Georgia COVID-19 Vaccine National Deployment Plan

Approved by the Governmental Resolution #67 as of January 21, 2021

January 18, 2021

Abbreviations

ADB	Asian Development Bank
AEFI	Adverse Events Following Immunization
AESI	Adverse Events of Serious Interest
ECDC	European Centre for Disease Prevention and Control
ICC	Interagency Coordination
ILI	Influenza-Like Illness
IMEM	Immunization Management Electronic Module
LIC	Low Income Countries
MoILHSA	Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs
NCDC	National Center for Disease Control and Public Health
NITAG	National Immunization Technical Advisory Groups
NRA	National Regulatory Authority
PCR	Polymerase Chain Reaction
PHC	Primary Health Care
SARI	Severe Acute Respiratory Infection
UESOS	Unified Electronic Disease Surveillance System
UNICEF	United Nations Children Fund
WB	World Bank
WHO	World Health Organization

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Introduction

The new coronavirus (SARS-CoV-2) and the illness it causes (COVID-19) are posing a great challenge to all mankind, particularly as the pandemic bears unprecedented economic costs in the wake of human loss. Dealing with COVID-19 has become a top priority for all governments.

Georgia began to prepare for the epidemic at an early stage. The containment measures the government imposed in the spring of 2020, along with the steps it took to overcome the crisis, helped to mitigate the negative effects associated with COVID-19, allowing a gradual easing of restrictions to begin in May of the same year. But due to various factors, as well as regional trends, the increase of new coronavirus cases in Georgia began to intensify in September, leading to massive spread of infection throughout the country. Increase in incidence has led to the red alert level for critical epidemiologic control parameters such as the reproduction number, the mortality rate, the test positivity rate and the use of hospital resources in the country. In reaction, in the late autumn, the government once again imposed mandatory targeted prohibitive measures and expanded mobility restrictions for prevention and stabilization of the infection spread. At the moment, this is the most effective approach to managing the pandemic, but it places a great burden on the country's economy and hinders the normal functioning of the education sector and the further development of the country. As of December, the confirmed cases per 100,000 people in Georgia was 5,834, while the estimated infection rate was 15% of the population. The recovery rate was 89% of infected and the case fatality rate-1%. COVID-19 became the leading cause of death in the country during the autumn, and by end of 2020 it will be the fourth leading cause of death.

To stabilize the existing situation and save more lives until an etiotropic drug against COVID-19 is developed, the optimal solution would be to introduce and administer safe and effective vaccines against COVID-19, which is ultimately the key to containing an epidemic.[1]

An Interagency Coordination Commission chaired by Georgia's Minister of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs (the MoILHSA) was established to facilitate the development and implementation of a COVID-19 vaccination policy in Georgia.[2]

The preparation of the vaccination implementation plan has been coordinated by the National Center for Disease Control and Public Health (NCDC). A team of experts was involved in the process with the support of the Asian Development Bank.

[1] Leung, K., Wu, J.T., Liu, D., & Leung, G.M. 'First-wave COVID-19 transmissibility and severity in China outside Hubei after control measures, and second-wave scenario planning: a modeling impact assessment.' Lancet 395, 1382-1393 (2020).

[2] Decree #2459 of the Government of Georgia on the Establishment of the Interagency Coordination Commission for the Implementation of COVID-19 Vaccination in Georgia, December 15, 2020.

A methodological document proposed by the World Health Organization (WHO) was used as a guidance.[3] Eight technical working groups were established in different thematic areas; these included industry experts, representatives of various agencies in the healthcare sector and service providers and development partners (see Annex 1). Through multilateral consultations and discussions, this document was developed as a series of guidelines for the implementation of the COVID-19 vaccination process.

The COVID-19 Vaccine Deployment Plan outlines the actions, responsibilities and financial resources required for an effective vaccination process in Georgia. Due to the constantly changing situation, and given the ongoing global developments in vaccine trials, registration, production, distribution and supply, Georgia will introduce periodic changes to and adapt its COVID-19 Vaccine National Deployment Plan according to new information.

Georgia's State Immunization Program

The state immunization program in Georgia provides free vaccinations according to immunization schedules based on the epidemic situation in the country. Vaccination is regulated by the Law on Public Health[4] and by subordinate normative acts.[5] The program has a traditionally well-maintained cold chain network, monitoring and surveillance system. Immunization rates are high for most vaccines, although for some antigens these lag behind both regional and country annual targets (95% of target population), primarily due to: less interest in vaccination among the private primary health care providers; low staff motivation; busy work schedules; weak communication between primary healthcare facilities and public health services; and parental resistance to vaccination (especially in large cities).

Since 2013, the state program has been carrying out influenza vaccination in pre-selected risk groups in accordance with the recommendations of the WHO. The number of vaccines purchased has been increasing from year to year and the list of vaccinated priority risk groups has been expanding. For the 2020-21 season, 235,000 doses of influenza vaccine have been imported and the coverage rate (by January 6, 2021) is 75%.

The capabilities and resources of the National Immunization Program are reflected in the given COVID-19 Vaccine Deployment Plan and will be optimally used to scaleup the immunization campaign nationwide, while existing shortcomings of the immunization program and the attitude of the population towards routine vaccines are considered in the sections of the service delivery and communication strategy.

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[3] "Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines". Geneva: World Health Organization, 2020 (WHO/2019-nCoV/NDVP/2020.1). Licence: CC BY-NC-SA 3.0 IGO

[4] Law of Georgia on Public Health, June 27, 2007

[5] Order of the Minister of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia on approving the National Calendar of Prophylactic Vaccinations, the list of infectious diseases for which prophylactic vaccinations are mandatory and age indicators, deadlines and immunization management rules, /01/16 09/2019.

Candidate and Authorized COVID-19 Vaccines

Due to the fact that information about the expected COVID-19 vaccines is constantly changing and updated daily, and that the timing of vaccine delivery is unclear and uncertain, the existing plan is mostly based upon information publicly available as of 14 January 2021 and considers the possibility of introducing the following vaccines in the country:

Table 1. Review of Candidate Vaccines as of January 14[6]

Manufacturer	Vaccine type	Required dosage and interval	Dosage/volume	State of development	Expected or received authorization
BioNTech/Pfizer	mRNA	2 doses, 0-21 Days	1 dose = 0.3 ml IM	Emergency Authorization: United Kingdom, USA, Canada, European Union	December 2020
Moderna/Lonza	mRNA	2 doses, 0-28 day	1 dose = 0.5ml IM	Emergency Authorization: USA, European Union	December 2020
Oxford/Astra-Zeneca	Non-replication virus vector	(1-) 2 doses 0, 28 day	1 dose = 0.5ml IM	Emergency Authorization: United Kingdom, Phase 3: USA, Argentina, Chile, Brazil, India	January 2021
Sinopharm	Inactivated virus	2 doses, 0-14 day	1 dose =0.5ml IM	Phase 3: Peru, Argentina, Bahrain, United Arab Emirates, Jordan Egypt	Received registration in UAE in December 2020
J&J/Janssen	Non-replication virus vector	(1-)2 doses 0, 56 day	1 dose =0.5ml IM	Phase 3: USA, Argentina, Brazil, Belgium, Columbia, other	Year 2021
SP/GSK	Recombinant	2 doses, 0-28 day	1 dose =0.5ml IM	Phase 3: USA	Year 2021
Sinovac Biotech Co., Ltd	Inactivated virus	2 doses, 0-14 day	1 dose =0.5ml IM	Phase 3: China, Chile, Turkey, Indonesia, Brazil	Year 2021
Novavax	Viral protein component	2 doses, 0-21 day	1 dose =0.5ml IM	Phase 3: United Kingdom, USA, Mexico, Puerto Rico	Year 2021
Serum Institute of India	Viral protein component	2 doses, 0-28 day	1 dose =0.5ml IM	½ phase: Australia	Year 2021

Two vaccines—Pfizer/BioNTech and Moderna—have already been authorized by the US and the European

[6] Information was extracted on December 22, 2020. https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/

Union (and other stringent regulatory authorities) and have been approved by the WHO in the list for emergency use,[7] whereas the Oxford/Astra-Zeneca vaccine has been authorized by the United Kingdom and is awaiting authorization by the European Union and the WHO in January. All these vaccines have only been authorized for emergency use.[8] The Sinopharm vaccine was authorized in the United Arab Emirates[9] on December 9, 2020.

It should also be noted that most of the vaccines in the table are stored at +2-8°C except for the Pfizer/BioNTech and Moderna vaccines, which must be stored at -70°C and -20°C, respectively. The plan is therefore based on the potential use of vaccines with three temperature regimen, although due to various considerations and logistical challenges, the use of the Pfizer/BioNTech vaccine as well as the Moderna one is mainly considered during the first phase of the program. At the same time, the maximum possible dose quantity to be obtained for both vaccines was only determined for the first 3% of the population, i.e. the priority groups. From the second quarter of 2021, it will probably be possible to receive +2-8°C vaccines, for which Georgia's cold chain and other logistics systems are fully adapted.

When selecting candidate vaccines, the country will apply the following criteria: (a) the stage of vaccine development and licensing, and the expected timeframes for market entry; (b) the temperature regime required for a vaccine storage and the related cold chain requirements (complexity and difficulty); (c) the possible registration dates for a particular vaccine by stringent regulatory authorities; (d) the presence of the vaccine in the COVAX platform;[10] and (e) the potentially negative attitude of a population towards specific vaccines based on their producers or countries of production, registered side-effects that may occur during vaccination programs in other countries, and accumulated evidence of vaccine impact on the disease prevention.

The Regulatory Environment

The rapid introduction of COVID-19 vaccines requires the full readiness of the country's regulatory body and of the MoILHSA as well as of other relevant structures, so that the process of importing the vaccines runs smoothly.

According to Georgian legislation, there are two ways[11] in which a pharmaceutical product can be registered in Georgia. The basis for the application of a **Recognition Regime** for pharmaceutical products is the

[7] The Emergency Use Listing Procedure is defined by the World Health Organization for new and unlicensed products (vaccines, therapeutics and diagnostics) for use primarily during public health emergencies. See *Emergency use listing procedure* (who.int)

[8] An Emergency Use Authorization is a mechanism which is used by the regulatory organs of a country during public health emergencies, such as pandemics, to facilitate the availability of unapproved vaccines or other medical countermeasures which are vital to treating a disease or containing its spread. Such authorization is only given when there are no adequate alternatives and when a product satisfies certain statutory requirements of a regulatory body in terms of its safety and efficacy. See https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

[9] https://www.nature.com/articles/d41586-020-03563-z

[10] Information extracted on January 14, 2020: https://www.unicef.org/supply/covid-19-vaccine-market-dashboard.

[11] Law of Georgia on Drugs and Pharmaceutical Activities, August 10, 2009.

differentiation made between state bodies of other countries or interstate regulatory authorities regulating such products in their own markets according to their credibility and their ability to allow the market access for only high-quality pharmaceutical products. Specifically, for markets under its control, Georgia unilaterally recognizes the quality requirements demanded by stringent regulatory agencies of foreign states or interstate regulatory authorities regarding the safety, efficacy and quality of pharmaceutical products, and does not carry out another expertise with the same or similar requirements in order to determine the safety, quality and therapeutic effect of a pharmaceutical product.

Such stringent regulatory authorities (European Medicines Agency and regulators from 37 countries),[12] the time required for the procedure (15 working days),[13] registration rules and conditions[14] are defined by bylaws.

The rules and conditions of the **National Registration** of a pharmaceutical product envisages the administrative and scientific and technical examination[15] of its registration documents. A three-month period is defined for the registration of immunological biological drugs (including vaccines).

None of the regimes contain provisions for emergency situations and appropriate exceptions.

Georgian legislation does define exceptional circumstances[16] for the entry regime of pharmaceutical products on the Georgian market, according to which, products are granted a one-time registration under special conditions (e.g. natural disasters, massive harm, epidemics, rare diseases) for humanitarian purposes or for other special state interests with the consent of the MoILHSA. The rules that apply to the importation of a pharmaceutical product in such a manner are defined by a normative order.[17] The time for importing a pharmaceutical product (along with all required documents) is usually no more than a few days. Accordingly, the COVID-19 vaccine will be allowed to be imported and used in Georgia under the one-time registration rule once it has been authorized by the stringent regulatory authority or has been included in the WHO's Emergency Use Listing.

The documents required for a single registration and customs clearance will be submitted in advance to the

[12] Regarding the definition of a list of the state regulatory bodies of other countries or international regulators of pharmaceutical products. Resolution N188 of the Government of Georgia of October 22, 2009.

[13] Regarding the establishment of rules and conditions for verifying the authenticity of an authorization given to a product issued by the relevant state body of another country or an interstate regulatory body authorizing pharmaceutical products to enter markets under their control – for the official (state) registration of a pharmaceutical product on the Georgian market through the recognition regime, and for allowing the different packaging of a pharmaceutical product already registered on the Georgian market.

[14] Order N 344 / N of the Minister of Labor, Health and Social Affairs of Georgia, October 23, 2009

[15] Law of Georgia on Drugs and Pharmaceutical Activities, August 10, 2009 (Article 11^{11}).

[16] Law of Georgia on Drugs and Pharmaceutical Activities, August 10, 2009 (Article 11^{13}).

[17] Regarding the approval of a rule for a pharmaceutical product without authorization to enter the Georgian market, granting permission to enter the country's market by bypassing the entry regime to the Georgian market with non-commercial intentions under special circumstances (e.g. natural disasters, massive harm, epidemics, rare diseases) for humanitarian purposes or for other special state interests with the consent of the Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia. Order of the Minister of Labor, Health and Social Affairs of Georgia N 327 / N of October 13, 2009.

relevant agencies, which will minimize the time the pharmaceutical product will be held at the border.

The vaccine purchasing entity deals with the formal side of customs (submission of documents, customs clearance, warehousing, logistics to destination, etc.) to ensure the one-time registration and importation of shipment with exemption. After confirmation, the documents are uploaded to the portal of the Revenue Service, the documentation is reviewed immediately, and the cargo is placed in the central warehouse of the NCDC no later than 24 hours after entering the country.

It should be noted that there is no universal agreement on a uniform format and content for vaccine vials and packaging, although WHO has already developed a model for the unification of secondary packaging for vaccine labeling to be used by COVAX.[18] Manufacturers will also not take into account country requirements for packaging and labeling. Georgian legislation does not restrict the admission of a pharmaceutical product whose packaging is not in Georgian but requires the translation of the documentation (annotation) into Georgian. Due to the emergency situation, Georgia will assume responsibility for translating annotations into Georgian.

In light of the fact that manufacturers will not have insurance coverage that would protect them from risks associated with the possible side-effects of vaccination, manufacturers are requesting each country to shoulder this responsibility and to indemnify the manufacturer in this manner. This requires amendments to Georgian legislation that will be introduced in Georgia's Parliament by the end of January 2021.[19]

Legislative amendments will be introduced in Georgia to the Law on Public Health,[20] and the state itself will assume responsibility for any harm caused by the COVID-19 vaccine use, as defined by existing legislation for vaccines included in the National Immunization Calendar.

Table 2. Assessment of the regulatory environment and requirements for the introduction of a COVID-19 vaccine in Georgia

Field	Change/Action	Status
Regulatory environment regarding the freeing of producers from responsibility	Required	Amendments will be introduced by the end of January 2021
Annotation translation into Georgian	Required	After vaccine selection will be done by the purchaser (state)
Trainings	Not required	
Electronic systems	Not required	
Standard operation procedures, methodological recommendations	Not required	

[18] https://www.who.int/teams/regulation-prequalification/eul/covid-19/covid-19-model-packaging.

[19] Additional Information on Indemnification for COVAX AMC Participants, Working draft under discussion. Briefing note, November 2020.

[20] Georgia's law on Public health, Legislative Herald of Georgia, №26, 11.07.2007, art. 244

Organizational Structure and Coordination of the Vaccination Program

The effectiveness of the introduction of COVID-19 vaccination will depend on the management and coordination of planned activities at all decision-making levels. As mentioned above, Georgia has established a COVID-19 vaccine deployment interagency coordination commission to coordinate and monitor the elaboration and implementation of the Plan.

Table 3 and Figure 1 indicate the components of vaccination introduction, the responsible parties for vaccination, and decision-making and implementation levels.

Table 3. Components of Vaccination Introduction and Responsible Parties

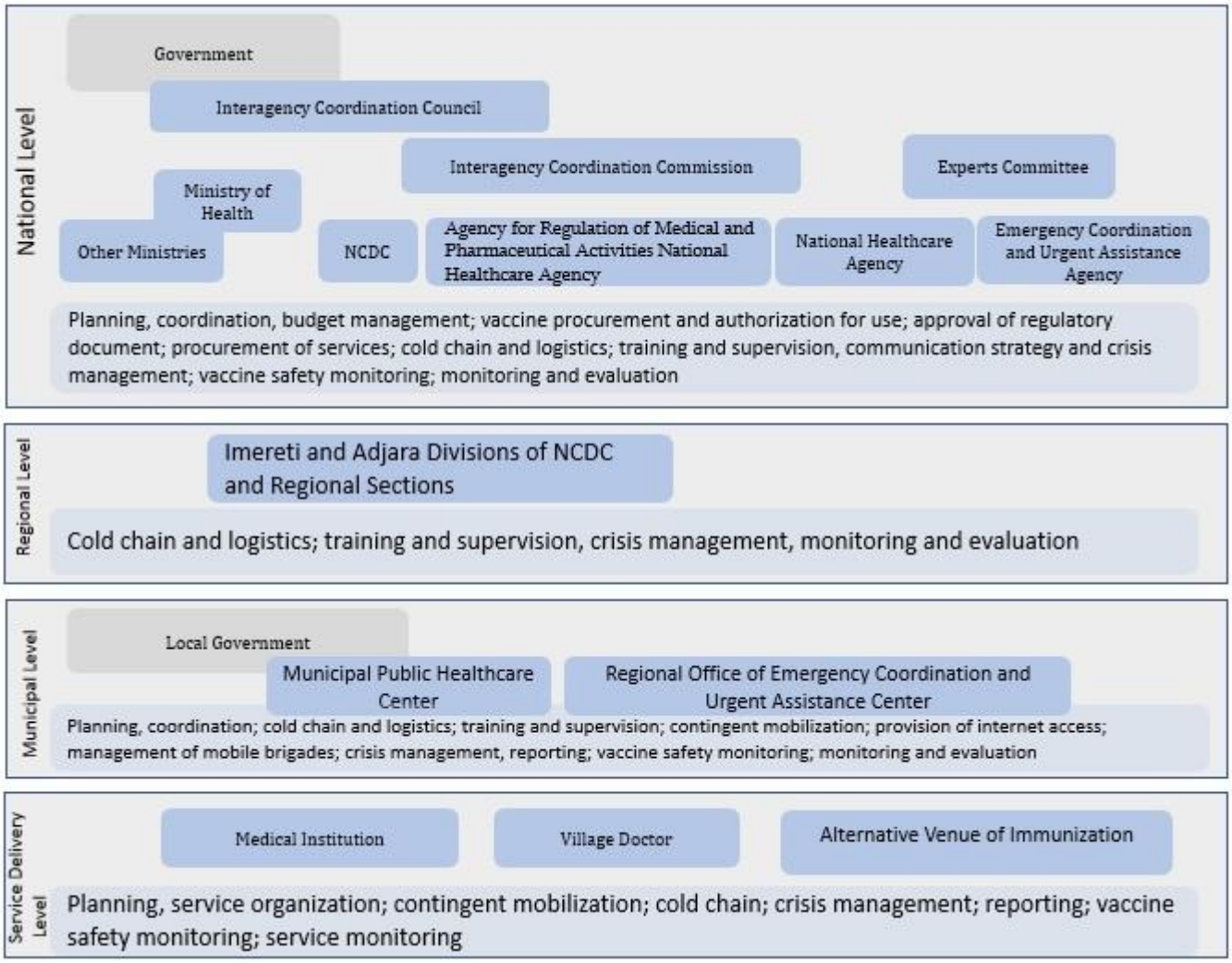
Component	Responsible Party
Coordinating and monitoring the implementation of the COVID-19 Vaccine National Deployment Plan	Interagency Coordination Commission
Ensure the process of preparing a National Vaccination Introduction Plan	NCDC with Support of Donors
Preparing a National Vaccination Introduction Plan	Technical Working Group
Considering recommendations on priority groups	National Immunization Technical Advisory Group (NITAG)
Approval of National Vaccination Delivery Plan	Government
Procurement of Vaccines	Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia
Procurement of consumables	NCDC
Placing vaccines on the market Procurement of immunization services from medical organizations or institutions	Medical and Pharmaceutical Regulatory Agency / Relevant Commission of the Ministry[21] NCDC
Training and supervision locally	NCDC
Local supervision	Municipal Public Health Centers
Vaccine storage, central level logistics	NCDC
Vaccine storage, logistics at national level Vaccine logistics at municipal level Coordination of the contingent to be vaccinated	NCDC Divisions and Regional Offices Municipal Public Health Centers Local Government, Medical Service Providers Regional services of the Emergency Coordination and Emergency Assistance Center
Assistance in Service Organization	Local Government
Vaccination of the Contingent by Mobile teams	Municipal Public Health Centers and service providers jointly
Immunization of the Contingent to be Vaccinated	Service providers
Implementation of Communication Strategy Monitoring of adverse effects following vaccination Monitoring and Evaluation	All levels Medical and Pharmaceutical Regulatory Agency NCDC, Service Providers NCDC
International Coordination and Cooperation	Government, Donors, Partners

[21] By order of the Minister of Labor, Health and Social Affairs of Georgia N 327 / N of October 13, 2009.

The involvement of local authorities is of particular importance in the planning, mobilization and service organization of the contingent to be vaccinated locally. More precisely, local authorities should assist COVID-19 vaccination on their territories, and in order to do so must develop and approve local plans for the implementation of this vaccination approved by the regional unit of the COVID-19 Response Interagency Coordination Committee, which should include the following components (as a minimum):

- In order to implement the service:
    - Allocating additional vaccination areas for mass vaccination centers (where needed)
    - Providing quality internet connections to selected vaccination sites
    - Mobilizing volunteers for vaccination teams (where needed)
- In order to mobilize population groups for vaccination:
    - Ensuring the transportation of certain population groups to be vaccinated in order to increase geographical availability
    - Preliminary listing of people with physical disabilities in order to ensure they are vaccinated
    - Mobilizing volunteers for information campaigns
    - Using every means of communication in order to mobilize the population.

Figure 1. Decision-making and Implementation Levels



Resources and Funding

During the epidemic, COVID-19 vaccination in Georgia will be available free of charge for Georgian citizens.

Table 4 presents the program components, funding sources and current funding status for COVID-19 vaccination.

Table 4. Resources Required for Vaccination and their Current Status

Component	Financial needs are calculated	Source of funding	Provision as of today
Vaccines and Consumables	Yes	State Budget	Partially
Cold Chain	Yes (no need for extra resources)	_	_
Logistics	Yes	State Budget	Partially
Service	Yes	State Budget	Funds need to be allocated
Training and Surveillance	Yes	Donors	Partially Obtained
Information System	Yes	State Budget or Donors	Funds need to be allocated
Demand Creation and Communication	Yes	Donors and State Budget	Small initial funds have been obtained
Compensation in case of damage linked to immunization	No	State Budget	
COVID-19 Vaccine Readiness Support	Yes	Donor Support (Asian Development Bank, World Bank, WHO)	

Necessary Financial Resources

The financial resources needed for the introduction of a COVID-19 vaccine include costs the vaccine itself, the procurement of consumables and operational costs. These financial resources were estimated for the purchase of 1,484,400 doses of vaccine guaranteed by the COVAX platform, as well as those required for the total coverage of all the priority groups (described below) and the entire financial resources needed to cover 60% of the adult population. Financial needs according to the components of the immunization program are summed up in Table 5 below.

Table 5: Necessary financial resources for COVID-19 vaccination by component

Component	Necessary financial resources for covering doses guaranteed by COVAX only		Necessary financial resources for covering every priority group		Financial resources necessary for covering 60% of the adult population*	
	Min. cost (GEL)	Max. cost (GEL)	Min. cost (GEL)	Max. cost (GEL	Min. cost (GEL)	Max. cost (GEL)
Vaccines	18,075,539	44,767,084	23,794,534	80,906,555	48,456,260	141,985,429
Syringes and other supplies and consumables	1,847,586	1,847,586	2,439,291	2,566,744	4,960,082	5,087,534
Service delivery	3,208,259	3,280,891	4,457,048	4,555,951	8,834,300	9,034,300
Trainings	24,927	24,927	24,927	24,927	34,900	34,900
Vaccine logistics/ distribution	82,040	82,040	113,975	113,975	164,085	164,085
Information system**	60,900	60,900	84,605	84,605	167,695	167,695
Supervision and monitoring of the vaccination process	26,746	26,746	37,156	37,156	53,500	53,500
Demand generation and communication	1,662,800	1,662,800	1,662,800	1,662,800	1,662,800	1,662,800
Total budget	**24,988,797**	**51,752,974**	**32,614,336**	**89,952,713**	**64,333,622**	**158,190,243**

* At this stage, financial estimates include neither the cost of creating mass vaccination centers and their operational costs, nor that of establishing and operating special inter-sectoral groups for managing immunization. These calculations will be done later.

** Financial resources for information systems only imply necessary expenditure on additional staff (e.g., for the seamless functioning of a hot line), and do not include the costs of creating new software for electronic modules or the necessary technical support for improving existing ones.

As is shown in the table, 72-89% of total financial needs is necessary for vaccine purchase. Service delivery is the second-largest financial component, representing 6-13% of the total budget.

Four scenarios were developed for estimating the financial resources needed to implement a COVID-19 vaccination according to four different types of vaccine. These scenarios are given schematically in Table 6.

In order to cover 60% of the adult population, and considering vaccine wastage, it is necessary to purchase a total of 3,979,327 doses. Currently, Georgia is planning to purchase a guaranteed 1,484,400 doses of vaccine from the COVAX platform during 2021, despite the fact that the financial resources were calculated for 3,979,327 doses with the assumption that the country will be able to receive an additional 2,494,927 doses from alternative sources.

Table 6: Scenarios

	Scenario I		Scenario II		Scenario III		Scenario IV	
	AstraZeneca	Pfizer	AstraZeneca	MODERNA	AstraZeneca	Any other 2-8 C	AstraZeneca	
Any sources		200,000		200,000		200,000	200,000	
COVAX	1,484,400		1,484,400		1,484,400		1,484,400	
Any sources	2,294,927		2,294,927		2,294,927		2,294,927	

- **Scenario 1:** 200,000 doses of Pfizer/BioNTech vaccine become available in Georgia alongside 1,484,400 doses of the AstraZeneca vaccine from the COVAX platform, and the country also

imports the additional amount of vaccines necessary for vaccinating 60% of the adult population—i.e. in total, 3,979,327 doses of vaccine are imported in the country.

- **Scenario 2:** Georgia imports 2,000,000 doses of the Moderna vaccine, 1,484,400 doses of the AstraZeneca vaccine from the COVAX platform, and the additional amount of doses needed to vaccinate 60% of the adult population (3,979,327 doses in total).
- **Scenario 3:** Georgia imports 2,000,000 doses of any of the+2-8°C temperature regime vaccines,[22] 1,484,400 doses of the AstraZeneca vaccine from the COVAX platform and additional AstraZeneca vaccines from other sources (3,979, 327 doses in total).
- **Scenario 4:** Georgia imports only the AstraZeneca vaccine to fully cover all priority groups and other additional population groups (3,979,327 doses in total).

The methodology for calculating the financial needs of every component of the immunization program as well as detailed calculations according to different scenarios are given in Annex 2.
Additional tables giving detailed calculations for each scenario can be found in Annex 2.

Priority Groups and Vaccination Strategies

Target population groups in Georgia for 2021 have been selected for gradual coverage according to relevant international recommendations and Georgia's epidemiological characteristics (see Table 7). The selection of these groups was based upon the recommendations of ETAGE,[23] and was aimed primarily at maintaining vital health services and reducing morbidity and mortality in high-risk groups. The selected groups were reviewed and recommended by the National Immunization Technical Advisory Group (NITAG) of Georgia on December 12, 2020.[24]

As the availability of vaccines increases, more population groups will be vaccinated to reach the coverage target of 60% of the adult population.[25]

Once these groups are selected, a gradual coverage plan is based upon a guideline schedule for vaccine delivery and dose quantities set by the COVAX platform and then additional doses by the end of 2021. In the case of parallel or bilateral imports, the plan is expected to be modified according to the vaccine and volumes imported by the country, with calendar replacements of its stages.

A detailed description of the priority groups is provided in Annex 3. The priority groups distribution by municipalities and their gradual coverage has also been prepared.

[22] A high-priced vaccine is taken conventionally to illustrate additional financial resources, however any other vaccine of the +2-8°C temperature regime could be imported in the country that will receive WHO authorization.

[23] European Technical Advisory Group of Experts on Immunization.

[24] Protocol of the NITAG meeting, December 12, 2020.

[25] Georgia's adult population (>18 years) is 2,834,600 (source: National Statistics Office of Georgia).

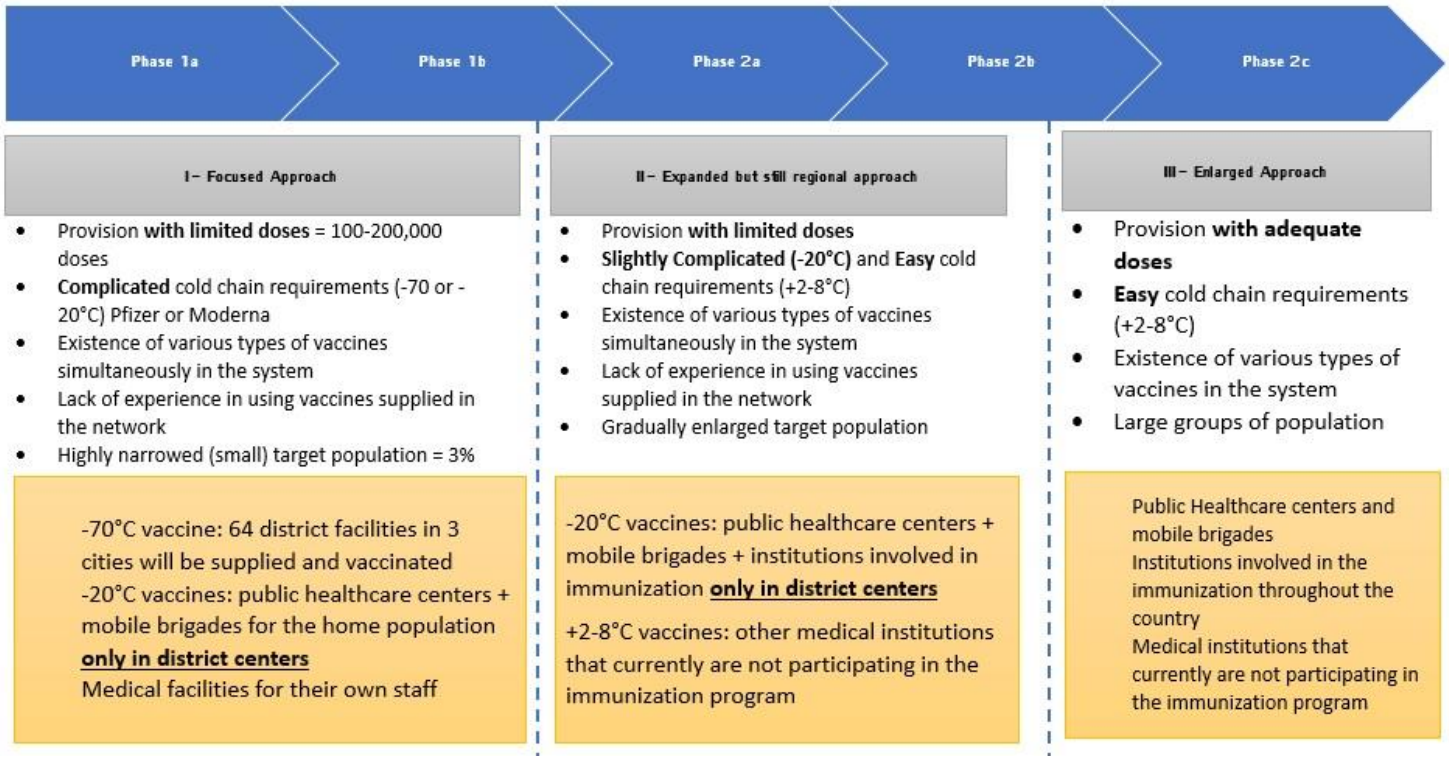
Table 7: Priority Groups: Size and Gradual Coverage

Stages	Priority Groups and Sequence	Target population*	Coverage rate (%)	Contingent to be vaccinated*
Ia	**Healthcare sector**	71,415	65%	46,420
Ia	**Beneficiaries and staff of a long-term care facilities**	2,600	60%	1,560
Ia	**>75 years old population**	226,800	60%	136,080
Ib	**65-74 years old population**	329,183	60%	197,510
IIa	**Essential services providers**	180,373	60%	108,224
IIa	**55-64 years old population**	478,400	60%	287,040
IIb	**18-54 years with chronic disease**	89,400	60%	53,640
Total (high risk and essential services)				**830,474**
III	**Other population groups**	1,434,567	60%	860,740
Total				**1,691,214**
Adult population %				**60%**

* The contingent to be vaccinated is corrected to account for duplication and is recalculated by coverage rates. Vaccination of the adult population at highest risk at initial stage (I) is given in green, whereas yellow and orange show vaccination of the high-risk adult population as well as of groups providing essential services through the program's gradual development. Reach of 60% adult population coverage is anticipated during stage III.

The vaccination of the selected target groups planned for 2021 requires Georgia to **almost quadruple the throughput of its existing immunization system**, which poses significant challenges. Accordingly, in order to adequately cover selected groups, a three-stage strategy was defined for widening vaccination based upon (a) selected target groups and their size, (b) population density and (c) the gradual increase of the system's throughput capacity, i.e., the gradual development of the capacity of relevant bodies as well as the training of personnel and their gradual involvement in the immunization program.

Figure 2. A three-stage strategy for expanding vaccination



The phased, gradual development of COVID-19 vaccination also envisages the possibility of using more complex vaccines with complex cold chain requirements (-70°C to -20°C) during the first phase of vaccine delivery if the country is faced with such a choice. For planning purposes, it was determined that the amount of such vaccines would not exceed the number of doses needed to reach 3% of the adult population, i.e. approximately 200,000 doses. Therefore, in the first stage, only priority groups (personnel working in the healthcare sector, residents and personnel of long-term care facilities, and people over 75) will be vaccinated.

For the Pfizer vaccine (scenario 1), it will be distributed from three warehouses (Tbilisi, Kutaisi, Batumi), 1 per week,[26] and delivered to one hospital facility selected in regional centers for vaccine administration (no more than two in exceptional cases). This decision is based on (a) the specifics of the vaccine packaging, i.e. the box contains 195 five-dose vials for a total of 975 doses, which (b) can be used for a maximum of 5 days[27] after thawing from -80°C. **The dispensing points are therefore supplied on a weekly basis and 975 doses of multiple volumes are supplied to a separate point (or will be repackaged into smaller doses), which requires the institution to vaccinate the number of people corresponding to its daily supply of vaccines. In case it receives a full package, an institution will have to vaccinate a minimum of 230-240 people, requiring it to employ 6 or 7 vaccination teams in a separate facility**. The planned mobilization of the

[26] Weekly because the vaccine's maximum shelf-life after thawing at +2-8°C is 5 days.

[27] Of these 5 days, 1 will be needed to distribute the vaccine to the vaccination points, which leaves only 4 days for vaccination.

vaccination contingent will take place at these hotspots with the active involvement of the municipality's authorities, head of public health centers and health facilities. Separate municipalities will develop a vaccination schedule for the vaccinated contingent and the measures needed to attract the contingent. Considering the logistical features related to this vaccine, the vaccination of specific essential service representatives may be planned after or in parallel with the vaccination of medical staff and residents and personnel of the long-term care facilities.

In the case of the Moderna vaccine (scenario 2), the vaccine is delivered from Tbilisi and regional warehouses to the municipal public health centers, where it is possible to store it at -20°C. From there, once a month, each facility will be supplied with a 4-week vaccination supply, because after thawing the vaccine can be stored at +2-8°C for 30 days. In this case, the first target will be medical facilities and their staff, followed by the residents and staff of long-term care facilities and people over 75. Selected institutions in the district will be responsible for organizing the vaccination, and the planned mobilization of the vaccination contingent will be entrusted to the municipality authorities and head of public health centers, with the active involvement of local health facilities. Each municipality will develop and follow a vaccination schedule for the vaccination contingent and the measures needed to attract them.

Accordingly, at the first stage and depending on the type of vaccine, vaccinations will first be given to health sector personnel, and only then will the other priority groups be covered.

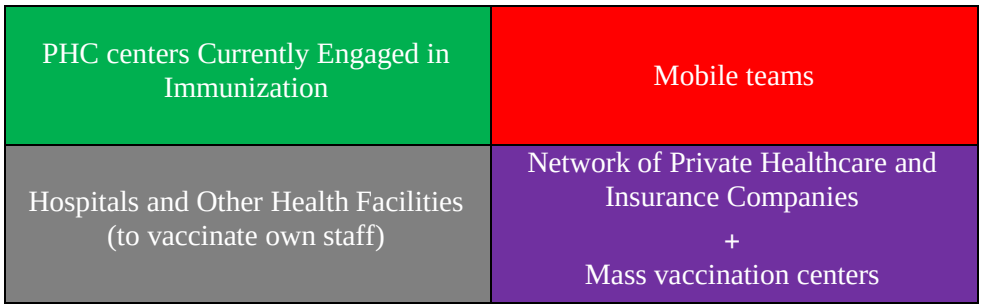
During the second phase of vaccination expansion, at the municipal level both immunization and non-immunization institutions will engage in the program (if these institutions agree to participate), while the third phase envisages vaccinating the target population with a more expanded network and organizing mass vaccination centers in big cities.

Mobile teams will be created and equipped for vaccinating residents and personnel of long-term care facilities as well as people with restricted mobility at every municipal level through the coordinated efforts of local health care facility and Public Health Centers. Municipalities will be instructed to prepare lists of this contingent and to quickly communicate these to the mobile teams.

Organizing COVID-19 Vaccination Service Delivery

In 2021, to vaccinate 60% of the country's adult population, it will be necessary to quadruple the capacity of the immunization services network. If today the system receives an average of one million vaccination visits in 12 months, for the immunization against COVID-19 an additional 3.4 million vaccination visits will take place in about 7-8 months of 2021 alone (as routine immunization continues). As of today, 351 legal entities and 929 individuals, mainly rural doctors, are participating in the immunization program (see Figure 3, Green Square). Therefore, in order to increase the existing capacities and at the same time use them effectively, the following is planned:

Figure 3. Immunization Network Expansion Plan



(a) During the first stage of immunization, all health facilities will be involved in the vaccination of health personnel, regardless of their participation in the immunization program (except if the Pfizer vaccine is administered, when vaccinations will be given only at specially selected hospital facilities at the municipal level and at more than one institution in large cities). Institutions that do not participate in the immunization program will register as immunization service providers (and receive adequate training – see training and human resource section).

(b) At the same stage, mobile teams jointly created by public health centers and selected health facilities will be tasked with vaccinating the residents and staff of long-term care facilities (during the first stage) as well as non-mobile contingents at home in parallel with the program's expansion. A total of 70 mobile teams are planned to be created (for each municipality and 5 cities in Tbilisi). Mobile teams will be staffed with a doctor, nurse and driver and will be supplied with appropriate equipment (see details in the financial resources section).

(c) During the next stage of the expansion of the COVID-19 immunization program, in order to vaccinate the population and other target groups, the main burden will be borne by the health institutions located in the municipal centers and participating in routine immunization (without the involvement of rural doctors). To cope with the increased volume, additional vaccination brigades and cabinets will be set up in these facilities. The PHC network of private healthcare and insurance companies that are not currently participating in the immunization program will also be involved. And finally, mass vaccination centers will be set up in large cities according to the guidelines of the CDC in the United States in order to increase throughput.[28]

Vaccination among medical staff will be voluntary. Prior to vaccination, people should be provided with complete information on the risks and benefits of vaccination and their informed consent must be obtained.

Services from institutions participating in the program will be purchased by the NCDC. The cost of vaccination visit was determined separately for medical institutions as well as for mobile teams and was illustrated in budget calculations. The payment principle for the service envisages 2 vaccination visits per

[28] https://www.cdc.gov/h1n1flu/vaccination/statelocal/settingupclinics.htm

person, which is the number required to achieve an adequate immunity. Accordingly, 30% of the total of 2 visits will be reimbursed after the first visit, whereas the remaining 70% after the second vaccination has been carried out. The information system of Georgia's immunization system is fully capable of following this principle as well as ensuring adequate monitoring.

Vaccination-related medical waste is considered to be hazardous and its management is regulated by relevant technical regulations.[29] The financial costs associated with the management of waste generated by the increased vaccination load are counted and reflected in the calculated amount of reimbursement.

Table 8. Assessment of technical needs for organizing vaccination services

Field	Change/action	Responsible party	Status
Regulatory Environment	Approval of COVID-19 Vaccine National Deployment Plan	Government of Georgia	To be approved
Including health service providers in the program and reimbursing provided services	Change in state program (targeted state program to ease damage caused by the novel Coronavirus (SARS-COV-2) infection (COVID-19)	Government MoILHSA	Ongoing
Trainings	Training of Local Government on Service Provision (Details in the Chapter "Human Resources and Training)	NCDC	To be conducted
Electronic System	Adapting the system to the specific requirements of COVID 19 vaccination	NCDC, MoILHSA	Ongoing
Standard Operational Procedures / Methodological Recommendations/ Instruments	Vaccination Operational Plan (General Plan and Municipal Plans)	NCDC, Municipal Public Health Centers	Ongoing
Pricing	Service and waste management pricing	Working Group	Completed
	Arranging necessary organizational and financial issues for establishing mass vaccination centers	Working Group	To be conducted

Cold Chain

The Cold Chain and Logistics Group has developed various scenarios for the importation and distribution of vaccines along with the relevant technical characteristics for these scenarios.

A detailed description of the scenarios is given in the relevant chapters of this document.

The selection and implementation of a specific scenario will depend on the availability of vaccines and the organization of imports.

The technical characteristics of each submitted scenario include the following information:

- The vaccine used for immunization
- Target groups, group characteristics, numbers and percentage of the group in relation to the population

[29] Resolution #294 of the Government of Georgia on the Approval of the Technical Regulation "Medical Waste Management", June 16, 2017.

of the country

- Cold chain system readiness for vaccine reception, storage and distribution at different levels of the system
- Volume and weight of medical waste accumulated as a result of vaccination

Scenario I

Vaccine used: -70°C temp. regime (Pfizer) and +2-8°C temp. regime (AstraZeneca)

Scenario Characterization: **Immunization of health workers and organized groups with the Pfizer vaccine** and vaccination of the rest of the high-risk population with the AstraZeneca vaccine.

Vaccine Logistics: If the Pfizer vaccine is used, a total of three warehouses in which its temperature regime can be ensured will be required:

- Tbilisi Central Warehouse, which will serve as both a national central warehouse and a regional warehouse for Eastern Georgia
- Kutaisi Regional Warehouse for Western Georgia
- Batumi Regional Warehouse for Adjara

The scenario will be implemented in two stages:

Stage 1 - Temperature regime -70°C - Immunization with the Pfizer vaccine

Stage 2 - Temperature regime +2-8°C - Immunization with the AstraZeneca vaccine

A total of 717,982 people will be immunized under Scenario I.

Conclusion – Scenario I

- The available cold chain volume meets the requirements of the AstraZeneca vaccine and does not require additional investment (see Table 6, separate document).
- The existing cold chain system does not require additional investment to maintain the Pfizer vaccine according to current regulations (-70°C temperature regime) and in order to ensure distribution if the vaccine is only stored in regional warehouses and if vaccination is rapidly carried out (within 4-5 days of its delivery from the warehouse)
- The volume of Pfizer vaccine is 1,384 liters, while the existing volume is equal to 3,205 liters. Detailed information is given in the relevant table in a separate document.

Scenario II

Used vaccine: **-20°C temp. regime** (Moderna) and **+2-8°C temp. regime** (AstraZeneca)

Scenario characterization: **Immunize healthcare workers, organized groups with the Moderna vaccine** and the rest of the high-risk population with the AstraZeneca vaccine.

The scenario will be implemented in two stages:

Stage 1 - Temperature regime -20°C - Immunization with the Moderna vaccine

Stage 2 - Temperature regime +2-8°C - Immunization with the AstraZeneca vaccine

A total of 717,982 people will be immunized under Scenario II.

Conclusion - Scenario II

- The existing cold chain capacity is adequate to receive the AstraZeneca vaccine and does not require additional investment.
- The size of the existing cold chain system is adequate and does not require additional investment to store the Moderna vaccine according to current rules (-20°C temperature regime) and to ensure distribution.

Scenarios III and IV

Used vaccine: **+2-8°C temp. regime** (AstraZeneca fully or partially and other vaccines of same temperature regime)

Scenario Characterization: High-risk group vaccination with +2-8°C vaccine.

The scenario will be implemented in one stage:

Stage I - Temperature regime +2-8°C - Immunization with +2-8°C regime vaccine(s)

Target Group (number): 717,982 people;

Target group (characterization): All groups

Conclusion - Scenarios III and IV

- The existing cold chain system does not require additional investment to ensure storage and distribution of the vaccine according to its current requirements (+2-8°C temperature regime) (see a separated document).

In case of vaccinating 60% of adult population (with additional dosages of the +2+8°C vaccine), under conditions of rational time distribution of vaccine supply and adequate consumption, the cold chain capacity does not require additional investment.

Distribution of Vaccines

At the regional level, transportation will be carried out by special vaccine-carrying vehicles capable of maintaining vaccines at +2-8°C and -20°C.

Such "vaccine carriers" are currently used throughout the country to replenish three-month supplies of routine vaccines at the municipal level. Stocks are regularly replenished (every 2 months).

It should be noted that if vaccines are to be transported at -70°C, the same vehicle will not be able to transport other consumables and diluent (solvent).

Details of the distribution of vaccines—particularly needs for transport equipment at each level of the facility, e.g. cold chain transport boxes and the corresponding number of ice elements, as well as the needs of the "vaccine carriers"—will be detailed at a later stage.

+2-8°C vaccines could be distributed like routine vaccines, but according to different schedules and routes.

As for the distribution of vaccines requiring other temperature regimes, the relevant route, number of routes and other details of the distribution of vaccines from the central level to the municipal level will also be planned based on vaccine characteristics during the development of operational plans.

During the vaccination planning phase, logistics and cold chain personnel involved in COVID-19 immunization will be rapidly and comprehensively trained in matters pertaining to logistics and cold chain management (see the section on Human Resource Management and Training).

Waste Management

Waste generated by the COVID-19 vaccination campaign will be managed in accordance with current regulations and mechanisms in facilities responsible for other planned or unplanned vaccinations. However, at each level of the cold chain system, additional waste disposal requirements will be identified according to the vaccine used along with additional ancillary and consumable material requirements.

Electronic Stock Management Module

Depending on its specifications, selected vaccines will be managed by an existing electronic inventory management module in which all standard inventory and transportation reports are generated at the central, regional, municipal or agency levels.

The inventory management module is integrated with the electronic immunization module, and balances are registered automatically at the time of vaccination registration. Vaccines will be registered in the stock module according to batch or to the serial numbers that will be affixed to the secondary packaging.

A model for the unification of secondary packaging for the labeling of vaccines has already been developed by WHO (see the Regulatory Environment section). WHO also considers the use of two-dimensional technology barcodes on secondary packaging for the electronic tracking of the application process, although this is not mandatory and will not replace the obligation to comply with national requirements.

The two-dimensional barcode indicates the production serial number of a particular lot. Vaccines with serial number registration are logged in the electronic inventory management module, and there is therefore no need to introduce an additional barcoding system.

In parallel with vaccine registration and expenditure accounting in the electronic inventory management module, real-time inventory information is generated at the national, regional and municipal levels.

Table 9. Assessment of Cold Chain-related Needs

Field	Change/Action	Responsible Party	Status
Regulatory Environment	Not necessary		
Trainings	On Cold Chain and Logistics (See section Human Resources Management and Training)	NCDC	To be implemented
	On usage of electronic module of storage (See section Human Resources Management and Training)	NCDC	To be implemented
Electronic Systems	Clarification of reporting requirements	NCDC	Currently in Process
Pricing	No extra need for Cold Chain		
Logistics	Needs are being considered and financial support will be defined	Working Group	Currently in process

Management of Human Resources and Training

Human resources are essential to the introduction of the COVID-19 vaccine, and must be provided with a high standard of relevant knowledge and skills.

A specialized training plan, design and methodology for training these human resources has been developed; the target audience has been identified; training modules based upon materials developed by the WHO and other global immunization partner organizations must be translated and adapted; and so-called auxiliary monitoring must be enhanced.

Specialized training for the introduction of a COVID-19 vaccine in Georgia includes the following:

- A training plan, design, methodology, training modules—NCDC/Departments of Communicable and Non-Communicable Diseases, Information Technology Maintenance Division, Other Stakeholders
- Target audience—a service provider across the country (provider clinic doctors, nurses, managers); cold chain and logistics (persons responsible for cold chain and logistics of regional and municipal public health centers), media, speakers
- Auxiliary monitoring - relevant NCDC departments

Training design:

- Online format
- Mixed formats if needed

Training topics:

- Practical immunization
- Cold chain and logistics
- Adverse Events Following Immunization (AEFI) and their monitoring
- Communication
- Service organization
- Reporting

Modules	Topics	Audience (Number)	Duration Of Module
Module 1: Practical Immunization	Immunization Rules Vaccine Characterization	Persons responsible for Immunization at Public Health Centers Service Provider Doctors, Nurses	4-6 hours
	Adverse Events		
	Storage conditions		
	Entering Data into module		

	Vaccine product -related reactions Vaccine quality defect - related reactions Immunization error - related reactions (so called program errors) Immunization anxiety- related reactions Coincidental Events Reporting, registration and examination rules	Persons responsible for Immunization at Public Health Centers Service Provider Doctors, Nurses Service Provider Managers	
Module 2: Cold Chain and Logistics	Vaccine Transportation and Warehousing Electronic stock management module Medical Waste Management	Regional and Municipal Public Health Centers, persons responsible for cold chain and logistics	2-3 hours
Module 3: Communication and Crisis Communication	Fundamentals of Behavioral Science Determining Vaccine Acceptance Interventions Interpersonal communication (AEFI communication) Advocacy of vaccine importance and developing behavioral change directed messages Dealing with the group opposing vaccination Infodemic and misinformation Social media engagement and interaction Communication of Public Health Crisis Situations Management Principles and Risks Advocacy of vaccine importance and developing and disseminating behavioral change-directed messages Relations with Media Engagement in Social Media and Interaction Dealing with the group opposing vaccination	Persons responsible for Immunization at Public Health Centers Service Provider Managers Representatives of local government	4-6 hours
	Media training	Media representatives	4 Hours
Module 4: Service Organization	Planning Contingent Mobilization Mobile Team Work Monitoring and Evaluation	Heads of PHCs Heads of Service Provider Institutions Representatives of Local Government	4-6 Hours
Module 5: Immunization Safety Issues	AEFI issues	Members of National Immunization Experts Committee	2 hours

Table 10. Evaluation of Training-related Needs

Field	Change/action	Responsible party	Status
Regulatory Environment	No need		
Trainings	For 5 above-mentioned modules	NCDC	To be conducted
Modules	To be developed	NCDC	Ongoing
Electronic systems	Web portal for virtual trainings	NCDC	To be conducted
Pricing	To be priced	Working Group	Completed

Demand Creation and Communication

Many years of experience and evidence of the introduction of new vaccines confirm that clear and effective communication is essential for the successful implementation of the COVID-19 vaccination program, and that this communication should be initiated before vaccines become available.

In addition to public awareness, vaccine acceptance is affected by three factors that need to be considered in order to understand the problem and identify strategies; these are: supportive environment, social impact, and motivation.[30]

Increasing confidence in the vaccine in the general population and especially in the first target groups, as well as dispelling the misinformation surrounding the vaccine, is important to ensure high vaccine uptake. A successful COVID-19 vaccination program, in turn, will have a significant impact on the country's immunization program and routine vaccination coverage in the coming years.

Goal

Increase confidence, acceptance and demand for a COVID-19 vaccine using the following approaches: advocacy, communication, social mobilization, risk and safety issues communication, community involvement, training, and crisis communication.

Objectives:

- Mobilize and engage key partners and the community
- Dialogue with internal and external partners regarding the implementation of the COVID-19 vaccine program to understand their key views and needs
- Media information, mobilization and media advocacy
- Develop and implement a crisis communication action plan
- Prepare daily and weekly dashboards, and develop a standard form
- Develop a detailed guide to the technical nature and effective communication of COVID-19 vaccination and conduct training for local provider medical facility managers, nursing staff and other stakeholders
- Provide constantly updated information to the public on the development, authorization, introduction, distribution and use of COVID-19 vaccines, using a strictly defined communication hierarchy
- Ensuring public confidence in the safety, efficacy and introduction of the COVID-19 vaccine
- Disseminate active, timely accessible and effective messages on community consolidation,

[30] Behavioural considerations for acceptance and uptake of COVID-19 vaccines: WHO technical advisory group on behavioural insights and sciences for health, meeting report, October 15, 2020. https://apps.who.int/iris/handle/10665/337335

expectations management, public health, safety

- Mobilize the target population of a COVID-19 vaccine, as well as effective communication for both first and second-dose vaccination invitations
- Infodemic management and countering disinformation
- Monitoring, overseeing and impact assessment of the strategy implementation process

Target Audience

1. Parties engaged in the COVID-19 introduction process:
    - Coordination Council
    - NITAG members
    - Ministry of Health and NCDC
    - Regional and District Public Healthcare Centers
    - Local Government
    - Local and International Partners
2. Medical Service Providers and personnel (entire medical sector)
3. High risk-group representatives
    - Beneficiaries and personnel of long-term care facilities
    - Persons over 55
    - People with chronic diseases (18-54 years old)
    - Essential service providers, etc.
4. Parts of the population that are not included in first-stage groups (expectation management)
5. Stakeholders or influencers
    - Policy makers and politicians
    - Civil society
    - Scientists, academics
    - Non-Governmental Organizations
    - Critical and negative groups
    - Business sector
6. Mass media and social media
    - Central and regional television (including channels in ethnic minority languages)
    - Radio
    - Press
    - Social media groups and Influencers

- STOPCOV.ge
- MOH.gov.ge
- NCDC.ge
- Facebook, Instagram pages

Strategic Directions

International experience and research show that only informing or individual interventions are ineffective in overcoming vaccination barriers and that different strategies and approaches need to be integrated and combined.[31] Examples include reminders[32] and guideline planning,[33] the training of healthcare workers and building population trust in them.[34] It is also possible to involve volunteers (e.g. students, public servants) in the social mobilization of the target contingent and their physical mobilization (i.e. bringing them) for vaccination.

The Communication Action Plan builds on four interrelated strategic elements of an integrated approach to vaccine demand:

1. Social listening, media engagement and disinformation management

- Listen to and understand target populations, develop targeted communication strategies by collecting behavioral and social data on key factors
- Create a supportive and transparent information environment and neutralize misinformation through social listening and evaluation to plan further interventions

2. Risk communication and public engagement

- Increase trust in and acceptance of vaccines through the involvement of civil society

3. Capacity building of healthcare specialists

- Raise awareness and knowledge of medical staff about COVID-19 vaccination as the first target group of vaccination, a reliable source of information, influential people and vaccine; interpersonal communication skills of the target population and the community should be strengthened

4. Crisis communication

- Readiness of the country to manage crisis situations, to respond quickly and in a coordinated manner

[31] Brewer NT, Chapman GB, Rothman AJ, Leask J, Kempe A. "Increasing vaccination: putting psychological science into action." *Psychol Sci Public Interest.* 2017;18(3):149–207. doi:10.1177/1529100618760521.

[32] Harvey H, Reissland N, Mason J. "Parental reminder, recall and educational interventions to improve early childhood immunisation uptake: a systematic review and meta-analysis." *Vaccine*. 2015;33(25):2862–80. doi:10.1016/j.vaccine.2015.04.085.

[33] Milkman KL, Beshears J, Choi JJ, Laibson D, Madrian BC. "Using implementation intentions prompts to enhance influenza vaccination rates." *Proc Natl Acad Sci USA*. 2011;108(26):10415–20. doi:10.1073/pnas.1103170108.

[34] Brewer NT, Hall ME, Malo TL, Gilkey MB, Quinn B, Lathren C. "Announcements versus conversations to improve HPV vaccination coverage: a randomized trial." *Pediatrics*. 017;139(1):e20161764. doi:10.1542/peds.2016-1764.

in case of possible complications after immunization at all levels

Phases of Introduction and Priority Measures:

Usage of timely notifications for the current phase of the COVID-19 vaccination program:

- Before vaccination begins
- The vaccine is available in limited numbers for high-risk priority groups
- Vaccine availability is increasing for priority population groups and for the general population groups
- The vaccine is widely available for the adult population

Resources are currently being sought according to priority issues.

Table 11. Assess the Needs for Demand Creation and Communication

Field	Action/change	Responsible party	Status
Regulatory Environment	No need		
Trainings	For medical personnel (including PHC personnel), local government	NCDC	To be conducted
	Media	NCDC	To be conducted
Modules	To be developed	NCDC	Ongoing
Electronic System	Web portal for virtual training	NCDC	Ongoing
Pricing	Is being prioritized	Working Group	Completed

Vaccine Safety Monitoring, AEFI Management and Vaccine Safety

The monitoring of Adverse Events Following Immunization (AEFIs) is an integral part of the National Immunization Program, and its effective operation both enhances the safety of all vaccines in the country and helps maintain long-term public confidence in the immunization program.

AEFI monitoring has been carried out under the State Immunization Program for over two decades. The last update was made in 2019.[35] The current surveillance system fully complies with WHO recommendations. The vaccine safety system in Georgia includes pharmacovigilance over vaccines carried out by the staff of the relevant authority. The system works well and monitoring adverse events of a COVID-19 vaccine will not require drastic changes or rethinking approaches. Information flows will continue to flow in the prescribed manner.

However, the new technologies used to create the COVID-19 vaccine and the urgency of using the vaccine

[35] Order of the Minister of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia #01-193.

pose some challenges to the system. In order to address these challenges effectively, additional regulations should be developed in conjunction with the introduction of COVID-19 vaccines, which will include adjustments based on the urgency of this process. In the current situation, software readiness is very important both before the introduction of the vaccine and during its delivery. In the current surveillance system, efforts need to be further strengthened in all five cause-specific areas of AEFI (see annex 4 for details):

1. Vaccine product-related reactions
2. Vaccine quality defect-related reactions
3. Immunization error-related (so-called programmatic) reactions
4. Immunization anxiety-related reactions
5. Coincidental events

National Committee of Immunization Safety Experts

The National Committee of Immunization Safety Experts was established in 2014[36] and is based on WHO recommendations. It is an independent body and consists of 14 different experts. The committee was set up under routine vaccination conditions and is mainly staffed by pediatricians. Considering the target population (elderly), the campaign nature of the vaccination, the novelty of the vaccine and the theoretically expected number of AEFIs (around 14,000 cases in 7-8 months, i.e. around 60 cases per day),[37] - the specifics of the patients (target groups) changes and the workload of the committee increases. In order to ensure the Committee's efficient and timely work, its composition is being expanded, additional members have been identified or appointed, and the approval of the relevant order is ongoing.

Table 12. Assessment of technical needs associated with vaccine safety

Field	Action/Change	Responsible Party	Status
Regulatory Environment	Vaccine Safety Monitoring and AEFI Issues in the Order of the Minister regarding the COVID-19 vaccine	Government of Georgia (approval) MoILHSA, NCDC (development)	Ongoing
	Renewal of the National Committee of Immunization Safety Experts	Ministry	The Order has been prepared and is awaiting approval
Training	Epidemic surveillance of medical personnel over vaccine safety monitoring, AEFI issues, Covid-19 Vaccination and Covid-19 Surveillance based on new cause-effect topic	NCDC NCDC	To be carried out To be carried out

[36] Order # 01-185 / O of the Minister of Labor, Health and Social Affairs of Georgia, July 30, 2014.

[37] Calculations are based on the upper limit of the probable frequency range of unusual complications of Moderna and Astra-Zeneca vaccines 1/100.

Electronic System	Adaptation of Electronic Integrated Disease Surveillance System for Registration of COVID vaccine AEFIs	NCDC	Ongoing
	Adaptation of the online electronic immunization and stock management module for the registration of COVID vaccine AEFIs	NCDC	Ongoing
Standard Operational Procedures/Guidelines	Side effects and warnings for COVID vaccine (preliminary) Establish surveillance of adverse events of special interest (AESI) National background rates of existing conditions of special interest Introduce monthly reports on AESI Reflection of AESI in the form of emergency notification Reflection of COVID vaccination and AESI in AEFIs epidemiological form	NCDC	Accomplished

Information System, Monitoring and Epidemic Surveillance

From the very beginning of this process, the monitoring, surveillance and evaluation of the COVID-19 vaccination will be critical to its management and to the adaptation of the strategy. Standardized tools will enable Georgia to conduct processes in a transparent and accessible manner and to ensure that set goals are achieved through interim reporting and problem identification.

Reporting

The surveillance and reporting model takes into account current practices in Georgia, and includes: immunization/vaccination, vaccine administration, unusual post-vaccination reactions and complications (AEFI), as well as reporting of vaccine status in cases of COVID-19.

Vaccination registration and reporting will be carried out through the existing **immunization management electronic module (IMEM)**.

An IMEM has been used since its development in 2013 and was fundamentally updated in 2020 as a tool to improve the administration of the immunization program and vaccine logistics. The module is part of the Healthcare Management Information System (HMIS), which in turn integrates with the birth module, inventory management system and national registry, and is based on the identification of citizens through their unique personal number.

To date, COVID-19 vaccination is recommended for population age groups not belonging to the target contingent of the routine vaccination (see Priority Groups and Vaccination Strategies).

The IMEM provides for the registration of other additional vaccinations, therefore the vaccine against COVID-19 will be registered in the immunization module according to the rules already tested.

All actors responsible for carrying out the vaccination should be given adequate advance access to the IMEM (including all facilities that have not previously been involved in immunization processes), and vaccines should not be delivered to service providers that do not have such access. It is the prerogative of local (municipal) public health centers to verify the availability of admissions and readiness for vaccination registration in the module. When adding vaccination facilities during the planning and implementation phase of the process, immunization personnel (including mobile teams) should be trained in the access, use and technical support of the module.

The vaccines serial codes are registered in the IMEM and are followed according to the established rule through integrated the stock management module (See the section on Inventory Management on the usage of barcodes.)

Along with the integration with the vaccination and cold chain registration system, the immunization reporting system is currently being renewed, allowing the national, regional and municipal levels to receive reports in real time: a) individual lists of vaccinated individuals, in doses; b) in aggregated form—the number of vaccinated people by age groups or priority category as well as total of priority and age groups in given subunits, at the municipal, regional and national levels.

In turn, the module's own inventory management component ensures the generation of standard reports on stocks held by healthcare centers.

In order to produce other additional and immediate non-standard reports, which will be aggregated according to priority groups, age groups and geographical units (municipality, region, national), a standard format has been developed. The denominators at the municipal level have been determined by the national level and have been shared with the municipal and regional Public Health Centers. The target denominators will be reviewed by the municipal and regional Public Health Centers, and the updated information or consent on the reality of the values will be returned to the national level. The processing of data on vaccination coverage at the municipal level is the responsibility of the Public Health Centers. The frequency and format of the standard reporting forms is being discussed.

The described part of the registration and reporting processes will be reflected in existing systems from February 2021.

To ensure that people are summoned to receive the 2nd dose of their vaccination, the possible date of vaccination will be determined upon receipt of the first dose and a notification with short text message (SMS) will be sent immediately. This will be enabled by the existing immunization module (which will be adapted to a specific vaccine). The same will be provided in the immunization web application. The mobile app was originally designed for parents as a source of information about vaccinations being conducted and planned. The application allows users to obtain information about vaccines in Georgia and the diseases that they prevent. Form 063 ("Vaccination Card") can be printed from the application as a document confirming a

vaccination. The application enables SMS to be sent to beneficiaries informing them of the next vaccination. The application can be downloaded at: https://www.ncdc.ge/Pages/User/LetterContent.aspx?ID=a34502f9-a7eb-4812-aa4b-f04fb6831756

The introduction of a queue management system is being planned in order to both help medical institutions manage the flow of citizens and citizens to pre-register an appointment for vaccination at a nearby medical facility. That said, such a system could only be activated after comprehensive testing, and may not yet be available at the initial stage of vaccination.

The vaccination certificates of beneficiaries must become part of the immunization application, and users will receive a vaccination certificate through the application. The document must meet internationally recognized requirements and have anti-counterfeiting mechanisms.

International reporting of AEFIs will be performed in accordance with the requirements of the WHO, the European Center for Disease Control and Prevention (ECDC) and the European Union (EU).

Monitoring

The planning of the monitoring process depends on the type of vaccine (according to the scenarios listed above) and includes:

- Monitoring vaccine logistics
- Monitoring the process of immunization services
- Monitoring the cumulative growth of coverage
- Comparing the coverage rate with the planned rate

National vaccination coverage rates will be shared through the NCDC website and updated weekly. The NCDC is responsible for the update.

Vaccine logistics are monitored by the NCDC and Public Health Centers (through IMEM) on an ongoing basis while on site, and by municipal Public Health Centers at the vaccination facilities before vaccines are received (should include assessing the capacity and readiness of vaccination facilities) as well as periodically during the process of vaccination. This monitoring phase will integrate the monitoring of the vaccine logistics and immunization service process and will be carried out at least once a week.

The comparison of the coverage rate with the planned rate will be done permanently, at the end of each round of vaccination.

The coverage targets for individual groups of the target population are defined in the list of the document's priority groups. The indicator used for monitoring purposes includes the achievement of the target within the set time and is produced at the municipal, regional and national levels.

COVID-19 case registration is carried out through an electronic integrated disease surveillance system

(EIDSS), whose flexible structure allows the vaccine status to be registered after the introduction of vaccination. This upgrade to the EIDSS system will take place as soon as the vaccine is introduced in the country.

The same system registers any AEFI detected across the country.

The trainings will include up-to-date information on standard case identification, COVID-19 and AEFI notification obligation, vaccination registration, reporting format and timing for service providers and public health professionals.

Surveillance

Influenza-like illnesses (ILIs) and severe acute respiratory infections (SARIs) are part of the country-based surveillance.

ILIs and SARIs caused by other respiratory viruses have similar symptoms and often a common case definition. As in other countries, efforts to monitor the spread of COVID-19 in Georgia are being integrated into the syndromic sentinel surveillance system for ILIs and SARIs, which will continue to function after the pandemic. The integrated system is of particular importance during phases when the pandemic and flu will coincide. Laboratory testing of samples routinely collected from the ILI and SARI support bases is carried out by the Flu Laboratory of the National Center for Disease Control and Public Health. Due to the increased load of the COVID-19 pandemic, it is planned to decentralize this function and overall laboratory research of influenza, SARS-CoV-2 and other respiratory viruses (PCR diagnostics) to the NCDC regional laboratories in Kutaisi, Batumi and Zugdidi.

As part of sentinel surveillance, selected case studies are routinely collected for influenza vaccination for the last and current season. With the introduction of the COVID-19 vaccine, information will begin to be gathered about the latter vaccination as well.

Special studies will be carried out at the stage of introduction and implementation of COVID-19 vaccination in case of need and existence of adequate sources of funding. The country is ready to participate in the study of vaccine efficiency - according to the priority groups, the type of manifestation of the vaccine species, representative data will be collected taking into account the international research practice, adapted procedures and the relevant material and technical base.

Table 13. Assessment of technical needs related to information systems

Field	Action/Change	Responsible Party	Status
Regulatory Environment	Formalization of vaccination certificate The Minister's order on COVID-19 vaccination	MoILHSA (approval) NCDC (development)	Ongoing
Electronic Systems	Provide access to the online electronic immunization management module for all service providers	NCDC	Starts as from February

	Ensure the production of COVID-19 specific reports in the online electronic module of immunization management	NCDC	Ongoing
	Registration, accounting	NCDC	Will be completed as from February 1, 2021
	Provide a short text message function in the immunization application	NCDC	Ongoing Will be completed as from February 1, 2021
	Ensuring the generation of a vaccination document with protection mechanisms	NCDC	Ongoing Will be completed as from February 1, 2021
	Adaptation of EIDSS for Registration of COVID-19 vaccine AEFIs	NCDC	Ongoing
	Managing queues and online registration for the population to receive vaccination	NCDC	Ongoing
Standard Operational Procedures/Guidelines	Integrate COVID-19 surveillance into the sentinel system	NCDC	Have been developed

Monitoring of Plan Implementation

The monitoring of the implementation of the COVID-19 Vaccine National Deployment Plan will be supervised by the Interagency Coordination Commission in accordance with the selected indicators.

Annex 1 - Composition of Technical Working Groups

	Name, Surname	Institution	WG 1—PR. Groups	WG 2—Service Delivery	WG 3—Vaccine Registration	WG 4—Cold Chain	WG 5—Training	WG 6—Communication	WG 7—Information System	WG 8—Vaccine Safety
1	Ekaterine Adamia	Department of Health	X	X	X				X	
2	Ketevan Goginashvili	Department of Health	X	X	X				X	
3	Ekaterine Guntsadze	Head of the Budget Department of the Ministry of Finance		X		X				
4	Irina Javakhadze	Ministry of Finance, Curator of the Health Sector		X		X				
5	Irma Khonelidze	Deputy General Director, NCDC	X	X	X	X			X	X
6	Aleksander Turdziladze	Deputy General Director, NCDC							X	
7	Khatuna Zakhashvili	Head of the Department of Communicable Diseases, NCDC	X	X			X		X	X
8	Maia Kereselidze	Head of the Department of Statistics, NCDC	X						X	
9	Lia Jabidze	Head of Immunization Division, NCDC	X			X	X			
10	Vladimer Getia	Head of the Programs Department, NCDC		X	X	X				
11	Lela Sturua	Head of the Department of Non-Communicable Diseases, NCDC	X					X		
12	Natia Skhvitaridze	General Director's Advisor in Global and Public Healthcare Issues, NCDC	X							
13	Irakli Gabisonia	Specialist, NCDC				X				
14	Tamar Sulkhanishvili	Immunization Division, NCDC		X		X	X			
15	Gia Kachlishvili	Immunization Division, NCDC				X				
16	Nino Grdzelidze	Department of Statistics, NCDC	X							
17	Levan Kandelaki	Department of Statistics, NCDC	X							
18	Ketevan Gambashidze	Department of Statistics, DCJEC							X	
19	Nino Tsetskhladze	Department of Statistics								X
20	Gia Kobalia	Programs Department, NCDC			X	X				
21	Eka Zhorzholadze	Programs Department, NCDC		X						
22	Maia Makharadze	Department of Programs, NCDC							X	
23	Marine Topuridze	Communication Specialist					X	X		
24	Otar Namicheishvili	Programs Department, NCDC				X				
25	Rusudan Khutsishvili	Programs Department, NCDC			X	X				
26	Sopho Sikharulidze	International Relations Division, NCDC		X						
27	Shorena Chilashvili	Head of Procurement Division, NCDC				X				
28	Teona Kashibadze	Immunization Division					X	X	X	
29	Nona Beradze	Immunization Division					X			X
30	Tamar Dolakidze	Immunization Division					X		X	X
31	Gela Mgeladze	Head of the Biosafety Division, NCDC				X				
32	Ani Papaskiri	Department of Noncommunicable Diseases,						X		

		NCDC								
33	Ana Kasradze	Emergency Response Division, NCDC							X	X
34	Elene Godziashvili	International and Public Relations Division					X			
35	Sopho Sikharulidze	Senior Specialist, NCDC		X						
36	Tamar Melikidze	National Healthcare Agency								
37	Eka Urushadze	National Healthcare Agency		X	X					X
38	Zaal Kapanadze	Agency for Regulation of Medical and Pharmaceutical Activities			X					X
39	Gocha Aladashvili	Agency for Regulation of Medical and Pharmaceutical Activities			X					
40	Naili Shengelidze	Agency for Regulation of Medical and Pharmaceutical Activities			X					X
41	Zaza Chapichadze	Agency for Regulation of Medical and Pharmaceutical Activities			X					X
42	Manana Khochava	Head of the Department of Infectious Diseases, Professor								X
43	Givi Javashvili	Expert in Medical Ethics	X							
44	Akaki Abutidze	Epidemiologist, AIDS and Clinical Immunology Center	X							
45	Gela Chiviashvili	Tbilisi Municipal Health Service, Head		X						
46	Natia Verdzadze	Tbilisi Municipal Health Service		X						
47	Gocha Giorgidze	Director of Imereti Regional Center		X						
48	Neli Khizanishvili	Director of Kakheti Regional Center		X						
49	Rusudan Shavishvili	Director of Adjara Public Health Center		X						
50	Tiko Tsomaia	Journalist						X		
51	Maia Butsashvili	Infectious disease specialist	X							
52	Bidzina Kulumbekov	Allergologist, Center for Allergy and Immunology	X							
53	Archil Marshania	Clinician						X		
54	Ivane Chkhaidze	President of the Georgian Respiratory Association	X							
55	Marina Shikhashvili	Family Medicine Association		X						
56	Rema Gvamichava	Georgian Scientific Society of Oncologists	X							
57	Rusudan Kvantchakhadze	Endocrinologist, Society of Nutritionists	X							
58	Dali Trapaidze	Cardiologist	X							
59	Beka Jakeli	Head of the Financial-Economic Department from the Ministry of Health				X				
60	Koka Liluashvili	Primary health care specialist	X	X						
61	Mamuka Chkaidze	Intensive Care Specialist								
62	Zurab Pagava	Cardiologist								
63	Bejhan Tsinamdzgvrishvili	Cardiologist								
64	Tamar Rodonaia	GIPA PR - Corporate Communications Specialist						X		
65	Tina Stambolishvili	GPI Holding Cook. Head of Relationship Service-Corporate						X		
66	Tsitsi Dalakishvili	Communications Specialist							X	
67	Nata Anjaparidze	Corporate Communications Specialist						X		
68	Maia Mikashavidze	Corporate Communications Specialist						X		

69	Ana Keshelashvili	Communications Specialist						X		
70	Nino Danelia	Communications Specialist						X		
71	Ina Charkviani	Communications Specialist						X		
72	Tamar Ugulava	UNICEF, Health Specialist						X		
73	Nino Moroshkina	World Bank, Consultant						X		
74	Nino Mamukashvili	PR, International and Public Relations Division, NCDC						X		
75	Teona Todua	Communication Specialist, NCDC						X		
76	Nino Sarishvili	Communication Specialist, NCDC						X		
77	Verico Baziari	Health Department, Ministry						X		
78	Shorena Okropiridze	Legal Department, Ministry								X
79	Anzor Chavchavadze	Department of Health						X		
80	Zurab Alkhanishvili	UN Association Public Healthcare Program Coordinator						X		
81	George Gotsadze	Consultant		X						
82	Akaki Zoidze	Consultant		X				X		
83	Ivdity Chikovani	Consultant	X	X	X		X		X	X
84	Ketevan Goguadze	Consultant		X		X	X	X	X	
85	David Sulaberidze	Consultant				X				

Annex 2 - Methodology and Cost Calculation of the Financial Resources for the COVID-19 Vaccines Introduction by Different Scenarios

Methodology

The methodology and approaches used to calculate the financial resources required for the introduction of the COVID-19 vaccine are based on the WHO's Guideline for estimating costs of introducing new vaccines,[38] the Common Approach for the costing and financing analysis of routine immunization and new vaccine introduction developed by the Bill and Melinda Gates Foundation,[39] and the Harvard School of Public Health's Methodology for Evaluating Immunization Program costs.[40]

The calculations take into account only the additional financial resources associated to the introduction of a new COVID-19 vaccine in a country, and do not take into account such common costs as capital costs of buildings, recurrent costs, etc. Only those fiscal costs (capital and operational) that must be allocated by the state or attracted from donor and partner organizations are calculated.

Financial calculations were made for the following components:

Monovalent COVID-19 Vaccine	1. Vaccines, syringes, extra safety boxes, personal protective equipment 2. Vaccine storage and distribution 3. Additional human resources and additional time of available staff 4. Trainings 5. Social mobilization, advocacy, social media campaign 6. Information system (registration, reporting, inventory 7. Monitoring and supervision 8. Remuneration of medical institutions participating in vaccination by the state procurer, including remuneration of mobile teams

The cost of vaccines was calculated according to the target populations identified for each stage. The total cost of vaccines takes into account the vaccine waste factor, which is calculated by the formula $\frac{1}{1-w}$ where w

[38] WHO; Guidelines for estimating costs of introducing new vaccines into the national immunization system; 2002

[39] Logan Brenzel, BMGF, *Common approach for the costing and financing analysis of routine immunization and new vaccine introduction*, 2014.

40 Immunization Economics.org, Harvard School of Public Health, "How to Cost Immunization Programs: A practical guide on primary data collection and analysis", 2020.

is the vaccine waste rate/percentage. The waste rate in our calculations is 15% for all vaccines,[41] so the waste factor is 1.176. Prices for one dose of different vaccines were taken from [https://www.unicef.org/supply/covid-19-vaccine-market-dashboard] and were accurate on December 22, 2020. Calculations were made for each vaccine taking into account both its minimum and maximum price. We also added Procurement Supply Management (PSM) costs to the vaccine dose price, which is 23% and includes UN handling fee, freight and insurance.[42]

To calculate the financial resources required for vaccines, the target population was multiplied by 2 (since the full course of vaccination reportedly requires two doses of the vaccine), as well as the vaccine waste factor and the price of one dose of the vaccine, including PSM costs.

The cost of the syringes was calculated by multiplying the required number of syringes by unit cost and taking into account a loss factor of 1.05, as used by the UNICEF sizing tool for syringes.

The cost of safety boxes was calculated by multiplying the number of additional safety boxes required by unit price. To calculate the number of safety boxes required, it was assumed that one box could hold 80 syringes.

Vaccine logistics: Financial resources necessary for the distribution of vaccines from a central warehouse to regional and district warehouses were calculated according to the average kilometers and fuel costs. Necessary costs for vaccine distribution also included vehicle maintenance cost, which was calculated as 15% of the fuel cost as defined by the WHO cMYP costing guideline. Vaccine logistic costs also include travelling allowances for personnel.

Supervision: Monitoring/supervision costs of the vaccination process were calculated according to the number of the planned supervision visits.

Necessary financial resources for training were also calculated according to the training plan as well as the financial needs for social mobilization, advocating, communications and launching media campaigns have been estimated.

The conversion rate used was USD 1 = GEL 3.3[43]

Financial estimations

Vaccines

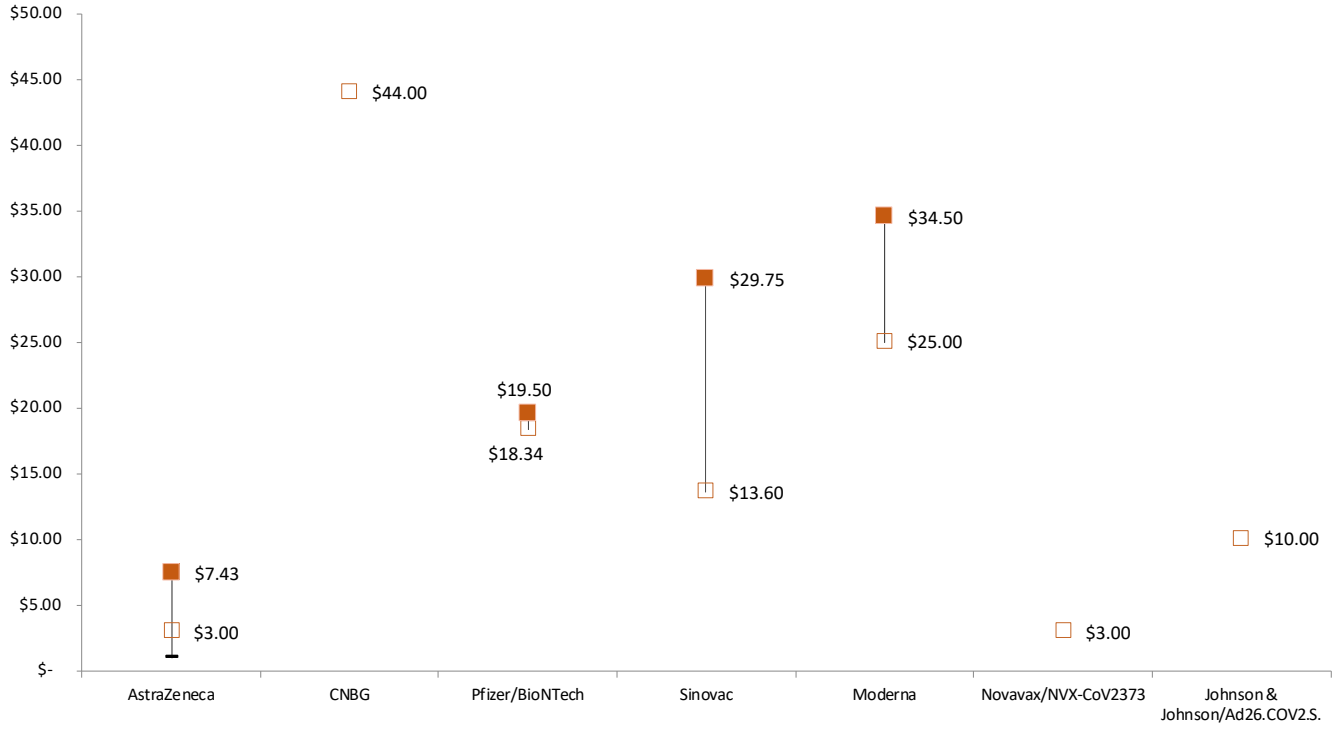
The price of one dose by type of vaccine is shown in Graph 1, which shows both the minimum and maximum prices of vaccines. Only one price is given for several vaccines.

[41] It is expected that this figure will be specified later by the NCDC, when the vaccine will be introduced and a country-specific figure will be obtained.

[42] NCDC; the latest data from Global Fund projects on the procurement of medicines and diagnostics.

[43] National Bank Exchange Rare as of January 15 https://www.nbg.gov.ge/index.php?m=582&lng=geo

Graph 1. Minimum and Maximum Price of One Dose of Vaccine



Source: *https://www.unicef.org/supply/covid-19-vaccine-market-dashboard*

The doses of vaccines required by priority group (and taking into account waste factors) are presented in Table 14.

Table 14: Number of Required Vaccine Doses by Priority Groups

Stage	Target Population	Target Group	Coverage Rate	Contigent to be vaccinated	Number of Doses	Wastage rate %	Wastega Factor	Number of Required Doses including Wastage
1a	Healthcare sector	71,415	65%	46,420	2	15%	1.176	109,223
1a	Beneficiaries and staff of a long-term care facility	2,600	60%	1,560	2	15%	1.176	3,671
1a	> 75 years old population	226,800	60%	136,080	2	15%	1.176	320,188
1b	65-74 years old population	329,183	60%	197,510	2	15%	1.176	464,729
2b	Essential services	180,373	60%	108,224	2	15%	1.176	254,644
2b	55-64 years old population	478,400	60%	287,040	2	15%	1.176	675,389
2b	18-54 years with chronic disease	89,400	60%	53,640	2	15%	1.176	126,212
3	Population other groups	1,434,567	60%	860,740	2	15%	1.176	2,025,271
	TOTAL	**2,812,738**		**1,691,214**				**3,979,327**

As explained above, in order to cover the vaccination of 60% of the adult population, and considering vaccine waste, a total of 3,979,327 doses of vaccine is needed. Currently, Georgia has guaranteed 1,484,400 doses of vaccine from the COVAX platform for 2021, but despite this the financial resources were calculated for the 3,979,327 doses with the assumption that the country will be able to receive an additional 2,494,927 doses from alternative sources.

The financial resources required to purchase vaccines according to these scenarios (and according to the current minimum and maximum price of the available vaccines) are given in Table 15.

Table 15: Minimum and Maximum Costs of Vaccine according to the scenarios

Scenarios	Minimum Costs of Vaccines $	Maximum Costs of Vaccines $	Minimum Costs of Vaccines (GEL)	Maximum Costs of Vaccines (GEL)
Scenario 1				
COVAX 1,484,400 Doses	**5,477,436**	**13,565,783**	**18,075,539**	**44,767,084**
Additional doses to cover all priority groups	5,506,669	7,261,355	18,172,007	23,962,471
Sub-Total	**10,984,105**	**20,827,138**	**36,247,546**	**68,729,555**
Additional doses needed to cover other groups of population	7,473,250	18,508,750	24,661,726	61,078,874
Total	**18,457,355**	**39,335,888**	**60,909,272**	**129,808,429**
Scenario 2				
COVAX 1,484,400 Doses	**5,477,436**	**13,565,783**	**18,075,539**	**44,767,084**
Additional doses to cover all priority groups	7,145,029	10,951,355	23,578,595	36,139,471
Sub-Total	**12,622,465**	**24,517,138**	**41,654,134**	**80,906,555**
Additional doses needed to cover other groups of population	7,473,250	18,508,750	24,661,726	61,078,874
Total	**20,095,715**	**43,025,888**	**66,315,860**	**141,985,429**
Scenario 3				
COVAX 1,484,400 Doses	**5,477,436**	**13,565,783**	**18,075,539**	**44,767,084**
Additional doses to cover all priority groups	3,528,829	9,780,395	11,645,135	32,275,303
Sub-Total	**9,006,265**	**23,346,178**	**29,720,674**	**77,042,387**
Additional doses needed to cover other groups of population	7,473,250	18,508,750	24,661,726	61,078,874
Total	**16,479,515**	**41,854,928**	**54,382,400**	**138,121,261**
Scenario 4				
COVAX 1,484,400 Doses	**5,477,436**	**13,565,783**	**18,075,539**	**44,767,084**
Additional doses to cover all priority groups	1,733,029	4,292,135	5,718,995	14,164,045
Sub-Total	**7,210,465**	**17,857,918**	**23,794,534**	**58,931,129**
Additional doses needed to cover other groups of population	7,473,250	18,508,750	24,661,726	61,078,874
Total	**14,683,715**	**36,366,668**	**48,456,260**	**120,010,003**

As the table shows, the necessary financial resources for vaccines are the highest in the 2nd scenario and minimum cost is approximately 66.3 million GEL, which is 1.4 times higher than necessary for the minimal amount of the 4th scenario. Detailed calculations for each scenario are given below in separate tables:

Table 16: Price of Vaccines under Scenario 1

Contigent to be vaccinated	Number of Doses	Wastage rate %	Wastega Factor	Number of Required Doses including Wastage	ვაქცინა	Minimum cost of vaccine 1 dose	Maximum cost of vaccine 1 dose	Minimum cost of vaccine 1 dose including PSM*	Maximum cost of vaccine 1 dose including PSM*	Total Cost of Vaccines (Minimum) $US	Total Cost of Vaccines (Maximum) $US
85,000	2	15%	1.176	200,000	Pfizer/BioNTech/BNT-162	18.34	19.5	22.56	23.99	4,511,640	4,797,000
630,870	2	15%	1.176	1,484,400	AstraZeneca/AZD1222	3	7.43	3.69	9.14	5,477,436	13,565,783
114,604	2	15%	1.176	269,656	AstraZeneca/AZD1222	3	7.43	3.69	9.14	995,029	2,464,355
860,740	2	15%	1.176	2,025,271	AstraZeneca/AZD1222	3	7.43	3.69	9.14	7,473,250	18,508,750
1,691,214				**3,979,327**						**18,457,355**	**39,335,888**

Table 17: Price of vaccines under Scenario 2

Contigent to be vaccinated	Number of Doses	Wastage rate %	Wastega Factor	Number of Required Doses including Wastage	ვაქცინა	Minimum cost of vaccine 1 dose	Maximum cost of vaccine 1 dose	Minimum cost of vaccine 1 dose including PSM*	Maximum cost of vaccine 1 dose including PSM*	Total Cost of Vaccines (Minimum) $US	Total Cost of Vaccines (Maximum) $US
85,000	2	15%	1.176	200,000	Moderna/mRNA-1273	25	34.5	30.75	42.44	6,150,000	8,487,000
630,870	2	15%	1.176	1,484,400	AstraZeneca/AZD1222	3	7.43	3.69	9.14	5,477,436	13,565,783
114,604	2	15%	1.176	269,656	AstraZeneca/AZD1222	3	7.43	3.69	9.14	995,029	2,464,355
860,740	2	15%	1.176	2,025,271	AstraZeneca/AZD1222	3	7.43	3.69	9.14	7,473,250	18,508,750
1,691,214				**3,979,327**						**20,095,715**	**43,025,888**

Table 18: Price of vaccines under Scenario 3

Contigent to be vaccinated	Number of Doses	Wastage rate %	Wastega Factor	Number of Required Doses including Wastage	ვაქცინა	Minimum cost of vaccine 1 dose	Maximum cost of vaccine 1 dose	Minimum cost of vaccine 1 dose including PSM*	Maximum cost of vaccine 1 dose including PSM*	Total Cost of Vaccines (Minimum) $US	Total Cost of Vaccines (Maximum) $US
85,000	2	15%	1.176	200,000	Any Vaccine 2-8 C	10.3	29.74	12.67	36.58	2,533,800	7,316,040
630,870	2	15%	1.176	1,484,400	AstraZeneca/AZD1222	3	7.43	3.69	9.14	5,477,436	13,565,783
114,604	2	15%	1.176	269,656	AstraZeneca/AZD1222	3	7.43	3.69	9.14	995,029	2,464,355
860,740	2	15%	1.176	2,025,271	AstraZeneca/AZD1222	3	7.43	3.69	9.14	7,473,250	18,508,750
1,691,214				**3,979,327**						**16,479,515**	**41,854,928**

Table 19: Price of vaccines under Scenario 4

Contigent to be vaccinated	Number of Doses	Wastage rate %	Wastega Factor	Number of Required Doses including Wastage	ვაქცინა	Minimum cost of vaccine 1 dose	Maximum cost of vaccine 1 dose	Minimum cost of vaccine 1 dose including PSM*	Maximum cost of vaccine 1 dose including PSM*	Total Cost of Vaccines (Minimum) $US	Total Cost of Vaccines (Maximum) $US
85,000	2	15%	1.176	200,000	AstraZeneca/AZD1222	3	7.43	3.69	9.14	738,000	1,827,780
630,870	2	15%	1.176	1,484,400	AstraZeneca/AZD1222	3	7.43	3.69	9.14	5,477,436	13,565,783
114,604	2	15%	1.176	269,656	AstraZeneca/AZD1222	3	7.43	3.69	9.14	995,029	2,464,355
860,740	2	15%	1.176	2,025,271	AstraZeneca/AZD1222	3	7.43	3.69	9.14	7,473,250	18,508,750
1,691,214				**3,979,327**						**14,683,715**	**36,366,668**

Syringes, Safety Boxes, Personal Protective Equipment and Other Consumables

The financial resources required for syringes, safety boxes, personal protective equipment (surgical masks, protective shields, gloves, disposable gowns) and other consumables (alcohol pads, bandages and vaccination cards) were also calculated according to the scenarios mentioned above. Additionally, and unlike other vaccines, the Pfizer/BioNTech vaccine also requires a syringe (to open the diluent), the diluent itself, and dry ice and special safety goggles for working with dry ice. Additionally, special (insulated) gloves are also needed for working with the Pfizer and Moderna vaccines as well as temperature data loggers. The financial resources required for all scenarios in total are given in Table 20.

Table 20: Total cost of Consumables according to Four Scenarios

Scenarios	Cost of Supplies $	Cost of Supplies (GEL)
Scenario 1		
COVAX 1,484,400 Doses	**559,874**	**1,847,586**
Additional doses to cover all priority groups	189,391	624,991
Sub-Total	**749,266**	**2,472,577**
Additional doses needed to cover other groups of population	763,876	2,520,791
Total	**1,513,142**	**4,993,367**
Scenario 2		
COVAX 1,484,400 Doses	**559,874**	**1,847,586**
Additional doses to cover all priority groups	217,927	719,158
Sub-Total	**777,801**	**2,566,744**
Additional doses needed to cover other groups of population	763,876	2,520,791
Total	**1,541,677**	**5,087,534**
Scenario 3		
COVAX 1,484,400 Doses	**559,874**	**1,847,586**
Additional doses to cover all priority groups	179,305	591,705
Sub-Total	**739,179**	**2,439,291**
Additional doses needed to cover other groups of population	763,876	2,520,791
Total	**1,503,055**	**4,960,082**
Scenario 4		
COVAX 1,484,400 Doses	**559,874**	**1,847,586**
Additional doses to cover all priority groups	179,305	591,705
Sub-Total	**739,179**	**2,439,291**
Additional doses needed to cover other groups of population	763,876	2,520,791
Total	**1,503,055**	**4,960,082**

As the table shows, the cost of consumables in the second scenario is the highest. Financial resources necessary for the third and the fourths scenarios are equal.

Cold Chain

An assessment of Georgia's current cold chain capacity (as described in the cold chain section) has shown

that this capacity is sufficient for all four scenarios and that no additional refrigerators and freezers would be required to be purchased. Georgia therefore has no need for additional financial resources in this regard.

Service delivery

As explained above, different types or models of service provision are being discussed. The financial resources needed for service provision were calculated per individual vaccination visit and covering one person totally (with 2 doses). These calculations were made for both medical facilities (hospitals and clinics) as well as for mobile teams. The cost of service provision for mass vaccination centers will be calculated later.

Table 1: Cost of providing services per individual dose/unit

Service delivery type	Unit Cost of service delivery per 1 vaccination visit	Unit Cost of service delivery per full immunized person (2 doses)
Hospitals and PHC	2.5	5
Mobile Teams	6.7	13.4

In the cost of this individual service are included direct as well as indirect costs. This price also includes waste management costs. For the unit cost of mobile teams, an antishock package price was also added as well as transportation costs and the investment needed for their functioning, e.g. tablets with internet cards, 4.4-liter capacity cold boxes and cold box thermometers.

Vaccine logistics/distribution

Operational costs for the distribution of vaccines from a central warehouse to regional and district warehouses include fuel costs, vehicle maintenance costs as well as travelling allowances for personnel.

The proper functioning of vaccine distribution-logistics system requires the hiring of 1 additional person. The salary of this person has been determined, and this cost was added to the operational costs of logistics. The total amount of costs for this component is shown in Table 5 above.

Supervision/Monitoring

In order to carry supervise and monitor the vaccination process, special visits were planned from the center level to the regions as well as regional visit to district levels. The financial resources needed for supervision consist of travelling allowances, accommodation costs and transportation costs. These costs are given in Table 5 above.

Information system

At this stage the financial resources of the information system component only includes the cost of hiring additional personnel for the proper functioning of a hot line (see Table 5).

Training

Financial resources for training were calculated according to the training plan (as described above in the section of training). The training budget includes every module—including crisis communications, interpersonal communications and trainings for media representatives (see Table 5).

Creating demand and communication

Financial resources for creating demand and communication were calculated according to the detailed plan for this component's implementation, and amount to GEL 1,662,800 or USD 503,879. Georgia will have to work actively with donor and partner organizations in order to mobilize and manage the necessary financial resources.

Annex 3 - Principles of Priority Group Selection

The WHO/SAGE Value Framework serves as the basis for the selection of priority groups for vaccination.[44]

Objectives

1. Reducing severe cases and mortality
2. Reducing the risk of infecting vulnerable groups
3. Sustainability of essential services

While determining priority groups, the following shall be taken into consideration:

- The wider global and national epidemiological image: widespread scenario as of December 2020
- The availability of vaccines according to supply stages
- Implementation possibilities, i.e., the practical possibility of parallel or simultaneous vaccination
- Ethical aspects: maximum benefit and minimum harm, fairness, equality, transparency

Vaccine Supply Stages

Stage I—Very limited availability of vaccines (1-14% of the adult population); Ia: 1-6%; Ib: 7-14%

Stage II—The supply of vaccines is increasing, but availability is limited (14-26% of the adult population)

Stage III—Moderate availability of vaccines (27–60% of the adult population)

Gradual Introduction of Vaccines in the Context of the Goals

- At the initial stage vaccine supply will be limited, and prioritization therefore means achieving the set objectives with maximum effect. As vaccine stocks increase, vaccinated groups will expand by prioritizing and later by covering extended groups of the adult population. It is important to note that along the accumulated evidence of the vaccine, recommendations for the different groups of the population may change depending on the characteristics of each vaccine, the epidemiology of the disease, and other contextual factors.

Reducing Severe Cases and Mortality

To stop the transmission of COVID-19, the vaccination of a large proportion of the population would be highly effective in preventing the spread of infection.[45] High-level evidence at the beginning of vaccination on virus transmission is not be available, and vaccine availability is limited. The best strategy to reduce morbidity and mortality in the early stages of vaccination is therefore to directly protect those at increased risk of morbidity and mortality from infection.

[44] WHO/SAGE values framework for the allocation and prioritization of COVID-19 vaccination, September 14, 2020.

[45] "COVID-19 vaccines: no time for complacency". *Lancet*. 2020 Nov 21;396(10263):1607. doi: 10.1016/S0140-6736(20)32472-7. PMID: 33220729.

Reducing the Risk of Infecting Vulnerable Groups

- **Healthcare personnel** are considered to be one of the highest-risk groups in terms of infection, and in turn pose a risk to the vulnerable groups they provide medical care to.[46] [47] Protecting healthcare personnel from infection will reduce post-infection transmission to vulnerable groups and help maintain the healthcare system during an epidemic. WHO/SAGE recommends that very high and high-risk healthcare personnel be vaccinated at the first stage. At the initial stage, in case of limited vaccine availability (<1%), personnel employed in the healthcare system will be prioritized according to this principle (see more detailed information below). When the vaccine will become available for 3% of the population, it is advisable to vaccinate every person employed in the healthcare system at the first stage (Ia) of vaccination. In addition, one-stage vaccination will facilitate the work processes related to vaccination (planning, contingent recruitment, vaccine logistics, accounting, monitoring).
- **Beneficiaries of long-term care facilities** are at high risk due to the rapid spread of infection in the facility, while staff working at this facility pose a risk to the beneficiaries in terms of transmission. Due to these risks, vaccination of this contingent is planned during Stage I, during which the vaccination of persons with disabilities in organized groups (community, family-type organizations) is also planned.
- International evidence and analysis of the epidemiological situation in Georgia indicate that the greatest risk of COVID-19 mortality is **high age**, and that risk increases exponentially with age. As of December 2, 2020, the total age structure of deaths from COVID-19 in Georgia is as follows: > 75 years: 39.2%; 65-74: 33.2%; 55-64: 18.8%; 50-54: 4.1%; 18-49: 4.6%.[48] In terms of age-related risk, the strategy envisages the gradual vaccination of people by decreasing age group, regardless of concomitant pathologies. During the first stage (Ia: vaccine availability 6.5% of adult population), the population aged 75 and over will be vaccinated; whereas during the next stage (Ib: 7-13.5%) people aged 65-74 will be vaccinated. During the second stage (availability: 14-26%), people aged 55-64 will be vaccinated. As the COVID-19 mortality analysis shows a significant reduction in the risk of death in the under-55 age group, the next step is to cover the remaining adult age group (18-54) with concomitant chronic diseases. Vaccination by age group also makes it easier to persuade people of the importance of vaccination, thus achieving a higher coverage rate and helping to speed up the process.

[46] "Transmission of SARS-CoV-2: implications for infection prevention precautions: scientific briefing", July 9, 2020. Geneva: World Health Organization, 2020. (https://apps.who.int/iris/handle/10665/333114, accessed December 5, 2020).

[47] "Infection prevention and control during healthcare when coronavirus disease (COVID-19) is suspected or confirmed: interim guidance", June 29, 2020. Geneva: World Health Organization, 2020. (https://apps.who.int/iris/handle/10665/332879, accessed December 5, 2020).

[48] National Center for Disease Control and Public Health

- Evidence (international as well as local epidemic analysis) indicates that certain **chronic conditions** increase the risk of severe COVID-19 morbidity and mortality.[49] [50] In general, the risk of concomitant chronic disease increases with age, but because the vaccination strategy envisages delivery to people over 55 regardless of comorbidities, this will reduce the risk of severe complications and death from chronic diseases in vulnerable populations. Given the availability of the vaccine, vaccination will be available to people aged 18-54 with the following comorbidities:
    - Diabetes (types I and II)
    - Cardiovascular diseases:
        - Ischemic heart disease (every clinical form, with or without revascularization)
        - Cardiomyopathy
        - Valve pathology, congenital heart defects in adult age
        - Atrial fibrillation (permanent form)
        - Idiopathic long QT syndrome (high risk of fatal arrhythmias and sudden cardiac death)
        - Chronic heart failure of B,C,D (ACC/AHA) stages and II-IV (NYHA) functional class
        - Deep vein thrombosis
        - Pulmonary embolism in anamnesis

      Note: Arterial hypertension will be covered in age groups above 55.
- Chronic respiratory diseases
    - Chronic obstructive pulmonary disease
    - Asthma
    - Cystic fibrosis
    - Idiopathic pulmonary fibrosis
- Onco-hematological diseases
- Cancer (considering the contraindications of a particular vaccine)
- Chronic renal failure
    - Persons on dialysis
- Chronic liver pathology

[49] European Centre for Disease Prevention and Control. Available from: https://www.ecdc.europa.eu/en/covid- 19/latest-evidence/epidemiology.

[50] (CDC) USCfDCaP. Evidence used to update the list of underlying medical conditions that increase a person's risk of severe illness from COVID-19 [Internet]. Atlanta: CDC; 2020. Available from: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/evidence-table.html

- Hepatic fibrosis - stage 3 and 4
- People having suffered a stroke
- Post-transplant conditions
- Immunosuppressed patients
- Extreme obesity (BMI $\geq$ 40 kg/m^2)

Sustainability of Essential Services

- The functioning of essential services is extremely important for maintaining the health of the population and for the safety and management of the education process. It will be possible to remove the burden of staff disease on the healthcare system through vaccinations carried out in Phase I. Personnel involved in the operation of other essential services will be covered during Phase II and III. Essential services include:
  - Staff of the Ministry of Internal Affairs (including front-line staff of the Emergency Management Service)
  - Ministry of Defense (army)
  - Long-distance transport operators (drivers, persons involved in sea, air or rail transport)
  - Pharmacy front-line staff
  - Service staff of early pre-school educational institutions, as well as teachers and personnel of public schools (if necessary, priority will be given to the teaching staff of classes up to 4th grade, and later to the personnel of higher classes).
  - Public transport staff (drivers, train drivers, ticket inspectors)
  - Taxi and mini-bus drivers
- During phase III, the vaccination of other high-risk groups will be carried out: detained persons, prison inmates (according to the same approach as to the population age groups, and citizens with chronic conditions), those in direct contact with them and miners.
- A target coverage rate is provided for each priority group (65% of the personnel employed in the health sector, 60% of the age and essential groups of the population). This target rate is higher than existing evidence of the achievable coverage level of the first year of a new vaccine introduction. However, given that the COVID-19 vaccine has a different context than other vaccines, coverage will depend significantly on the general population and specific groups (e.g. medical staff) in terms of initial acceptance and the progress of vaccination. Current evidence indicates that acceptance of the

COVID-19 vaccine varies between 55% (Russia) and 99% (China),[51] whereas according to a survey carried out by the WHO and UNICEF in Georgia, 56% of the population would agree to be vaccinated if the vaccine is available and recommended.[52]

- During the process of vaccination, the coverage of priority groups will be constantly monitored. In case of excessive demand, or if the coverage of a specific priority group exceeds the forecasted rate, priority groups will be reprogrammed.
- According to available evidence, infection is not a contraindication to vaccination, but this recommendation may be revised according to new evidence.
- Pregnant women and children under 16 are not considered in the COVID-19 immunization groups due to lack of solid evidence related to safety.
- After covering 20% of the population, the remaining adult population will be vaccinated according to the number of vaccines. The definition of contingents (by age group or following other approaches) will be determined by the number of vaccines.
- When calculating the timing of vaccination stages, the dose to be delivered should be taken into account. At the first stage (Ia), the vaccination of the upper age group can be started in parallel with that of healthcare sector representatives (or after a certain period of time). A person not entitled to vaccination who comes to a vaccination facility during that period should not be refused vaccination if the stock of vaccines in the country includes the coverage of a specific contingent.

All groups according to priority and according to vaccine availability are:

- Phase 1a (1-6.5% of adult population).
    - Personnel employed in the **healthcare sector** are being divided according to priorities into the following sub-groups:
        - **At very high risk and high risk**: *personnel at risk of being exposed to aerosols with SARS-Cov-2, being in close contact with infected patients or those suspected of being infected, or in contact with contaminated surfaces.*
            - Every personnel (medical and non-medical) employed in functioning Covid clinics
            - Doctors working in other (non-Covid) clinics (including junior and resident doctors), nurses, cleaners, anesthesia-ICU staff, critical medicine, emergency care, ambulances (including drivers), medical radiology (X-ray, computer tomography), infection control/epidemiology/public healthcare (those included in taking tests, contact tracing), laboratory specialists (those included in taking

[51] Lazarus, J.V., Ratzan, S.C., Palayew, A. et al. "A global survey of potential acceptance of a COVID-19 vaccine". *Nat Med* (2020). https://doi.org/10.1038/s41591-020-1124-9

[52] WHO/UNICEF, preliminary data, 7 December 2020.

tests/analysis), security personnel

- Every person working in potential (currently non-active) Covid-clinics

- **At medium risk**: *personnel who are not required to be in direct contact with the public, with people known to be or suspected of being infected; who have frequent and close contact with the people in busy staff work areas within a healthcare facility and work activities where safe physical distance may be difficult to maintain, or tasks that require close and frequent contact between co-workers*: every other medical and non-medical personnel employed in the healthcare sector
- **At low risk**: *people who are not required to be in frequent or close contact with the public or with people suspected of being infected*—e.g. medical personnel involved in telemedicine, people doing distance administrative work.

- Beneficiaries and staff of long-term care facilities, as well as those of community and family like homes
- People over 75

- Phase 1b (7-13.5% of the adult population)
  - 65-74 age group
  - Essential services (1 group)
    - Staff of the Ministry of Internal Affairs (including front-line staff of the Emergency Management Service)
    - Long-distance transport operators (drivers, persons involved in sea, air or rail transport)
    - Ministry of Defense (army)
- Phase II (11-20% of the entire population, 14-26% of the adult population)
  - 55-64 age group
  - 18-54 age group suffering from chronic diseases
- Phase III (Above 20% of total population, 26%-60% of the adult population)
  - Groups providing essential services (II group)
    - Pharmacy front-line staff
    - Public transport staff (drivers, train drivers, ticket inspectors)
    - Service staff of early pre-school (kindergartens) educational institutions
    - Teachers and personnel of public schools (if needed priority will be given to the personnel of up to 4th grade and later to the personnel of higher classes)
    - Long-distance transport operators (drivers, persons involved in sea, air or rail transport)
    - Prisoners/convicts (>55 years, citizens 18-54 with chronic conditions) and personnel

in contact with them due to their professional duties

- Miners
- Taxi and mini-bus drivers

- Other groups of the population

Used data sources: Public healthcare sector: NCDC; Long-term care facilities: the Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia; Population groups: National Statistics Office of Georgia; Essential services: relevant ministries, local authorities, National Statistics Office of Georgia.

WHO/SAGE Value Framework

PRINCIPLE	OBJECTIVE
Human Wellbeing	Reduce deaths and disease burden from the COVID-19 pandemic;
	Reduce societal and economic disruption by containing transmission, reducing severe disease and death, or a combination of these strategies;
	Ensure the continuous operation of essential services, including health services
Equal Respect	Treat the interests of all individuals and groups with equal consideration as allocation and priority-setting decisions are being taken and implemented;
	Offer vaccination opportunities to all individuals and groups who meet the priority criteria
National Equity	Prioritize the risks and needs of vulnerable groups due to social, geographical or biomedical factors
	Establish immunization delivery systems and infrastructure needed to provide access to and prioritize COVID-19 vaccine populations to ensure equal access for all those included in the priority group, especially vulnerable populations
Reciprocity	Protect those who bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others, including health and other essential workers.
Legitimacy	Provide a transparent consultation process to agree on what scientific, public health and value criteria should be used to make vaccine distribution decisions

Annex 4 - Monitoring and Reporting COVID-19 Vaccine related AEFI

Issues to consider before introducing the COVID vaccine and providing immunization services include:

Monitoring of Vaccines and Quality Defect-related AEFI

Action	Status	Responsible Party
Determining and applying the list of health conditions of special interest (s) in addition to the post-vaccination status already subject to surveillance and reporting in the country	Has been defined	NCDC
Determining national background rates of AESI	Has been defined 2019 version has been selected, requires some refinement	NCDC

Reactions Related to Immunization Error

It is possible to prevent error-related reactions to immunization, and the timely detection and correction of such errors is very important. The AEFI of this class can be minimized to the cost of enhancing program elements, which implies:

Action	Status	Responsible Party
Selecting service providers	See Service Provision section	MoILHSA/NCDC
Determining the methods of service delivery	See Service Provision section	MoILHSA /NCDC
Determining cold chain volume, provision and supply needs	See Cold Chain section	NCDC
Determining requirements and supply of immunization materials (syringes, needles, safe disposal boxes, appropriate restorations, vaccine carriers, etc.)	See Cold Chain section	MoILHSA /NCDC
Identifying contraindications and warning conditions for COVID-19 vaccine	Determined according to the vaccines to be introduced	MoILHSA /NCDC
Prepare training materials and train service providers on the following issues: 1. Cold chain storage and management of COVID-19 vaccine supplies 2. COVID Vaccine handling 3. COVID vaccine immunization technique 4. Contraindications and warnings of COVID vaccine 5. Expected AEFIs for COVID vaccine 6. Manage the vaccination service delivery process	Determined according to the vaccines to be introduced See Human Resources section	NCDC

Immunization-related Reactions

Action	Status	Responsible Party
Informing the population	See Communication section	National, Subnational
Information campaign before and during immunization service provision	See Communication section	National, Subnational
Preparation and supply of information leaflets	See Communication	NCDC/Municipal Public

	section	Health Centers National, municipal Public Health Centers
Ensure the proper management of the vaccination process by minimizing friction between injection recipients, resulting in reduced waiting times, a comfortable room temperature and confidentiality during the procedure		Administration of selected service providers
Provide a clear and convincing explanation of immunization from the service provider to reduce the level and spread of concerns due to injections	See Communication section	National immunization personnel
Crisis Communication Plan in place	See Communication section	MoILHSA/NCDC

Monitoring AEFI related to Coincidental Events

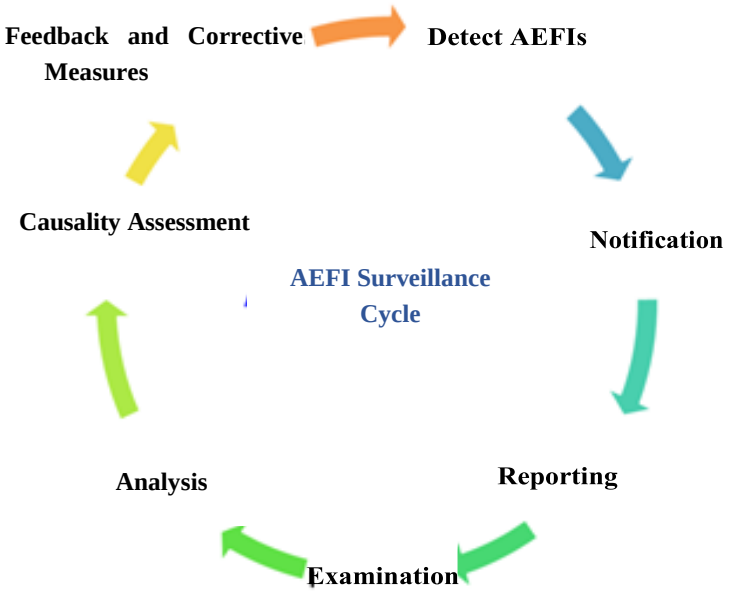
The assumption of an increase in vaccine-related events is logical when campaigning for a high-age target contingent. In chronic concomitant disease, it is very difficult to make a differential diagnosis between a coincidental event in time and AEFI. Minimizing such cases will allow the state program to save resources and pay more attention to the management of other cause-specific AEFIs. In order to prevent these events:

Action	Status	Responsible Party
An assessment of the health status of the vaccinated person should be provided in accordance with the pre-vaccination procedure	Endorsed in 2019	Service Provider Medical Personnel
Identify national background rates of existing conditions and AESI under supervision	To be refined	NCDC

AEFI Accounting and Reporting

Georgia's AEFI monitoring system is sound and rapidly adaptable, so the principles of passive monitoring and reporting channels for the possible AEFI of a COVID-19 vaccine do not require a fundamental change and will be carried out in accordance with the established rule.

The current cycle of AEFI-related information is:



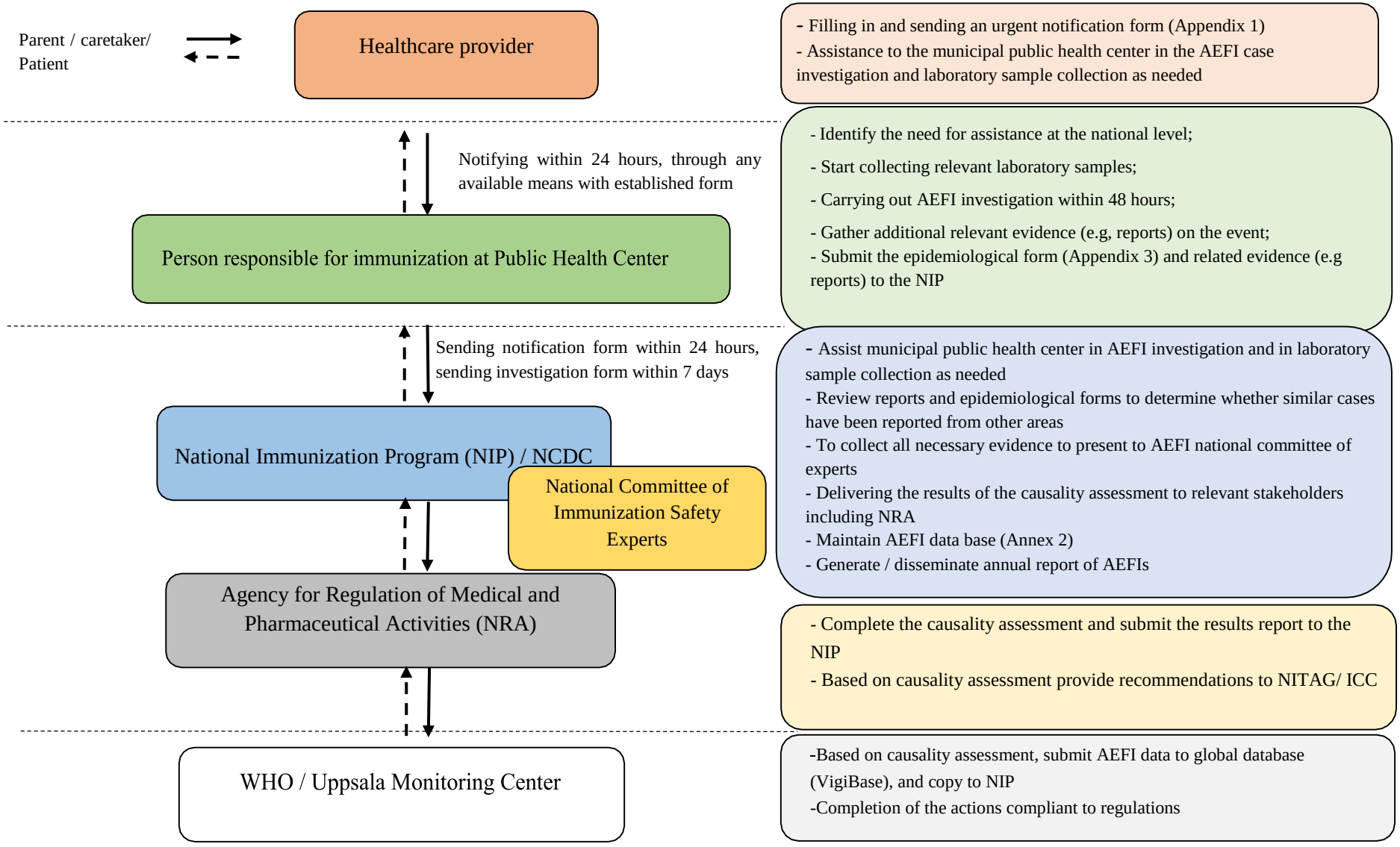
Georgia's current AEFI surveillance system focuses on:

- Rapidly detecting AEFIs and quickly responding to their origin
- Identifying, correcting and preventing error-related reactions to immunization
- Facilitating AEFI causality assessments
- Knowledge of AEFI clusters or unusually high rates
- Identifying potentially dangerous signals (including previously unknown reactions to vaccines) and developing hypotheses that may require further investigation
- Generate information on the safety of vaccines used in Georgia, which helps to communicate effectively with stakeholders.

The parties involved in the reporting and investigation of AEFIs are:

- At the sub-national level: healthcare personnel, municipal public health service staff responsible for immunization, Autonomous Republic / regional public healthcare services
- At the national level: State Immunization Program, Agency for the Regulation of Medical and Pharmaceutical Activities, National Committee of Immunization Safety Experts.

AEFI reporting, routing actions, flows and timelines



The introduction of a COVID-19 vaccine requires adjustments to the existing rule for reporting:

Action	Status	Responsible Party
Monthly reporting on AEFI has been introduced	Has been prepared	MoILHSA/NCDC
Special interest events added to AEFI notification form	Has been prepared	MoILHSA/NCDC
Changes to AEFI investigation form by adding COVID vaccine and AESI	Has been prepared	Public Health Center
Adapt the EIDSS for the registration of COVID-19 vaccine AEFIs	See Information Systems section	NCDC
Adapt the online electronic immunization and stock management module to register COVID-19 vaccines	See Information Systems section	NCDC
Coding AEFI cases and data transformation for international notifications	TBD	MoILHSA/NCDC
Coding AEFI cases	See Information Systems section	NCDC

Existence of Readiness Regulations

1. Develop draft rules for the monitoring of AEFIs before and during COVID-19 vaccination
2. Description of key issues related to the introduction of epidemiological surveillance, AEFI requirements and problem management
3. Detailed information to the National Committee for Immunization Safety to support the assessment of AEFIs (with the participation of the scientific community, regulatory authorities and the immunization program)
4. Description of steps to ensure the safety of injections
5. Reporting, staff roles and responsibilities.