems.

BMC Health Services Research 13:505", and using a similar formula as that used by the US Centers for Medicare and Medicaid Services and various other national systems throughout the past three decades.

⁵³ Proposal submitted on April 15th 2014 by the three committees of the ESPISP-II project, financed by the World Bank. Ref.: https://www.moph.gov.lb/userfiles/files/Programs%26Projects/ESPISP%20II/HospitalPerformanceContracting2014.pdf

⁵⁴ The results mentioned in this document are transitory and will be updated upon completion of the patient satisfaction survey.

To increase the accuracy of the weights used in calculation of medical CMI, we used cost data based on all admissions from June 2011 to May 2013 (2 years). This is useful as medical admissions, unlike surgical admissions, have non-flat rates and therefore more affected by outliers when the number of admissions is small for certain conditions. A similar reasoning is also behind the exclusion of gastric bypass and cochlear implant in the calculation of surgical CMI, as these were ill-regulated expensive procedures that are performed in very few hospitals, thereby over-influencing their results. Unspecified neurotic disorders, unspecified hemiplegia and unspecified respiratory disorders were similarly excluded, as their distribution was skewed as a result of miscoding.

Once a medical CMI and surgical CMI were calculated for each hospital, they were used to develop a 'combined' CMI by giving each figure a weight based on the relative proportions of medical and surgical admissions to the specific hospital. For example, a hospital with medical CMI of 1.0 and surgical CMI of 1.6, and 100 medical admissions and 200 surgical admissions, would have a combined CMI of 1.4 (i.e. medical CMI is given 33% weight (100/300) and surgical CMI 67% weight (200/300).

Combined CMI was given a weight of 35% in the final contracting score relative to other factors.

4. Intensive Care Unit (ICU) admissions

The proportion of admissions to Intensive Care Units (ICU, CCU, NCO, PCU) out of all admissions was calculated for all hospitals. Each hospital admitting more than the average ICU admissions for all hospitals (6.8%) received the full score of the 5% dedicated to the ICU indicators in the final contracting score. Hospitals admitting below this average received a half-score (i.e. 2.5%).

5. Proportion of surgical to medical admissions

The proportion of surgical to medical admissions was calculated for each hospital, using the same data set of regular stay (2-15 days) admissions used in CMI calculation. This included 82,901 medical admissions and 95,990 surgical admissions, i.e. 54% of regular stays are surgical admissions. Hospitals in the highest quartile of surgical to medical admissions received a 5% incentive by using a multiplier of 1.05, while the three remaining quartiles had a neutral multiplier of 1.00. The quartiles were defined separately among public and private hospitals. Penalizing the lowest quartile remains a possibility to be considered in the future.

6. Deduction proportion

The deduction proportion of each hospital as calculated by the MoPH Auditing Committee has been used as a proportion of total amount billed by the individual hospital. Hospitals with more than 15% deduction are given a -5% disincentive; those between 5.1 and 14.9% are neither given an incentive nor disincentive (neutral); and those with less than 5% deduction are given an incentive of 5% to the final contracting score. It is planned to lower in the future the upper cutoff point to 10% instead of 15%.
Contracting Score

The final contracting score may be expressed as below:

Contracting Score = Accreditation + Patient Satisfaction + Case-Mix Index + Intensive Care Unit proportion + Surgical/Medical proportion + Deduction proportion

CS = Acd + PS + CMI + ICU + Surg/Med + D

These are weighted as follows: 40% Acd, 10% PS, 35% CMI, 5% ICU, 5% Surg/Med and 5% D.

Mean and standard deviation of contracting scores for all hospitals were calculated, and used in a z-score to express the distance of each hospital from the mean. This was done separately for public and private hospitals. Among private hospitals, those with a z-score above 0.00 (i.e. 0 or more standard deviations above the mean) were given highest tariff 1; those between 0 and -0.50 were given middle tariff 2; and those below -0.50 were given lowest tariff 3. Among public hospitals, those with a z-score above 0 were given highest tariff 1; those between 0 and -0.50 were given middle tariff 2; and those below -0.50 were given lowest tariff 3.

This resulted in the below distribution of hospitals:

TARIF	Private	Public
Τ1	29	9
Т2	45	6
Т3	31	9
Total	105	24

Future Contracting Outlook

We anticipate that the evaluation of hospital performance for contracting with MoPH in 2015 will include a greater emphasis on intensive care unit admissions, utilization of respirators, and the deduction proportion from the MoPH auditing committee.

Annex D: Summary of COVID-19 Vaccination Readiness Assessment

1. *Planning and Coordination*: With Word Bank support, the COVID-19 vaccination readiness assessment using the integrated VIRAT/VRAF 2.0 instrument has been completed to inform the planning process for the COVID-19 vaccination program. A National COVID-19 Vaccine Committee and seven Technical Working Groups have been formed to prepare the National COVID-19 Vaccine Deployment Plan (NCVDP). The World Bank is represented in the National Committee and Working Groups. MOPH will share the draft sub-plan for the Pfizer vaccine deployment within the next two days; however, the key elements of the plan have already been identified.

2. *Costing and Financing:* The full costing of NCVDP will be done after the plan has been finalized. In the meantime, the costs of deploying Pfizer and COVAX Facility vaccines to 11%⁵⁵ and 20% of the total population respectively have been estimated and details are available in the VRAF/VIRAT 2.0 readiness assessment. Other than the \$4.3 million down payment to the COVAX Facility using the routine vaccination budget (which too needs to be replenished as it will affect routine immunization program next year), the GOL has no budget for COVID-19 vaccination. For the Pfizer \$18 million contract, the GOL has requested the use of LHRP project funds.

3. *Regulations:* MOPH issued an emergency use authorization (EUA) for the Pfizer vaccine on December 16, 2020. The World Bank recommends a legal advisor be consulted for the regulatory measures related to the COVID-19 vaccine. The legal framework to protect data privacy is nascent and needs strengthening. The GOL also needs to put in place regulatory pathways for: (i) expedited custom clearance and release of the COVID-19 vaccines at the port-of-entry; (ii) data protection and data governance to ensure appropriate use of vaccination data; (iii) accommodating requests for no-fault liability funds and any related regulatory requirements; (iv) consent to vaccinations, the process for agreeing to or refusing to be vaccinated, and measures to protect those that refuse to be vaccinated; and (v) personnel who will be carrying out vaccinations and include requirements relating to chemical, physical and biological substances, not engaging in sexual exploitation and abuse and sexual harassment, participation in training, reporting and non-retaliation.

4. *Prioritization, Targeting and COVID-19 Surveillance:* The GOL identifies healthcare workers (HCWs), adults above 60 years of age (who constitute around 20% of the population) and adults with comorbidities as priority groups for vaccination. In the first batches of Pfizer vaccine, 50,000 HCWs and individuals with comorbidities (determined based on top causes of mortality⁵⁶) will be vaccinated. Elderly without comorbidities will be included subsequent batches. People under 16 years and pregnant and lactating women have been excluded for now and will be reviewed for inclusion later as more information on vaccine safety and efficacy among them become available. The GOL will use pre-registration to establish the database of eligible priority population. Health workers are already in the process of filling out pre-registration forms with private professional syndicates and Order of Physicians and Nurses and health facilities. For the elderly, municipalities will undertake a census and pre-register them. The MOPH is also exploring mechanisms to identify and target people with co-morbidities based on physician registers and through municipalities.

5. *Service Delivery:* The MOPH has identified the criteria for the selection of the vaccination sites, accounting for geographic location, cold chain, logistics, and enhanced Infection Prevention and Control (IPC) procedures. For the Pfizer vaccine roll out, MOPH plans to establish 10 sites in Q1; 25 in Q2 and 40 in Q3 and after. In addition, 10 mobile units have been earmarked for emergency vaccination in outbreak areas. Vaccinators will include HCWs in public hospitals, volunteers from NGOs like Red Cross and possibly the military. MOPH is currently assessing the capacity of vaccinators in the public sector and the military. Per the World Bank team's estimates, 178 HCWs are needed to deliver the procured doses of

⁵⁵ Pfizer's proposed donation of the 600,000 doses for registered refugees living in Lebanon will likely use similar deployment mechanisms with slight variations, but the costing of this modality is yet to be conducted as the details are still to be worked out.

⁵⁶ One working group is specifically assigned this task.

Pfizer vaccine based on the assumption that: (i) one vaccinator can vaccinate six persons per hour and (ii) one administrative staff is needed per vaccination site. The estimates will be updated as the MOPH finalizes the NCVDP.

6. *Training and Supervision:* 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. 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. In the interim, the World Bank team has calculated the budget for face-to-face training based on cost estimates provided by MOPH. Supervisory focal points at each vaccination site have not yet been identified; however, nine public health officers are needed to oversee COVID-19 immunization activities at the district as per the Expanded Program of Immunization (EPI) human resources plan.

7. *Monitoring and Evaluation (M&E):* The M&E Technical Working Group is still developing a framework for NCVDP. As part of the M&E framework, an information system will be established to monitor vaccine coverage and follow-up. The MOPH has multiple channels for grievance reporting, including a hotline, a mobile application, and the MOPH website. In addition to these channels, the MOPH has also launched two alternative numbers dedicated to COVID-19 related grievances as part of its COVID-19 response. MOPH is planning to add a new hotline for COVID-19 vaccine related grievances.

8. *Vaccine, Cold Chain, Logistics and Infrastructure:* The procurement plan for ancillary supplies and PPEs has not yet been developed. Based on the expected number of doses, the World Bank team (in consultation with MOPH) has prepared a draft estimate of the quantities and costs of vaccines and ancillary supplies (syringes, diluents, safety boxes, alcohol swabs, hand hygiene, and adrenaline/epinephrine).

9. As discussed above, the Pfizer vaccine requires ultra-cold chain. WHO had previously procured and installed 15 Ultra Low Temperature (ULT) freezers at 12 sentinel sites (6 private hospitals and 6 public hospitals) in all eight governorates (as part of the influenza pandemic preparedness between 2015 and 2017). Per a rapid assessment of the ULT freezers by MOPH, the ULT freezers are still functional although some require minor maintenance. In addition, MOPH has sent an official request to WHO to procure additional 6 ULT freezers. The MOPH has developed a distribution strategy for the Pfizer vaccine. The main storage facility will be Rafic Hariri University Hospital in Beirut, and two more can be added as needed. The vaccine will be transported from the storage facilities to vaccination sites every other day. At the vaccination sites, MOPH has two options:

(i) vaccines will be stored in 2-8°C refrigerators for a maximum of five days. Since each tray includes up to 975 doses of vaccines, a minimum of 200 doses should be administered daily to use up one tray in five days; or

(ii) vaccines will be stored temporarily in the thermal shippers provided by Pfizer for up to 15 days. These shippers should be replenished with dry ice (up to 3 replenishments; 2 kg of dry ice per thermal shipper). With every replenishment of dry ice, the thermal shipper can maintain ULT for five days, with 2 openings per day. Around 100 vaccines should be administered daily to be able to complete a tray of 975 doses. Local dry ice suppliers will need to be contracted for the procurement of dry ice.

10. Pfizer vaccine price includes shipment and insurance to a maximum of 5 storage facilities. Transportation from the point-of-entry to the storage facilities will be managed by Pfizer and will be included in the vaccine's cost.

11. For regular cold chain required for COVID-19 vaccines, UNICEF (given its immunization expertise) and MOPH will be conducting a gap analysis at the national and subnational levels to assess the existing cold chain's delivery and storage capacity as part of the Effective Vaccine Management (EVM) assessment, using the supply chain sizing tool. The Karantina central warehouse, which includes the cold

rooms, was damaged following the Beirut port explosion. Rehabilitation of the warehouse is expected to be completed by May-June 2021. The existing seven cold rooms are already used in full capacity for routine vaccines, and an expansion is being discussed with the MOPH to purchase additional 4-5 new cold rooms, which can store 1.2 million doses of vaccines (one cold room costs about \$30,000). One of the options discussed by the MOPH is renting cold chain equipment from private medical centers and labs in the interim.

12. *Traceability*: As more than one COVID-19 vaccine will be deployed, it is vital to develop a product-specific system to trace (i) different types of vaccine and (ii) the people have been vaccinated. Pfizer vaccine trays have bar codes that can be tracked to the facility level. Individual vials however cannot be tracked. 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). Pfizer has offered support for the development of this system as needed for their vaccines. Individuals will have to submit their national IDs to pre-register (ID number will be used as a unique identifier for each patient). MoPH has also confirmed that vaccination cards will be issued to the people who have received the vaccines.

13. MoPH has not yet identified specific safeguard measures to protect (i) vaccine at central and subnational levels (in storage facilities to which Pfizer will deliver and while in transit to vaccination points) and (ii) vaccination personnel. The SOPs for vaccine waste management (previously developed by UNICEF) are available. The SOPs should be revised based on the specifics of COVID-19 vaccine. As noted, MOPH is considering using the military for security.

14. *Safety Surveillance:* Through its National Vaccination Program, MoPH has a national pharmacovigilance system to monitor and report Adverse Events following Immunization (AEFI). This system will be adapted to include the COVID-19 vaccine. This will also be complemented by Pfizer's online platform for health workers to report adverse events and MoPH's online platform for patients to report adverse events.

15. *Demand Generation and Communication:* Communication activities will be implemented through the Ministry of Information. An outline for the external communication and community engagement and accountability plan has been developed. A list of Q&A will also be prepared by the technical group. In addition, MoPH is planning to expand the existing call center (adding new hotline) for COVID-19 vaccine related grievances and address public queries. For Pfizer vaccine, Pfizer will be supporting the communication campaign for which materials have already been developed.

Annex E: COVID-19 vaccination training Report by MoPH

Background and Rational

In December 2019, Wuhan city, the capital of Hubei province in China, became the center of an outbreak of pneumonia of unknown cause. By January 2020, Chinese scientists had isolated a novel coronavirus, severe acute respiratory syndrome coronavirus from patients infected with viral pneumonia, which was later designated coronavirus disease 2019 (COVID-19) by the WHO (Zhou et al, 2020). Although the outbreak likely started from a zoonotic transmission, associated with a large seafood market that also traded live wild animals, it soon became clear that efficient person-to-person transmission was also occurring (Liet al, 2020). By March 2020, COVID-19 had been declared a global pandemic and since then affected tens of millions of people globally (Polack et al, 2020).

Older adults, persons with certain coexisting conditions and front-line workers are at highest risk for the disease and its complications (Polack et al, 2020). Recent data also shows increasing rates of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and COVID-19 in other populations, including younger adults (CDC, 2020). As with other respiratory pathogens, including flu and rhinovirus, the transmission is believed to occur through respiratory droplets (particles >5-10 μ m in diameter) from coughing and sneezing (Cascella et al, 2020). Aerosol transmission is also possible in case of protracted exposure to elevated aerosol concentrations in closed spaces (Cascella et al, 2020). Analysis of data related to the spread of SARS-CoV-2 seems to indicate that close contact between individuals is necessary. Of note, pre- and asymptomatic individuals may contribute to up 80% of COVID-19 transmission (Cascella et al, 2020).

The SARS-CoV-2 virus primarily affects the respiratory system, although other organ systems are also involved (Yuki, Fujiogi and Koutsogiannaki, 2020). Lower respiratory tract infection related symptoms including fever, dry cough and dyspnea were reported in the initial case series from Wuhan (Huang et al, 2019). In addition, headache, dizziness, generalized weakness, vomiting and diarrhea were also observed (Shi et al, 2020). It is now widely recognized however that respiratory symptoms of COVID-19 are extremely heterogeneous, ranging from minimal symptoms to significant hypoxia with acute respiratory stress disorder (Yuki, Fujiogi and Koutsogiannaki, 2020). The time between the onset of symptoms and the development of ARDS may be as short as 9 days, suggesting that respiratory symptoms could progress rapidly and the disease could be fatal (Yuki, Fujiogi and Koutsogiannaki, 2020). Epidemiological studies have shown that mortalities higher in elder population (Zhou et al, 2020) and the incidence lower in children (Zhang et al, 2020). Current medical management is largely supportive with no targeted therapy available (Yuki, Fujiogi and Koutsogiannaki, 2020). Several drugs including lopinavir-ritonavir, remdesivir, hydroxychloroquine, and azithromycin have been tested in clinical trials, but none of them were proven to be a definite therapy. Other therapies are still being tested in clinical trials. As a response to the pandemic, a large number of countries have implemented social distancing and lockdown to mitigate the further spread of the virus (Yuki, Fujiogi and Koutsogiannaki, 2020), meanwhile safe and effective prophylactic vaccines are urgently needed to contain the pandemic which has had devastating medical, economic, and social consequences (Polack et al, 2020).

Due to the urgent need to combat COVID-19, diverse SARS-CoV-2 several vaccine types are currently under development, including inactivated vaccines, nucleic acid vaccines, adenovirus-based vector vaccines, and recombinant subunits vaccines (Dong et al. 2020). The development of Pfizer-BioNTechBNT162b2 mRNA COVID-19 vaccine was initiated on January 2020 when the SARS-CoV-2 genetic sequence was released by the Chinese Center for Disease Control (Polack et al, 2020). The

vaccine received emergency use authorization from FDA and EMA in December 2020 and by mid-January 2021 the Ministry of Public Health in Lebanon had signed a contact with Pfizer to deliver the BNT162b2 mRNA COVID-19 vaccine to the country.

Training Objectives

Educate healthcare professionals, responsible for the storage, handling, preparation and administration of Pfizer-BioNTech COVID-19 mRNA vaccine of its stringent quality requirements for safe handling and use. Training objectives include:

- Literature Evidence on Pfizer-BioNTechCOVID-19 mRNA Vaccine
- Safe Receipt, Handling and Unpacking of Vaccine Thermal Shipping Containers at Site of Storage
- Utilization of Shipment Data Loggers and Quality Clearance of Vaccines Vials for Use
- Appropriate Storage and Transportation Conditions of Vaccine Vials
- Preparation of Vials for Administration
- Understanding Personal Protective Equipment and Ancillary Supply Requirements

Methods and Materials

Target Audience

Healthcare professionals including physicians, hospital pharmacists, nurses and administrative staff who are responsible for receiving, handling, storing, preparing and administering Pfizer-BioNTechCOVID-19 mRNA vaccines in both public and private hospitals and points of vaccination and storage in Lebanon.

Number of Sessions:

- 35 Sessions

Training Methodology

- Interactive sessions with power point presentation
- Awareness pamphlets, leaflets and instructional material
- Participants to share experience, concerns and inquiries with trainer

Training Organization

The training session will be conducted by Pfizer in coordination with Ministry of Public Health

Draft Training Agenda

Time	Details
9:00AM-9:10AM	Registration
9:10AM-9:30AM	Medical Training
9:30AM-10:30AM	Supply and Quality Training
10:30AM-11:00AM	Q&A Session

Financial Costs

None Identified

Training Calendar, Preparation and Execution

COVID 19 Vaccine Training Schedule							
Date	Day	Hospital	Location (Training)	Number of Sessions	Expected Number of Participants		
20-1-2021	Wednesday	MoPH	1PM	1	75		
21-1-2021	Thursday	SGHUMC	11AM	1	25		
22-1-2021	Friday	HDF	9AM	1	25		
22-1-2021	Friday	RHUH	12:30PM	1	25		
25-1-2021	Monday	AUBMC	10AM	1	25		
25-1-2021	Monday	LAUMCRH	1PM	1	25		
26-1-2021	Tuesday	Rassoul el Aazam	1PM	1	25		

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Annex F: Standard Operating Procedure for COVID-19 Immunization prepared by the Primary Healthcare Department at the MoPH

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Standard Operating Procedure for COVID 19 Immunization

1 Scope

This document outlines the standard operating procedure for COVID 19 immunization services provided to all eligible residents of Lebanon, including Lebanese and non-Lebanese citizens. Abidance by this SOP is mandatory to every provider delivering COVID 19 immunization services both in the public and private sectors. Considering the rapidly changing situation of the pandemic and recommendations regarding immunization for COVID 19, updated versions of this guidance will be developed as updates arise.

1.1. Leadership and governance:

The national COVID 19 immunization initiative is led by the MoPH of Lebanon with technical and operational support from the Parliamentarian Health Committee, the National COVID 19 Technical Committee and UN agencies, mainly the WHO and UNICEF. All vaccines to be procured and made available on the Lebanese territories are certified, licensed and cleared by the MoPH and the technical committees.

1.2. Implementation:

Public immunization services will be provided free of charge for all eligible beneficiaries registered on the national COVID 19 vaccine registry at the identified public immunization sites. Prioritization based on clinical vulnerability criteria will be implemented.

The private sector will utilize the same eligibility criteria to provide immunization services for individuals who prefer immunization in the identified private outlets.

All recipients of the vaccine, in the public and private sector have to be registered in the National COVID 19 Vaccine registry.

1.3. Vaccination sites:

Public sector: In the public sector the immunization sites will be hosted in public and private hospitals that are equipped with appropriate cold chain. A total of 40 vaccination sites will be functional in the first phase.

Private sector:

COVID 19 immunization will also take place in the private sector and all vaccination data and information will be included on the national COVID-19 vaccination registry.





2- Preparation for vaccination sites

2.1 Physical setting and supplies

Physical setting

In the public sector the vaccination unit will consist of a waiting, vaccination and observation room.

The area of the setting needs to allow for physical distancing measures (1.5m between each individual), 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.

In the private sector, the vaccination patient flow will follow the vaccination site's regular flow while respecting physical distancing measures.

Supplies required

All Infection Prevention Measures have to be respected at all times to ensure the safety of healthcare providers and vaccine recipients during the COVID 19 pandemic.

The below list of consumables are mandatory at all vaccination sites:

- Personal Protective Equipment:
 - i. Surgical masks: 4 masks per health care provider per day
 - ii. Face shields: 1 face shield per health care provider per day

iii. Surgical gloves (non-sterile): one pair for each healthcare provider per vaccinate recipient

- iv. Disposable gowns: 1 gown per health care provider per day
- Infection Prevention and Control supplies essential for ensuring the disinfection of surfaces and hand sanitation in the COVID-19 immunization clinic:

i. The recommended product for surface disinfection is 70% alcohol or sodium hypochlorite solution 0.1 %





ii. The recommended product for hand sanitization is alcohol based hand sanitizing solution (60% alcohol), with one in the waiting room and one in the vaccination clinic.

- Vaccination consumables, all items needed to safely provide immunization to the beneficiaries including the below:
 - i. Syringes procured for dilution (2 or 3mL) to withdraw the diluent and 1 ml low dead-volume syringe for administration
 - ii. Alcohol swabs to the skin at the injection site
 - iii. Adhesive bandage to cover the injection site
 - iv. Diluents to reconstitute the COVID 19 vaccine
- Miscellaneous
 - i. Plastic waste bags (yellow for infectious medical waste, black for regular and noninfectious medical waste)
 - ii. Sharps containers (one dedicated for syringes, one for used/empty vials)

Waste management

Waste resulting from the immunization process will be segregated and considered as medical waste (infectious and noninfectious) and handled according to national policies on the management of medical waste.

Types of medical waste:

- Medical waste/ Non-Infectious: includes waste which does not come in contact with the beneficiary or any bodily fluids such as syringe wraps and plastic covers, packaging of the alcohol swabs...etc. This type of waste is discarded in black plastic bags.
- Medical waste/ Infectious: any item or consumable used in immunization that comes in contact with the patient and his/her bodily fluids such as alcohol swabs, adhesive bandage. In addition to PPEs worn by the healthcare provider, including gloves, masks, disposable gowns.... This type of waste is discarded in yellow plastic bags.
- **Sharps' containers:** syringes used for dilution and vaccine administration will be discarded in one sharps' container. Used vials empty or with traces of the vaccine will be discarded in a separate sharps container.

The waste will be collected at the vaccination site in color coded waste bags in dedicated clearly marked containers. Non-infectious medical waste will be





discarded with regular waste. Infectious medical waste will be collected on a daily basis and stored in a dedicated cold chain.

In the public sector, the contracted NGO, specialized and licensed to manage infectious waste.

Private providers need to abide by the waste segregation and storage guidelines and make their own arrangements by contracting a licensed medical waste management organization.

2.2 Human Resources in Public COVID-19 Vaccination Clinic

Vaccination services in the public sector will be provided by a team of trained healthcare providers composed of one physician and 8 or more vaccinator nurses, who will be supported by non-clinical staff including the center director or senior administrator, two administrative clerks, and one non-clinical observer/security officer. All staff will abide by primary preventive measures for COVID-19 by wearing appropriate PPEs.

Table 1 provides a brief description of team members qualifications and duties.

Job description and ToRs of HR in the COVID-19 vaccination clinic will be developed.

Role	Qualifications	Duties
Administrative clerk/data operator	Non- clinical, admin paperwork/electronic complete, validates on schedule, re recipient on future enters data from v administration and ha of certification	
Center Director (senior administrator or physician)	Clinical and/or admin	Monitors all activities, communicate with MoPH, collaborates with NCVC
Physician	Attending or resident physician (ACLS trained)	Physical assessment of vaccine candidates, administers screening checklist, responds to emergencies (ie: anaphylaxis shock) and oversees vaccination processes.

Table 1. Team composition, qualifications and duties





Vaccinator Nurse	Clinical nurse (meets Order of Nurses vaccinator criteria) (Annex 1)	Physical assessment of vaccine candidates, administers screening checklists, removes vaccine from cold storage, dilutes, draws up doses from multi dose vials, labels vaccine, administers vaccine and responds to emergencies (i.e.: anaphylaxis shock) and provides education on AEFI, signs off on 15 minutes well assessment
Non-clinical Observer/ security officer	Security officer	Monitors and secures vaccination storage and administration area and flow of individuals

2.3 COVID 19 Vaccine Recipient Journey in the Public Sector

Pre-vaccination

- Patient fills pre-registration form via the designated online application OR via phone call submitted to MoPH call center
- Patient stratified by risk according to national prioritization scheme
- Patient contacted either by phone call or SMS to schedule date, time and place of vaccination (place to be fixed by MoPH to reduce traffic on certain centers)
- Patient alerted of booking date few days beforehand with designated ID number

Arrival at Vaccination Site

- Patient arrives during specified time-slot (5min capacity for early/late arrivals)
- Traffic flow managed by administrator clerk
- Patient directed to hand sanitizing station by entrance
- Administrator clerk verifies patient information data, registers patient and directs him/her to designated seat in the waiting area

Vaccination

- Patient called in 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





- Patient undergoes physical assessment and screening
- Patient vaccinated
- Patient is provided with a vaccination card
- Patient instructed to move to observation area

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
- Follow up alerts from application OR follow up phone call from MoPH to be conducted daily for 7 days after vaccination (AEFI follow up)
- Follow up text or call to confirm date of subsequent injection



Figure 1. Patient Flow in COVID-19 Vaccination Site

3 Patient Eligibility to receive the COVID-19 vaccine

The National Prioritization Scheme will be adopted at the MoPH level through a risk and age-based approach for prioritization of COVID-19 vaccine target groups according to international guidelines in 5 stages (the WHO SAGE





values framework, WHO SAGE prioritization roadmap and the fair allocation mechanism for COVID-19 vaccines through the COVAX Facility.

Eligibility criteria:

- Name of patient and appointed registered in the system
- Patient registered on the backup list
- Patient present both individual ID and system-based ID (ID number)

Exclusion criteria for COVID-19 vaccination:

- Individuals who had a severe allergic reaction after a previous dose of this vaccine
- Individuals who had a severe allergic reaction to any ingredient of this vaccine.
- Pregnant/breastfeeding females
- Individuals between the age of 16-17 without parental consent
- Children under the age of 16

4 COVID-19 Vaccines and Supplies Inventory

4.1 COVID-19 Vaccines Dosing Schedule

Vaccines that will be deployed will be accompanied by the pertinent information regarding storage, dosage and administration, this document will be updated to include all vaccines which receive import license from the MoPH. Below is a table with some of the COVID-19 vaccines that are either currently being marketed under the FDA's emergency authorization or are under final clinical stages.

COVID-19 Vaccine Manufacture r	COVAX R&D Candidate	Platform	Туре	Number of doses	Dosing Interval	Route of admini stratio n	Storage Consideration	Clinical Phases
University of Oxford/ Astrazeneca	Yes	Non- replicatin g viral vector	ChAd OX1-S	2	28 days	IM	2-8 degree	UK approval
Moderna	Yes	mRNA	LNP- encaps ulated	2	28 days	IM	-20 degrees	FDA emergen cy





			mRNA					approval
Pfizer/BioNte ch		mRNA	3 NLP- mRNA s	2	28 days	IM	-70 degrees	FDA emergen cy approval
Novavax	Yes	Matric M Adjuvant	Recom binant protein nanop article	2	21 days	IM	2-8 degrees	Phase 3
Curevac	Yes	mRNA	mRNA	2	28 days	IM	2-8 degrees	Phase 2

4.2 Vaccine Specific Information

4.2.1 Pfizer/BioNTech Vaccine BNT162b2

On December 11, 2020, the U.S. Food and Drug Administration issued the first emergency use authorization (EUA) for a vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The emergency use authorization allows the Pfizer-BioNTech COVID-19 Vaccine to be distributed. The following information has been extracted from the BNT162b2 FDA approved leaflet for providers administering the vaccine.

A- Storage and handling:







During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials

Prior to Use Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice.

Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F). Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light until ready to use.

Thawed Vials Before Dilution





• Thawed Under Refrigeration

Thaw and then store undiluted vials in the refrigerator [$2^{\circ}C$ to $8^{\circ}C$ ($35^{\circ}F$ to $46^{\circ}F$)] for up to 5 days (120 hours).

A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

• Thawed at Room Temperature

For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Vials After Dilution

- After dilution, store vials between 2°C to 25°C (35°F to 77°F) and with a 6 hours' window for usage from the time of dilution.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Any vaccine remaining in vials must be discarded after 6 hours
- Do not refreeze vials

B- Dosing and Schedule

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart.

There is no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series.

Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

Dose Preparation Prior to Dilution

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative.
- Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] (see Storage and Handling).
- Refer to thawing instructions in the panels below.





THAWING PRIOR TO DILUTION		Pull back plunger to 1.8 mL to remove air from viai	
No more than 2 hours at room	 Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to fine (420 hours) 		 Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
temperature (up to 25 °C/77 °F)	 Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes. Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours. 	Gently x 10	 Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. <u>Do not shake</u>. Inspect the vaccine in the vial. The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
Gently x 10	 Before dilution invert vaccine vial gently 10 times. <u>Do not shake</u>. Inspect the liquid in the vial prior to dilution. The liquid is a white to offwhite suspension and may contain white to off-white opaque amorphous particles. Do not use if liquid is discolored or if other particles are observed. 	Record date and time of dilution. Discard 6 hours after dilution. Dilution date and time:	 Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. Store between 2°C to 25°C (35°F to 77°F). Discard any unused vaccine 6 hours after dilution.

C- Dilution

- Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to dilute the Pfizer-BioNTech COVID-19 Vaccine.
- ONLY use 0.9% Sodium Chloride Injection, USP as the diluent, as it is the only approved diluent per the vaccine leaflet
- Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- Do not add more than 1.8 mL of diluent.
- After dilution, one vial produces only 6 doses of 0.3 mL single doses of the vaccine.
- Gently invert the vaccine vial 10 times. Do not shake.
- Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL.
- The information in this Fact Sheet regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.
- Refer to dilution and dose preparation instructions in the panels below.









D- Administration

- Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension.
- During the visual inspection, monitor the following:
 - Verify the final dosing volume of 0.3 mL.
 - \circ $\,$ Confirm there are no particles and that no discoloration is observed.
 - Do not administer if the vaccine is discolored or contains particulate matter.
- Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.
- After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain up to six doses of 0.3mL.
- Low dead-volume syringes and/or needles can be used to extract up to six doses from a single vial.
- If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
- Irrespective of the type of syringe and needle:
 - $\circ~$ Each dose must contain 0.3 mL of vaccine.
 - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and content.
 - Do not pool excess vaccines from multiple vials.

5 Vaccine administration

Both the vaccinator nurse in the public sector and the pharmacist in the private sector, will follow the below steps to ensure proper and safe





administration of the COVID 19 Vaccine as administration of lipid containing vaccines are directly correlated to their efficacy.

5.1 Administration of IM vaccine in the Deltoid muscle:

- 1. Prepare all the needed supplies for vaccination.
- 2. Sanitize hands according to ICP (hand washing is preferable in settings where it is not possible to use alcohol based hand sanitizer).
- 3. Put on gloves.
- 4. Explain the procedure to the vaccine recipient and ask about preferred arms for vaccine administration since the site might be sore.
- 5. Ask the vaccine recipient to sit with both feet on the ground in order to avoid falls in case of syncope (in recipients has fear of injections)
- 6. Make sure the Deltoid muscle is relaxed
- 7. Find the injection site by first locating the acromion process, once found measure about 2 fingers widths below this area, this will be the injection site.
- 8. Clean the site with an alcohol swab in a clockwise motion and then wait for the site to dry completely
- 9. Quickly insert the needle at a 90-degree angle into the skin.
 - Steady the needle by using the thumb and forefinger of the nondominant hand. This prevents potential damage to the muscle or surrounding tissues along with accidental displacement of medication.
 - Use the dominant hand to inject the solution at a rate of 10 seconds per mL.
 - Once the solution is injected completely, wait 10 seconds before removing the needle. Remove the needle at the same angle it was inserted (90' degrees).
- 10. Discard the syringe and needle it in the sharps container.
- 11. Apply light pressure if bleeding occurs.
- 12. Place adhesive bandage on the vaccination site.
- 13. Remove gloves
- 14. Sanitize hands
- 15. Document vaccination details on the MERA and the recipient immunization card
- 16. Provide patient with immunization card and mark a follow up vaccination date
- 17. Guide the patient to the monitoring area for observation and education





In case of Anaphylactic shock post COVID 19 immunization, the following steps need to be taken by the attending physician:

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MINISTRY OF PUBLIC HEALTH

- Rapidly assess airway, breathing, circulation, and mentation (mental activity).
- Call for emergency support from the ER department at the hospital.
- Place the patient in a supine position (face up), with feet elevated, unless upper airway obstruction is present or the patient is vomiting.
- Epinephrine⁵⁷ (1 mg/ml aqueous solution [1:1000 dilutions]) should be administered immediately.
 - In adults, administer a 0.3 mg intramuscular dose using a premeasured or prefilled syringe
 - The maximum adult dose is 0.5 mg per dose.
 - Epinephrine dose may be repeated every 5-15 minutes (or more often) as needed to control symptoms while waiting for emergency medical services.
 - Because of the acute, life-threatening nature of anaphylaxis, there are no contraindications to epinephrine administration

⁵⁷ Or any pharmacologic alternative





The following supplies should be made available at the vaccination site for cases of anaphylactic shock²:

Mandatory supplies available at all vaccination sites	Supplies available only if feasible (not mandatory)
Epinephrine prefilled syringe or auto injector	Pulse oximeter
H1 Antihistamine (diphenhydramine)	Oxygen
Blood pressure cuff	Bronchodilator (albuterol)
Stethoscope	H2 Antihistamine (famotidine, cimetidine)
Timing device to assess pulse	IV fluids (normal saline)
	Rapid intubation kit
	Adult-sized pocket mask with one-way valve (also known as cardiopulmonary resuscitation (CPR) mask)

6 Vaccine recipient education

The vaccinator nurse will provide each vaccine recipient with education regarding any possible AEFI, how to manage them, when and where to seek care and the way to report any adverse event on the National COVID-19 Registry including the importance of zero reporting.

7 Appointment, arrival, check-in and informed consent if available

8 Post vaccination observation:

Every vaccine recipient will be asked to wait for 15 minutes in the waiting room post vaccination. During this time the registered nurse will monitor the patient for any symptoms of AEFI especially anaphylaxis symptoms and will provide post vaccination education. In case any symptoms appear, the registered nurse will inform the attending physician.

9 Record management:

All patient records will be documented on the National COVID-19 Registry including the consent form (if available), documentation of pre vaccination screening and assessment, post vaccination monitoring. All vaccine recipients will receive a hard copy vaccination card, filled and signed by the vaccinator nurse.





10 Vaccination in special settings

Vaccinator teams deployed for provision of immunization services out of the vaccination sites, in long term healthcare facilities (elderly homes, Rehab centers) and prisons, will abide by the vaccine administration protocol, Infection Prevention and Control measures, and waste management processes detailed in this document.



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Annex 1. Qualifications requirements for vaccinator nurses



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Annex 2. Audit tools

The following audit tools will be used to guide and develop the electronic software to be used:

- Temperature Humidity Monitoring Checklist
- Receiving Checklist
- Inventory sheet
- Censor Calibration Log
- Adverse reaction form
- Audit Checklist
- Quarantine log
- Pest Rodent Control log
- Cleaning checklist





Annex G: Technical Note: Public Consultations and Stakeholder Engagement in WB-supported operations when there are constraints on conducting public meetings

With the outbreak and spread of COVID-19, people have been advised, or may be mandated by national or local law, to exercise social distancing, and specifically to avoid public gatherings to prevent and reduce the risk of the virus transmission. Countries have taken various restrictive measures, some imposing strict restrictions on public gatherings, meetings and people's movement, and others advising against public group events. At the same time, the general public has become increasingly aware and concerned about the risks of transmission, particularly through social interactions at large gatherings.

These restrictions have implications for World Bank-supported operations. In particular, they will affect Bank requirements for public consultation and stakeholder engagement in projects, both under implementation and preparation. WHO has issued technical guidance in dealing with COVID-19, including: (i) Risk Communication and Community Engagement (RCCE) Action Plan Guidance Preparedness and Response; (ii) Risk Communication and Community engagement (RCCE) readiness and response; (iii) COVID-19 risk communication package for healthcare facilities; (iv) Getting your workplace ready for COVID-19; and (v) a guide to preventing and addressing social stigma associated with COVID-19. All these documents are available on the WHO website through the following link: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance.

This Note offers suggestions to World Bank task teams for advising counterpart agencies on managing public consultation and stakeholder engagement in their projects, with the recognition that the situation is developing rapidly and careful regard needs to be given to national requirements and any updated guidance issued by WHO. It is important that the alternative ways of managing consultation and stakeholder engagement discussed with clients are in accordance with the local applicable laws and policies, especially those related to media and communication. The suggestions set out below are subject to confirmation that they are in accordance with existing laws and regulations applying to the project.

<u>Investment projects under implementation</u>. All projects under implementation are likely to have public consultation and stakeholder engagement activities planned and committed as part of project design. These activities may be described in different project documents, and will involve a variety of stakeholders. Commonly planned avenues of such engagement are public hearings, community meetings, focus group discussions, field surveys and individual interviews. With growing concern about the risk of virus spread, there is an urgent need to adjust the approach and methodology for continuing stakeholder consultation and engagement. Taking into account the importance of confirming compliance with national law requirements, below are some suggestions for task teams' consideration while advising their clients:

Task teams will need to review their project, jointly with the PMUs, and should:

- Identify and review planned activities under the project requiring stakeholder engagement and public consultations.
- Assess the level of proposed direct engagement with stakeholders, including location and size of proposed gatherings, frequency of engagement, categories of stakeholders (international, national, local) etc.
- Assess the level of risks of the virus transmission for these engagements, and how restrictions that are in effect in the country / project area would affect these engagements.
- Identify project activities for which consultation/engagement is critical and cannot be postponed without having significant impact on project timelines. For example, selection of resettlement options by affected people during project implementation. Reflecting the specific activity, consider viable means of achieving the necessary input from stakeholders (see further below).





• Assess the level of ICT penetration among key stakeholder groups, to identify the type of communication channels that can be effectively used in the project context.

Based on the above, task teams should discuss and agree with PMUs the specific channels of communication that should be used while conducting stakeholder consultation and engagement activities. The following are some considerations while selecting channels of communication, in light of the current COVID-19 situation:

- Avoid public gatherings (taking into account national restrictions), including public hearings, workshops and community meetings;
- If smaller meetings are permitted, conduct consultations in small-group sessions, such as focus group meetings If not permitted, make all reasonable efforts to conduct meetings through online channels, including WebEx, zoom and skype;
- Diversify means of communication and rely more on social media and online channels. Where possible and appropriate, create dedicated online platforms and chat groups appropriate for the purpose, based on the type and category of stakeholders;
- Employ traditional channels of communications (TV, newspaper, radio, dedicated phone-lines, and mail) when stakeholders to do not have access to online channels or do not use them frequently. Traditional channels can also be highly effective in conveying relevant information to stakeholders, and allow them to provide their feedback and suggestions;
- Where direct engagement with project affected people or beneficiaries is necessary, such as would be the case for Resettlement Action Plans or Indigenous Peoples Plans preparation and implementation, identify channels for direct communication with each affected household via a context specific combination of email messages, mail, online platforms, dedicated phone lines with knowledgeable operators;
- Each of the proposed channels of engagement should clearly specify how feedback and suggestions can be provided by stakeholders;
- An appropriate approach to conducting stakeholder engagement can be developed in most contexts and situations. However, in situations where none of the above means of communication are considered adequate for required consultations with stakeholders, the team should discuss with the PMU whether the project activity can be rescheduled to a later time, when meaningful stakeholder engagement is possible. Where it is not possible to postpone the activity (such as in the case of ongoing resettlement) or where the postponement is likely to be for more than a few weeks, the task team should consult with the OESRC to obtain advice and guidance.

<u>Investment projects under preparation</u>. Where projects are under preparation and stakeholder engagement is about to commence or is ongoing, such as in the project E&S planning process, stakeholder consultation and engagement activities should not be deferred, but rather designed to be fit for purpose to ensure effective and meaningful consultations to meet project and stakeholder needs. Some suggestions for advising clients on stakeholder engagement in such situations are given below. These suggestions are subject to the coronavirus situation in country, and restrictions put in place by governments. The task team and the PMU should:

- Review the country COVID-19 spread situation in the project area, and the restrictions put in place by the government to contain virus spread;
- Review the draft Stakeholder Engagement Plan (SEP, if it exists) or other agreed stakeholder engagement arrangements, particularly the approach, methods and forms of engagement proposed, and assess the associated potential risks of virus transmission in conducting various engagement activities;
- Be sure that all task team and PIU members articulate and express their understandings on social behavior and good hygiene practices, and that any stakeholder engagement events be preceded with the procedure of articulating such hygienic practices.





- Avoid public gatherings (taking into account national restrictions), including public hearings, workshops and community meetings, and minimize direct interaction between project agencies and beneficiaries / affected people;
- If smaller meetings are permitted, conduct consultations in small-group sessions, such as focus group meetings. If not permitted, make all reasonable efforts to conduct meetings through online channels, including WebEx, zoom and skype meetings;
- Diversify means of communication and rely more on social media and online channels. Where possible and appropriate, create dedicated online platforms and chat groups appropriate for the purpose, based on the type and category of stakeholders;
- Employ traditional channels of communications (TV, newspaper, radio, dedicated phone-lines, public announcements and mail) when stakeholders do not have access to online channels or do not use them frequently. Such channels can also be highly effective in conveying relevant information to stakeholders, and allow them to provide their feedback and suggestions;
- Employ online communication tools to design virtual workshops in situations where large meetings and workshops are essential, given the preparatory stage of the project. WebEx, Skype, and in low ICT capacity situations, audio meetings, can be effective tools to design virtual workshops. The format of such workshops could include the following steps:
 - Virtual registration of participants: Participants can register online through a dedicated platform.
 - Distribution of workshop materials to participants, including agenda, project documents, presentations, questionnaires and discussion topics: These can be distributed online to participants.
 - Review of distributed information materials: Participants are given a scheduled duration for this, prior to scheduling a discussion on the information provided.
 - Discussion, feedback collection and sharing:
 - ✓ Participants can be organized and assigned to different topic groups, teams or virtual "tables" provided they agree to this.
 - ✓ Group, team and table discussions can be organized through social media means, such as WebEx, skype or zoom, or through written feedback in the form of an electronic questionnaire or feedback forms that can be emailed back.
 - *Conclusion and summary:* The chair of the workshop will summarize the virtual workshop discussion, formulate conclusions and share electronically with all participants.
- In situations where online interaction is challenging, information can be disseminated through digital platform (where available) like Facebook, Twitter, WhatsApp groups, Project web links/ websites, and traditional means of communications (TV, newspaper, radio, phone calls and mails with clear description of mechanisms for providing feedback via mail and / or dedicated telephone lines. All channels of communication need to clearly specify how stakeholders can provide their feedback and suggestions.
- Engagement with direct stakeholders for household surveys: There may be planning activities that require direct stakeholder engagement, particularly in the field. One example is resettlement planning where surveys need to be conducted to ascertain socioeconomic status of affected people, take inventory of their affected assets, and facilitate discussions related to relocation and livelihood planning. Such survey activities require active participation of local stakeholders, particularly the potentially adversely affected communities. However, there may be situations involving indigenous communities, or other communities that may not have access to the digital platforms or means of communication, teams should develop specially tailored stakeholder engagement approaches that will be appropriate in the specific setting. The teams should reach out to the regional PMs for ENB and Social Development or to the ESSA for the respective region, in case they need additional support to develop such tailored approaches.
- In situations where it is determined that meaningful consultations that are critical to the conduct of a specific project activity cannot be conducted in spite of all reasonable efforts on the part of the client supported by the Bank, the task team should discuss with the client whether the proposed project activities can be postponed by a few weeks in view of the virus spread risks. This would depend on the COVID-19 situation in the country, and the government policy requirements to contain the virus spread. Where it is not possible to postpone the activity (such as in the case of





ongoing resettlement) or where the postponement is likely to be for more than a few weeks, the task team should consult with the OESRC to obtain advice and guidance.





Annex H: Technical note: Use of Military Forces to Assist in COVID-19 Operations Suggestions on how to mitigate risks – Version 1- March 25, 2020

It is common practice for Governments to utilize military or security personnel during public health emergencies. The ability to do this, and the requirements relating to such mobilization, are often set out in executive orders or instructions. A 'public health emergency' will usually be defined under national law. For example, the US Department of Defence (DoD Instruction 6200.03, March 28, 2019) defines a public health emergency to include "the occurrence or imminent threat of an illness or health condition that poses a high probability of a significant number of deaths, serious or long-term disabilities, widespread exposure to an infectious or toxic agent, overwhelmed health care resources, or severe degradation of mission capabilities".

For the reasons set out in section 1 below, it is expected that military or security forces will be utilized in different ways in response to COVID-19. They may be used directly to carry out activities in a World Bank-supported project. Or they may be mobilized more generally to implement Government programs, which are also supported by the Bank. Where military/security forces are utilized, either directly or indirectly, in connection with Bank-supported operations, questions will arise about the risk of the operation. Is it automatically high or are there effective ways of mitigating the risk? This guidance sets out suggestions for due diligence and mitigation measures to address the risk.

1. WHAT ARE THE POSITIVE ASPECTS ABOUT USING THE MILITARY?

Where relevant, consider the following and document relevant details:

• **Human rights:** Depending on the country, military personnel may be aware of the need to respect human rights and received relevant training.

- **"NBC" capabilities**: Many military forces have nuclear, biological and chemical capabilities. They may have existing biological defense capabilities e.g. ability to deploy with personal protective equipment (PPE); training in decontamination; procedures or advice on how to carry out relevant activities.
- **Medical expertise:** Medical and other professionals within the military are likely to be trained to deal with medical emergencies, and therefore may be better able to cope in situations in which there may be mass casualties.
- **Disciplined response:** Generally, military personnel are expected to respond in a disciplined manner to commands and will have capabilities which will be useful in these types of emergencies (medical, engineering, construction).
- **Civic action programs:** Military may also have specific civic action programs and infrastructure to support these (e.g. mobile clinics/communication procedures).

2. WHAT ARE THE THINGS TO WATCH FOR?

- (a) **Diversion of materials, aid and assistance:** Diversion can take the form of confiscations and re-use, misappropriation and theft. While a certain level of diversion may be inevitable in certain circumstances, this issue is likely to present reputational issues (especially when the crisis dissipates).
- (b) Allegations of human rights violations: This will be a risk, including as it relates to Sexual Exploitation and Abuse and Sexual Harassment (SEA/SH), and the Bank needs to be clear and transparent about what measures are being adopted to minimize these risks. Tools that should be





considered include the ESF Good Practice Note (GPN) on <u>Use of Security Forces</u>, on <u>SEA/SH</u>, and the IFC Good Practice Handbook on the <u>Use of Security Forces</u>: <u>Assessing and Managing Risks and Impacts</u>.

- (c) Putting World Bank staff at risk: This is particularly a concern where military/security forces are likely to be undisciplined. The risk may be heightened when Bank staff are trying to address the risk of diversion referred to above. While staff may try to address this risk by avoiding direct interaction with the military, this is not likely to be feasible in a project setting.
- (d) **International media comment and reaction:** This will be a challenge, and it may not be possible to avoid negative comment entirely. It is important to be transparent about the activities the World Bank is supporting and the mitigation measures that are being implemented to address risks.

3. WHAT ARE THE WAYS TO ADDRESS THE RISKS?

- (a) Get a view of the reputation and capability of the military: Talk to those who might have up to date and accurate information: e.g. the Defense Attaché at the relevant Embassy; the US or UK Government; refer to Jane's Defence Weekly.
- (b) **Identify the structure under which the military will be operating:** While they will continue to abide by their own rules and procedures, it is likely that the military will also be subject to relevant national requirements relating to the public health emergency and the specific activities that they are required to carry out e.g. instructions issued by public health officials. In the context of a Bank-supported operation, it is good practice to document (as far as possible) the structure under which the military are operating, including the chain of command, with specific reference to the activities they will or are likely to carry out (see paragraph (i) below).
- (c) **Clarify who is responsible for human rights issues nationally:** Many countries have a Human Rights Commission. If such commissions do not exist, there is usually an Ombudsman, Human Rights office or inspector general at the national level with jurisdiction to deal with such issues. Identify the relevant parties and consider whether it would be appropriate to consult them for advice.
- (d) Identify other specialized parties and ask for advice: There are both national and international NGOs which follow and support these issues (e.g. Human Rights Watch (HRW), Amnesty). There is also the International Committee of the Red Cross (ICRC) and the International Crisis Group. Identify relevant parties, with reference to the context and nature of the operations, who may be in a position to provide valuable advice.
- (e) As required under the ESF, cooperate with relevant stakeholders on a risk assessment: Carry out a risk assessment to identify the specific risks associated with the proposed use of military. This assessment needs to be conducted with those that are involved in the operation, including Government counterparts, to ensure that an accurate picture of the risks emerge, that appropriate mitigation measures are identified and that both the risk assessment and the mitigation measures are owned by the project and the Government.
- (f) **Be transparent about what the World Bank is requiring to mitigate the risks:** Document this, setting out key aspects in the ESRS and other project documentation. Consider the following:





- procedures relating to: e.g. risk assessment; how allegations of HR/SEA/SH violations will be dealt with, including through the project Grievance Mechanism (GM); preventing diversion of materials, aid and assistance (build on existing requirements)
- presence of World Bank representatives/third party monitors on the ground
- cooperation with specialist institutions/NGOs/Government agencies
- specific obligations set out in the legal agreement and (if possible and appropriate) a
- Memorandum of Understanding (see paragraph (k) below)
- monitoring and reporting
- (g) **Consider asking a credible party to act as an observer/third party monitor:** This can be considered under the ESF provisions for third party monitoring as noted in ESS1 and ESS10, as well as the ESF Good Practice Note on Third Party Monitoring. Relevant groups with experience in this field will depend on the context, and may include the parties referred to in paragraph (d) above.
- (h) Establish a procedure to be followed in cases of allegations of HR/SEA/SH violations or misbehavior: This should reflect the ESF Good Practice Note on SEA/SH and may include reference to the institutions referred to in paragraph (c) above. Include a specific HR and SEA/SH procedure in the project GM to address these allegations and identify specific individuals who have the expertise to address such allegations credibly. Understanding relevant Code of Conduct (CoC) requirements pertaining to such behavior is important, and, where necessary, improving the form and substance of such CoC.
- (i) Be clear on what the military will do: Identify the activities and set them out clearly in the legal agreement: e.g. construction, enforcing quarantine restrictions, distribution of medical supplies or vaccines, distribution of other supplies. This will support a more accurate risk assessment. Note that in some circumstances, what could otherwise be viewed as inappropriate behavior by the military (or at an extreme, a possible abuse of rights) may be authorized and necessary in situations of a public health emergency. This will depend on the activities that the military is required to carry out and will be particularly relevant where they are required to enforce public order or quarantine restrictions.
- (j) Set out specific requirements as covenants in the legal agreement and in the Environmental and Social Commitment Plan (ESCP) as appropriate: The provisions should set out the 'ground rules' for military engagement, including: (i) requirements to comply with ESS4 (see Annex attached); (ii) reporting obligations (specify on what, how often, to whom); (iii) specific prohibitions e.g. no child labor, no forced labor, restrictions on what military personnel under the age of 18 can do (if anything); (iv) health and safety requirements; (v) Code of Conduct (CoC) type obligations; (vi) requirements for the GM; (vii) training required and how often (specify on what – e.g. Voluntary Principles on Security and Human Rights, interactions with the community, operation of the GM, use of personal protective equipment (PPE), CoC).
- (k) Where possible, and if not already covered by applicable law/regulation, the Government should consider executing a Memorandum of Understanding (MoU) with the military: This should reflect the 'ground rules' set out in the legal agreement (see paragraph (j) above). An example of a MoU is available in the IFC Good Practice Handbook on the Use of Security Forces: <u>Assessing and Managing Risks and Impacts</u>. Even where it is not possible for individual military personnel to sign a CoC, the requirements should be set out in the MoU, and training should cover these obligations (amongst others).





ANNEX

Set out below is suggested wording on HR/SEA/SH:

1. Prior to deploying military or security personnel, the [Borrower/Recipient] shall take measures to ensure that such personnel are:

- i. screened to confirm that they have not engaged in past unlawful or abusive behavior, including sexual exploitation and abuse (SEA), sexual harassment (SH) or excessive use of force;
- ii. adequately instructed and trained, on a regular basis, on the use of force and appropriate behavior and conduct (including in relation to SEA and SH), as set out in the [*Training Procedure, Project Operational Manual, ESMF, Security Management Plan, MoU*]; and
- iii. deployed in a manner consistent with applicable national law.
- 2. The [Borrower/Recipient] shall promptly review all allegations of unlawful or abusive acts of any military/security personnel, take action (or request appropriate parties to take action) to prevent recurrence and, where necessary, report unlawful and abusive acts to the relevant authorities.

Set out below is suggested wording on reporting: Frequency of reporting will depend on the context and the risks associated with the activities the military is carrying out, and may be required monthly, weekly or even daily. Requirements should include:

- Immediate reporting (within 24 hours) of any serious incident
- A written weekly or monthly report (depending on the risk) covering
 - o status of activities being conducted by the military
 - training conducted (specifying subject matter)
 - o current status of review of serious incidents (if any) and any relevant reporting
 - o a summary of any minor (but reportable) issues, suspected incidents or potential issues
 - o details of any incidents involving use of force or weapons
 - details of upcoming activities which may pose a risk (e.g. distribution of supplies) and measures being put in place to reduce such risk
 - o lessons learnt, to inform conduct of future activities

Other reference documentation: <u>The International Code of Conduct under the Montreux Document.</u> While this relates to private security, it contains useful material.

Annex I: Form on Adverse Event Following Immunization Reporting Form for COVID-19 Vaccine(s)



Quality Management System

Adverse Event Following Immunization **Reporting Form for COVID-19 Vaccine(s)**



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Reporter, beneficiary & institution identities will remain confidential / Questions with an asterisk(*) sign are mandatory						
First Report			□ Follow Up Report			
1) Beneficiary Deta	ils *					
Name (or initials)						
Gender			□ Male	Female	□Pregnant	
					□ Lactating	
Date of birth						
Age at onset		Weight (kg)			Height (cm)	

2) Risk Factors *						
Renal disease		□ Hepatic disease	Cardiac disease			
Smoker		- Supplement use/ Specific				
Occasional Frequent		□ Supprement use/ Specify:	Other medical			
□ Alcohol intake			condition/ Specify:			
Occasional	□ Frequent	□ Allergy/ Specify:				

3) Vaccine	(s)							
Health Fac *	ility / Vaccina	tion Center	Name & A	Address				
Name of	Manufacturer	Expiry	Batch	Dose (1 st ,	Date of	Time of	Route of	Site of
Vaccine	Name	Date	Number	2 nd , etc.)	Vaccination	Vaccination	Administration	Injection

Diluent(s) (if applicable)								
Name of Diluent	Expiry Date	Batch Number	Date & Time of Reconstitution					

Concomita	Concomitant medicine(s) (if applicable)									
Medicine Brand Name + Active Ingredient	Indication	Off Label Use	Batch Number	Expiry Date	Dose, Frequency, Dosage Form & Route of Administration	Started on	Stopped on			

			Day	Month	Year	Day	Month	Year
			Day	Month	Year	Day	Month	Year



Quality Management System

Adverse Event Following Immunization Reporting Form for COVID-19 Vaccine(s)



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			Day	Month	Year	Day	Month	Year

Country of occurrence									
Suspected Adverse Event Following Immunization		O	Onset Date				Date (if ap	plicable)	
		Time (Hr and Min) Day		Month	Year	Time (Hr and Min)	Day	Month	Year
Local Reaction (Redness, Swelling)									
Fever \geq 38 C			T						
Allergy									
Fatigue			1						
Headache									
Pain at the injection site									
Febrile Seizure Afebrile Seizure									
Abscess									
Sepsis									
Encephalopathy									
Toxic Shock Svndrome									
Thrombocytopenia									
Anaphylaxis							1		
Other/ Specify:									
Adverse Event Following	g Immunization F	Description / (Case N	arrative (I	Developme	ent, Symptoms	s, Manage	ment, etc.)	
Relevant Laboratory and Diagnostic Test Performed	Date			Result					
--	------	-------	------	--------					
	Day	Month	Year						



Quality Management System

Adverse Event Following Immunization **Reporting Form for COVID-19 Vaccine(s)**



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5) Seriousness of	Adverse Event F	ollowing Immunization *				
		If yes, please indicate why				
		The Adverse Event led to:				
		□ Death	Date of Death Cause of Death			
		□ Life Threatening Situation				
	- Vec	Hospitalization				
Serious	□ Yes □ No	□ Prolongation of Hospitalization	Specify Additional Duration			
		□ Surgical Intervention				
		Congenital Anomaly				
		Persistent or Significant Disability	Persistent or Significant Disability or Incapacity			
		Other Serious Consequences				

6) Outcom	e of Adverse Event Following Immunization*
Actual Status of Beneficiary	Recovered
	Recovered with Sequelea
	Specify Sequelea
	Is Recovering
	No Improvement
	🗆 Fatal
	🗆 Unknown
7) Possible	Cause(s) of Adverse Event Following Immunization

•	()	5		
Questions		Yes	No	

Can the Adverse Event Following Immunization be due to:				
• Vaccine Product-Related Reaction	□ Yes	□ No		



Quality Management System

Adverse Event Following Immunization Reporting Form for COVID-19 Vaccine(s)



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 Vaccine Quality Defect- Reaction 	□ Yes	□ No
• Immunization Error-Related Reaction	□ Yes	□ No
 Immunization Anxiety- Related Reaction 	□ Yes	□ No
• Coincidental Event	Yes	□ No

Additional Note

Tell us more about any extra relevant information/complementary investigation not mentioned in the previous questions

8) Reporte	r *				
Who are you Beneficiary	? Vaccinator	Other Healthcare Professional	Responsible Party for Pharmaceutical Products	Drug Distributor	Others (Beneficiary's Relatives, Neighbors, etc.)
Name (or initi	als)				
Profession or	Specialty				
Professional A	Address				
Email Addres	s				
Phone Numbe	r				
Signature					
Date					
Please send	the completed forn For any addition	n filled electronically or man nal information, you may con	ually to the following email: <u>p</u> ntact <u>01/830255 o</u> r <u>01/830254</u>	<u>v@moph.gov.lk</u>	<u>)</u> or <u>phvg.phar@ul.edu.lb</u>