NATIONAL PLAN FOR COVID-19 VACCINE INTRODUCTION IN GEORGIA

Abbreviations used in the document

NCDC	LEPL - L. Sakvarelidze National Center for Disease Control and Public Health
NEDSS	National Electronic Disease Surveillance System
LIC	Low-income countries
AEFIs	Adverse events following immunization
PCR	Polymerase chain reaction
PHC	Public Health Centers
WHO	World Health Organization
ADB	Asian Development Bank
ECDC	European Centre for Disease Prevention and Control
ILI	Influenza-like illness
NITAG	National Immunization Technical Advisory Group
SARI	Severe acute respiratory infections
UNICEF	United Nations Children's Fund
WB	World Bank

1. Introduction

The novel coronavirus (SARS-CoV-2) and the disease it causes (COVID-19) have become a major concern for humanity as the pandemic has caused unprecedented economic losses along with human losses. The fight against COVID-19 has become a top priority for governments of all countries.

Georgia started preparing for the epidemic at an early stage. The containment measures taken by the government of the country in the spring of 2020 and the steps taken to overcome the crisis have mitigated the negative impacts associated with COVID-19, which made it possible to lift in stages the restrictive measures since May. Under the influence of various factors, as well as in accordance with trends in the region, an intensive increase in the novel coronavirus infections and new cases began in Georgia in September, which led to a massive spread of the epidemic throughout the country. With the increase in morbidity, Georgia reached an alarming level of use of important parameters for epidemiological control (including reproduction index, mortality rate, and positive test results) and the use of hospital resources, after which the Government of Georgia in late autumn again made certain prohibitive measures mandatory for prevention and stabilization purposes and extended the targeted restrictions. This approach to managing the pandemic is the most effective at the moment, but it puts a strain on the country's economy, hinders the normal functioning of the education sector and the further development of the country. As of December, the confirmed incidence rate in Georgia was 5,834 per 100,000 population, and the estimated infection rate was 15%. The recovery rate is 89%, while the mortality rate is 1%. COVID-19 became the country's leading cause of death in the fall and will be the fourth leading cause of death by 2020.

To stabilize the status quo and save more lives before an etiotropic medicinal product for COVID-19 is developed, introducing and administering safe and effective COVID-19 vaccines is ultimately the key to preventing the epidemic.[1]

To facilitate the definition and implementation of the COVID-19 vaccination policy in Georgia, an Interagency Coordination Commission for the Implementation of COVID-19 Vaccination in Georgia was established under the chairmanship of the Minister of IDPs from the Occupied Territories, Labour, Health and Social Affairs of Georgia.[2] The preparation of the vaccination plan is also coordinated by the NCDC. A team of experts was involved in the process with the support of the Asian Development Bank. A methodological document proposed by WHO was used as a guide.[3] Eight technical working groups were established in different thematic areas. The groups included industry experts, representatives of various structures in the healthcare sector, and service providers. Through extensive consultation and discussion, this document has been produced to guide the implementation of COVID-19 vaccination.

The Vaccine Implementation Plan outlines the activities, responsibilities and financial requirements necessary for the vaccination process to be effective in the country. Due to the constantly changing situation related to testing-registration and production-distribution-supply of vaccines in the world, the national plan for the introduction of the COVID-19 vaccine in Georgia will be periodically adjusted and adapted in accordance with new information.

2. State Immunization Programme in Georgia

[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 No. 2459 of the Government of Georgia of 15 December 2020 on the Establishment of the Interagency Coordination Commission for the Implementation of COVID-19 Vaccination in Georgia.

[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.

The state immunization programme in Georgia provides for free vaccinations with an immunization schedule and epidemiological vaccines. Vaccination is regulated by the Law of Georgia on Public Health[4] and regulations.[5] The programme has traditionally had a well-maintained cold chain network, monitoring and surveillance system. Vaccination rates are high for most vaccines, although for some antigens are lagging behind annual rates in both the region and the country (95%). The reasons for this are: less interest of private institutions in vaccination; Low staff motivation, tight work schedule; Insufficient communication between primary health care facilities and public health services; Parents' resistance to vaccination (especially in large cities) and other factors.

Since 2013, seasonal influenza vaccination has been carried out in pre-selected risk groups and in accordance with the recommendations of the World Health Organization (WHO) as part of a government programme. From year to year, the number of purchased vaccines is increasing and the list of priority risk groups subject to vaccination is expanding. During the season of 2020/21, 235,000 doses of influenza vaccine have been introduced in the country, and by January 6 of this year, the vaccination rate is 75%.

The capabilities and resources of the National Immunization Programme are reflected in this COVID-19 Vaccination Implementation Plan and will be optimally used to spread the vaccination campaign across the country, while existing deficiencies in the immunization programme and public attitudes towards routine vaccines are even factored into the service delivery and communication strategy parts of this implementation plan.

3. COVID-19 Candidate Vaccines and Approved Vaccines

Given the fact that information about expected COVID-19 vaccines is constantly changing and updated daily, and vaccine delivery times also vary, the current plan is based (for the most part) on reality as of 19 March 2021 and considers introducing the following vaccines:

Table 1. Review of Candidate Vaccines as of 19 March 2021[6]

Manufacturing company	Vaccine type	Required doses and interval	Dose / volume	Development stage	Expected or received authorization
BioN-Tech/ Pfizer	mRNA	2 doses, 0-21 days	1 dose = 0.3 ml IM	Allowed to use: Switzerland, Bahrain, Brazil, New Zealand, Saudi Arabia Emergency Authorization: United Kingdom, USA, Canada, European Union, Israel, Norway, Iceland and other countries	December 2020
Moderna/ Lonza	mRNA	2 doses, 0-28 days	1 dose =0.5ml IM	Allowed to use: in Switzerland. Emergency Authorization: USA,	December 2020

[4] Law of Georgia on Public Health (Adopted: 27/06/2007).

[5] Order №01-60/ნ of the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia of 16 September 2019 on the List of Infectious Diseases of the National Calendar of Prophylactic Vaccinations for Which Prophylactic Vaccinations Are Mandatory and Approval of Age-Appropriate Indicators, Timeframes and Rules of Immunization Management.

[6] https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/ Information was extracted on 19 march 2021.

				European Union, United Kingdom, Norway, Iceland, Israel and other countries	
Oxford/ Astra-Zeneca	Non-replicating virus vector	(1-) 2 doses 0, 28 days	1 dose =0.5ml IM	Emergency Authorization: European Union, United Kingdom, USA, Australia, Norway, Iceland, Argentina, Chile, Brazil, India and other countries	January 2021
Sinopharm	Inactivated virus	2 doses, 0-14 days	1 dose =0.5ml IM	Allowed to use: In China Emergency Authorization: Peru, Argentina, Bahrain, United Arab Emirates, Jordan, Egypt	Received registration in the United Arab Emirates in December 2020
J&J/Janssen	Non-replicating virus vector	(1-)2 doses 0, 56 days	1 dose =0.5ml IM	Emergency Authorization: USA, United Kingdom, Bahrain, Argentina, Brazil, Belgium, Colombia and ther countries	2021
SP/GSK	Recombinant	2 doses, 0-28 days	1 dose =0.5ml IM	The 3rd phase: USA	2021
Sinovac Biotech Co., Ltd	Inactivated virus	2 doses, 0-14 days	1 dose =0.5ml IM	Allowed to use: in China Emergency Authorization: Chile, Turkey, Indonesia, Brazil and other countries	2021
Novavax	Virus protein component	2 doses, 0-21 days	1 dose =0.5ml IM	The 3rd Phase: United Kingdom, USA, Mexico, Puerto Rico	2021
Serum Institute of India	Virus protein component	2 doses, 0-28 days	1 dose =0.5ml IM	½ phase: Australia	2021
Bharat Biotech	Inactivated virus	2 doses, 0-28 days		The 3rd Phase. Emergency Authorization: India, Iran, Zimbabwe	Bharat Biotech

Some above stated vaccines - Pfizer / BionTech, Moderna AztraZeneca and Johnson & Johnson are already approved by the US and the European Union (and other reliable regulatory bodies) and are on the

WHO Emergency Use Listing[7]. These vaccines are allowed for use in some countries, while in some countries they are only authorized for emergency use[8].

It should also be noted that most of the vaccines listed in the table are stored at 2-8 ° C, with the exception of Pfizer / BionTech and Moderna, which are stored at -700 ° C and -200 ° C, respectively. Thus, this plan is based on the use of vaccines among highly effective candidate vaccines with potentially three temperature regimens as a result of research. Taking into account the need for an ultracold chain and the associated logistical difficulties, the use of Pfizer / BionTech vaccine, as well as Moderna vaccine in limited quantities, is considered in terms of organized use for priority groups. The number of possible maximum doses of both vaccines was determined only for the first 3% of the population, that is, the priority groups. From the first quarter of 2021, it will be possible to receive vaccines according to the temperature control of 2-8 ° C, for which the cooling systems, cold chain and other logistic systems of Georgia are fully adapted.

In selecting candidate vaccines, a country is guided by the following criteria: (a) the stage of vaccine development / licensing and expected market launch dates; (b) the storage temperature control and requirements (complexity-variability) for a cold chain needed for vaccines; (c) deadlines for possible registration of a specific vaccine by strict regulatory authorities; (d) availability of the vaccine on the COVAX platform;[9] and (e) the risk of possible adverse public reactions to a particular vaccine, according to the accumulation of new evidence on the safety/frequency of adverse effects, spread and severity of the vaccine in large-scale vaccination programmes of the manufacturer and the country of manufacture, as well as in other countries.

4. Regulatory framework

The current reality in terms of the rapid introduction of vaccines requires a complete regulatory framework of the country and full readiness of the relevant structures of the Ministry for Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Protection (hereinafter referred to as the Ministry) for the smooth operation of the import process.

In accordance with the legislation of Georgia, there are two ways to register a pharmaceutical product on the Georgian market.[10] The basis for the application of a **recognition regime** is the differentiation of a state body regulating pharmaceutical products in a foreign country or internationally in terms of reliability and granting a market authorization to only high quality pharmaceutical products in markets under the control of this body. In particular, Georgia unilaterally recognizes the safety, efficacy and quality requirements for for granting market authorization to a pharmaceutical product in markets under the control of this body, set by a state body regulating pharmaceutical products in a foreign country or internationally. Georgia does not carry out a repeated expertise with regard to the above or similar requirements in order to determine the safety, quality and therapeutic efficacy of a pharmaceutical product.

[7] A procedure of Emergency Use Listing is a procedure defined by the World Health Organization for the use of new or unlicensed products (vaccines, treatment and diagnostic products) in public health emergencies.Emergency use listing procedure (who.int).

[8] An Emergency Use Authorization is a mechanism used by a country's regulators during public health emergencies, such as the current COVID-19 pandemic, to facilitate access to a completely unregistered vaccine or other medical countermeasures needed to treat or stop the spread of a disease. Such an authorization is only granted if there is no other alternative and the particular product meets the standard requirements of the regulatory body in terms of safety and efficacy. https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.

[9] https://www.unicef.org/supply/covid-19-vaccine-market-dashboard Information is obtained as of 19 march 2021.

[10] Law of Georgia on Medicinal Products and Pharmaceutical Activity.

Reliable regulators (European Medicines Agency and regulators from 37 countries),[11] the timeframe required for the procedure (15 working days), the rules and conditions for registration[12] are determined by secondary legislation.

The rules and conditions for the registration of a pharmaceutical product under **the national registration regime** provide for administrative and scientific- technical expertise of registration documents for a pharmaceutical product[13]. The deadline for registration of immunobiological preparations (including vaccines) is three months. None of the conditions of the regime provides for emergencies and benefits assigned to it.

The legislation of Georgia defines exceptional cases of regimes for placing a pharmaceutical product on the Georgian market[14], when the so-called pharmaceutical product is issued for a one-time registration under special conditions (natural disaster, massive damage to the population, epidemic, rare disease) for humanitarian purposes, as well as in the presence of other special state interests with the consent of the Ministry. The procedure for importing a pharmaceutical product in this way is determined by a regulatory order[15]. **Accordingly, the COVID-19 vaccine will be allowed to be used in Georgia through a single registration of the pharmaceutical product on the Georgian market after the vaccine is approved by a reliable regulatory authority or is included in the WHO Emergency Use Listing.**

The documents required for a single registration, as well as for import and customs clearance will be submitted in advance to the relevant authorities, which minimizes the delay of the pharmaceutical product at customs.

A buyer of the vaccine decides on the formal side of customs (filing documents, customs clearance, warehousing, logistics to the destination) foer registration at the time of import or under exclusive imports. Once verified, the documents are uploaded to the Revenue Service portal, the documents are immediately verified and the shipment is placed at the NCDC central warehouse not later than 24 hours after entering the country.

It should be noted that there is no universal agreement on a single format and contents for vaccine vials and packaging, although WHO has already developed a model for harmonizing secondary packaging for vaccine labeling to be used by COVAX.[16] Manufacturers will also disregard the country's packaging and labeling requirements. The legislation of Georgia does not restrict the admission of a pharmaceutical product, the packaging of which is not presented in Georgian, but requires translation of documentation (package inserts) into Georgian. Due to the emergency, the Georgian side will be responsible for the translation of the package insert into Georgian.

Given the fact that insurance will not be available for manufacturers, which protects the manufacturer from the risks of liability for potential harm caused by the vaccine, the manufacturers require each country to take this responsibility and in this way insure the manufacturer. To fulfill the

[11] Ordinance №188 of the Government of Georgia dated 22 October 2009 on Determining the List of State Bodies Regulating Pharmaceutical Products in a Foreign Country or Internationally.

[12] Order №344/ნ of the Minister of Labour, Health and Social Protection of 23 October 2009 on Establishing the Rules and Conditions for Verifying the Authenticity of Access to the Markets under the Control of the Relevant State Body Regulating Pharmaceutical Products in a Foreign Country or Internationally during the State Registration of a Pharmaceutical Product on the Georgian Market under the Recognition Regime, as well as during Different Packaging-Labelling of a Pharmaceutical Product already Registered on the Georgian Pharmaceutical Market.

[13] Law of Georgia on Medicinal Products and Pharmaceutical Activity (Article 11^{11}).

[14] Law of Georgia on Medicinal Products and Pharmaceutical Activity (Article 11^{13}).

[15] Order №327 / n of the Minister of Labour, Health and Social Affairs of Georgia of 13 October 2009 on Approval of the Import Rule for Non-Commercial Purposes, under Special Conditions (natural disaster, massive population damage, epidemic, rare disease) for humanitarian purposes, as well as in the presence of other special state interests, with the consent of the Ministry of IDPs from the Occupied Territories, Labour, Health and Social Affairs pof Georgia.

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

above requirement, the Parliament of Georgia on 28 January 2021, amended the Law of Georgia on Public Health.[17] In accordance with the legislative amendment, the state shall be liable for possible damage caused by the use of the COVID-19 vaccine in Georgia, except for cases when the damage is caused by a) an importer's mistake, b) a medical personnel or a medical institution; and c) a manufacturer of the pharmaceutical product, when the contract concluded with the manufacturer stipulates his/her responsibility.

Table 2. Assessment of the regulatory environment and associated needs for vaccine introduction in the country

Sphere	Change / Action	Status
Regulatory environment on the release of the manufacturer from liability	Required	The legislative change was implemented in January 2021
Translation of the vaccine package insert into Georgian	Required	A purchaser carries out it after selecting the vaccine
Trainings	Not required	
Electronic systems	Not required	
Standard operating procedures / methodological recommendations	Not required	

[17] Law of Georgia on Public Health. Legislative Herald of Georgia, №26, 11.07.2007, Article 244

5. Organizational structure and coordination of the vaccination programme

The effectiveness of COVID-19 vaccination implementation will depend on the management and coordination of planned activities at all levels of decision-makers. As mentioned above, the country has established an interagency coordination commission for the introduction of vaccination against COVID-19 in Georgia, which coordinates the development of the plan, its implementation and monitoring (Table 2).

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Translation of the vaccine package insert into Georgian	Required	A purchaser carries out it after selecting the vaccine
Trainings	Not required	
Electronic systems	Not required	
Standard operating procedures / methodological recommendations	Not required	

Table 3 and Figure 1 show the components of vaccination introduction, the parties responsible fot vaccination, as well as decision making and implementation levels.

Table 3. Vaccination introduction components and responsible parties

Component	Responsible party
Coordination and monitoring of the implementation of the National Vaccination Introduction Plan	Interagency Coordination Commission
Ensuring a process for preparing a National Vaccination Introduction Plan	NCDC with the support of donors
Preparation of a National Vaccination Introduction Plan	Technical working groups
Discussing recommendations for priority groups	National Immunization Technical Advisory Group (NITAG)
Approving the National Vaccination Introduction Plan.	Government
Purchasing vaccines	Ministry of IDPs from the Occupied Territories of Georgia, Labour, Health and Social Affairs
Purchasing consumables	NCDC
Accessing vaccines to the market	Regulatory Agency for Medical and Pharmaceutical Activities/ Relevant Commission of the Ministry [18]
Procurement of immunization services in health facilities	NCDC
Centralized training and surveillance	NCDC
Onsite surveillance	Municipal Healcare Centers
Vaccine storage, centralized logistics	NCDC
Vaccine storage, regional logistics	NCDC divisions and regional departments
Municipal vaccine logistics	Municipal Healthcare Centers
Coordination of the mobilization of the contingent to be vaccinated.	Local government; Medical service providers; Reginal services of Emergency Situations Coordination and Urgent Assistance Center
Assistance in organizing the service	Local government
Vaccination of the contingent by mobile teams	Municipal Healthcare Centers and Service Providers jointly
Vaccination of the infected contingent	Service Providers
Implementing a communication strategy	All levels
Monitoring vaccine adverse effects	Agency for Regulation of Medical and Pharmaceutical Activities NCDC, service providers
Monitoring and evaluation	NCDC
International coordination and cooperation	Government, donors, and partners

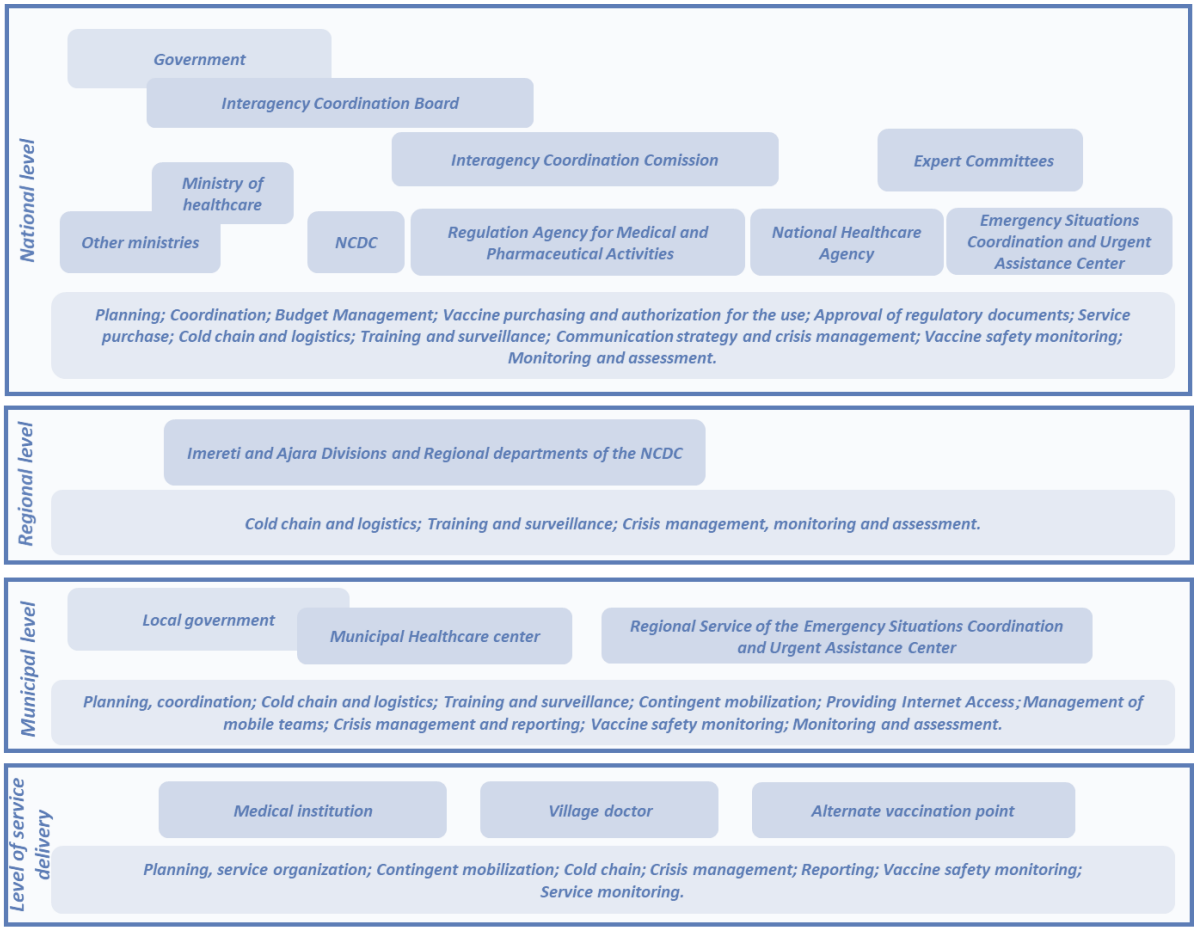
The involvement of local authorities is of particular importance in the planning, mobilization and delivery of services for onsite vaccination. In particular, the local government should promote vaccination against COVID-19 on its territory and for this purpose must develop and approve, in agreement with the regional headquarters of the Interagency Commission, a local vaccination plan, which must include at least the following components:

- In order to provide services:
  - Allocating additional vaccination zones to create mass vaccination centers (if necessary);
  - Ensuring high quality Internet connection for the selected vaccination units;
  - mobilising volunteers to train vaccination teams (if necessary);
- In order to mobilize the contingent to be vaccinated:

[18] By the order №13327 / n of the Minister of Labour, Health and Social Affairs of Georgia of October 13, 2009.

- Proving transport for certain groups of the population for getting vaccinated in order to increase geographical accessibility;
- Supporting the provision of vaccination services for persons with disabilities by pre-listing such persons;
- Mobilising volunteers to raise public awareness;
- Using all possible means of communication to mobilize the population.

Figure 1. Levels of decision-making and implementation



6. Resources and funding

During the epidemic in Georgia, vaccination against COVID-19 will be available to citizens of Georgia free of charge. Table 4 summarizes the programme components, funding sources, and current funding status for COVID-19 vaccination introduction.

Table 4. Resources required for vaccination and their current status

Component	Financial needs are calculated	Funding sources	Provision as of today
Vaccines and consumables	Yes	State budget	Partial
Cold chain	Yes (Does not require additional resources)	_	_
Logistics	Yes	State budget	Partial
Service	Yes	State budget	Funds are allocated
Trainings, surveillance	Yes	Donor	Partially attracted
Information system	Yes	State budget or donor	The funds are to be allocated
Demand creation and communication	Yes	Donor and state budget	Partially attracted
Compensation in case of immunization-related damage	No	State budget, in the manner established by law	
Support for COVID-19 vaccination readiness	Yes	Donor Support (Asian Development Bank, World Bank, WHO)	

Necessary financial resources

The financial resources required to introduce the COVID-19 vaccine include both the cost of purchasing vaccines and consumables and operating costs. The financial resources required for the introduction of 1,484,400 vaccine doses guaranteed only by the COVAX platform were calculated, as well as the financial requirements necessary to fully cover all priority groups (described in the document below), and financial resources in general, which is necessary to cover 60% of the adult population (over 18 years). The financial requirements by the components of the immunization programme are summarized below (Table 5).

Table 5: Financial resources required to introduce COVID-19 vaccine by components

Name of component	Financial resource required only for COVAX guaranteed doses coverage		Financial resources needed to cover all priority groups		Financial resources required to cover 60% of the total 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 consumables	1,847,586	1,847,586	2,439,291	2,566,744	4,960,082	5,087,534
Delivery of services	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
Logistics / distribution of vaccines	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
Surveillanceand monitoring of the vaccination process	26,746	26,746	37,156	37,156	53,500	53,500
Demand creation 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, the financial calculations do not take into account the costs of establishing and operating mass vaccination centers, as well as the costs of establishing and operating a specific intersectoral immunization management group. These calculations will be done later.

** The financial resources of the information system include only the necessary costs for additional personnel (for the smooth operation of hot lines) and do not include the necessary technical assistance for the development of new software for the electronic module or improvement of the existing one.

As can be seen from the table, 72% to 89% of the total financial requirements are for the purchase of vaccines. Service delivery is the second largest financial component, accounting for between 6% to 13% of the total budget.

Four scenarios were developed to calculate the financial resources required to introduce the COVID-19 vaccine, which involves the introduction of various types of vaccines in the country. These scenarios are shown schematically in Table 6.

A total of 3,979,327 doses are needed to protect 60% of the adult population, taking into account the loss of the vaccine. As of today, Georgia has guaranteed 1,484,400 doses of vaccine from the COVAX platform by 2021, however, financial resources have calculated for 3,979,327 doses of vaccine provided that the country can import an additional 2,494,927 doses from alternative sources.

Table 4: Scenarios

	Scenario I		Scenario II		Scenarios III		Scenario IV	
	AstraZeneca	Pfizer	AstraZeneka	MODERNA	AstraZeneka	Other 2-8° C	AstraZeneka	
Any source		200,000		200,000		200,000	200,000	
COVAX guaranteed	1,484,400		1,484,400		1,484,400		1,484,400	
Any source	2,294,927		2,294,927		2,294,927		2,294,927	

- **Scenario 1:** The country receives 200,000 doses of Pfizer / BioNTech vaccine, 1,484,400 doses of AstraZeneca vaccine from the COVAX platform, and additional vaccine doses needed to cover 60% of the population over 18; That is, in total 3,979,327 doses of vaccine are imported into the country.

- Scenario 2: The country imports 200,000 doses of Moderna vaccine, 1,484,400 doses of AstraZeneca vaccine from the COVAX platform, and the number of additional vaccine doses required for the coverage of 60% of the adult population (3,979,327 total vaccine doses).
- Scenario 3: The country receives 200,000 doses of any vaccine[19] within the temperature control of 2-8 ° C, 1,484,400 doses of AstraZeneca from the COVAX platform and additional doses of AstraZeneca vaccine (in total 3,979,327 vaccine doses) from other sources.
- Scenario 4: Only AstraZeneca vaccine is imported into the country to fully cover all priority groups and additional groups of population (total 3,979,327 vaccine doses).

The methodology for calculating the financial needs of all components of the immunization programme, as well as detailed calculations for the scenarios, are given in Appendix 1.

7. Priority groups and vaccination strategies

In accordance with international recommendations and the epidemiological specifics of the country, target groups of the population for 2021 have been selected in Georgia, the coverage of which will be carried out in stages (see Table 7). The selection of groups was based on ETAGE[20] recommendations and was primarily aimed at maintaining vital health services and reducing morbidity and mortality in high-risk groups. The selected groups were reviewed and recommended by the Technical Committee of Georgian National Immunization Experts on 12 December 2020[21]. As the availability of vaccines increases, the vaccinated groups of population will grow to reach the coverage of 60% of the adult population[22].

Once selected, a stage coverage plan for target groups is based on an indicative vaccine delivery and dosage schedule. According to the imported vaccines and volumes, it is expected to modify these target groups, their number and sequence, by calendar replacement of its stages without delaying access to vaccination for the highest risk groups, in accordance with the recommendation of the Interagency Coordination Commission for the Implementation of COVID-19 in Georgia, by an individual administrative-legal act of the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia.

Table 7: Target groups of the population, their volume and stage of coverage

Stages	Priority groups and sequence	Target population*	Target group coverage (%)	Total number of contingent to be vaccinated*
Ia	Health sector workers	64,051	65%	41,633
Ia	Beneficiaries and staff of a long-term care facility	2,600	60%	1,560
Ia	>75	226,800	60%	136,080
Ib	65-74	329,183	60%	197,510
IIa	Basic service providers and other risk groups**	210,700	60%	126,420

[19] A high-priced vaccine is conditionally taken to illustrate additional financial resources, although it is possible to import a 2-8^{0}C vaccine of any other price that will receive WHO approval.
[20] European Technical Advisory Group of Experts on Immunization.
[21] Minutes of the meeting of the Technical Committee of National Immunization Experts in Georgia, 12.12. 2020.
[22] The adult population of Georgia (> 18 years and older) is 2,834,600. Source the National Statistics Office of Georgia.

IIa	55-64	478,400	60%	287,040
IIb	18-54 Persons with chronic disease	89,400	60%	53,640
Sum (High Risk and Essential Groups)				**843,883**
III	Other groups of the population	1,410,452	60%	846,271
	Diplomatic Corps***	1,060	100%	1,060
In total				**1,691,214**
Adult population in %				**60%**

Note: *The population to be vaccinated shown in Table 7 is calculated by a coverage rate. The first phase involves initial coverage of the highest-risk adults and then high-risk adults and the groups of main (so-called essential) service providers in a phased expansion of the programme.

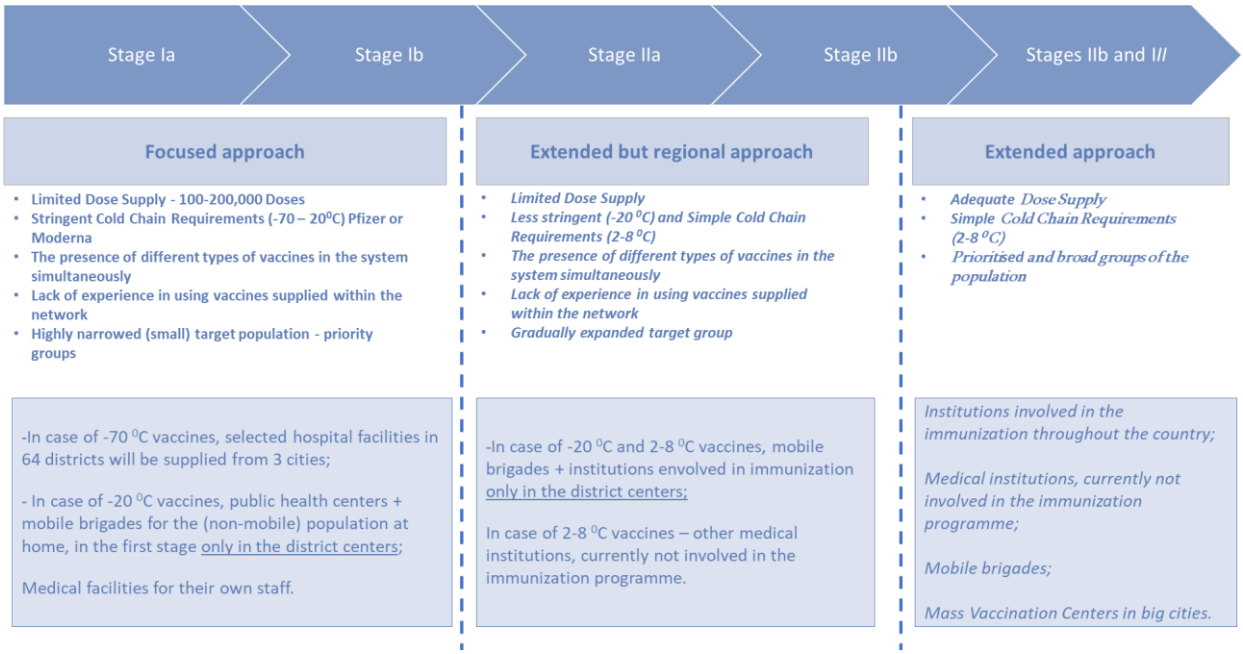
** Other risk groups include people with disabilities; Athletes who plan to participate in international tournaments.

*** Vaccinations of the diplomatic corps and their family members will be carried out in accordance with the priorities of the Georgian population.

At the third stage, vocerage of 60% of the rest of the adult population is determined.

The target group vaccination volume, which is due in 2021, will require **an almost fourfold increase in the capacity of the country's existing immunization system,** which poses serious problems for the system. Accordingly, a three-step strategy for scaling up vaccination was identified to adequately target the selected groups based on (a) the selected target groups and their size, on the one hand, (b) population density, on the other hand and (c) gradual increase of the system capacity, i.e. gradual capacity building of relevant institutions, training of staff and gradual involvement in the immunization programme.

Figure 2. Three-stage vaccination expansion strategy



The phased development of COVID-19 vaccination also includes the use of more sophisticated vaccines with complex cold chain requirements (-70 - 200 ° C) in the first phase of vaccine delivery, should the country be faced with such a choice. For planning purposes, it was determined that the amount of such vaccine would not exceed the number of doses required to cover 3% of the adult population, that is, ≈200,000 doses. Therefore, at the first stage, only priority groups will be vaccinated (people working in the health sector, residents and service personnel of long-term care facilities, as well as people over 75 years old).

In the case of Pfizer vaccine, the vaccine is distributed from three warehouses (Tbilisi, Kutaisi, Batumi) weekly[23] and delivered to one of the hospitals (maximum two in exceptional cases) selected in the regional centers. This decision is based on (a) the packaging of the vaccine, i.e. in the box there are 195 vials with 5 doses, or a total of 975 doses, which (b) can be used within a maximum of 5 days after thawing at -80^{0}C[24]. **Therefore, vaccination sites are supplied weekly, while an individual site is supplied with the volume of 975 doses (or repackaged in smaller doses), which challenges the institution to vaccinate the number of people corresponding to the daily doses received. In case of receiving a full package, the institution must vaccinate at least 230-240 people, which will require the work of 6-7 vaccination teams in a separate institution.** At these vaccination sites, the planned mobilization-attraction of the contingent to be vaccinated will take place, with the active participation of the head of health care and medical institutions located in the municipality. A separate municipality will develop a vaccination schedule for the population to be vaccinated and the measures necessary to attract the contingent. Depending on the logistic characteristics of the vaccine, vaccination of specific essential services may be scheduled after / in parallel with the vaccination of medical personnel and residents of long-term institutions.

In the case of the Moderna vaccine, the vaccine is delivered from the warehouses of Tbilisi and the regions to the municipal healthcare centers, where these vaccines can be stored at -20 ° C. From here, once a month, each facility is supplied with a 4-week supply, since the vaccine is stored after thawing at 2-8 ° C for 30 days. In this case, the first target group will be healthcare facilities and their staff, followed by residents and staff of long-term care facilities and the population 75+. Responsibility for organizing vaccinations will be assigned to the selected institutions in the region, and the planned mobilization of the contingent to be vaccinated will be assigned to the leadership of the municipality with the active participation of medical institutions located in the municipality. A separate municipality will develop and implement a vaccination schedule for the population to be vaccinated and the measures necessary to attract the contingent.

Accordingly, in the first stage and depending on the type of vaccine, vaccination will be carried out first for the health care sector, and only then other priority groups will be covered.

The second phase of expanding vaccination - at the municipal level - will include both immunization and non-immunization agencies (if these agencies agree to participate), while the third phase includes vaccination of the target population with a wider network and the establishment of mass vaccination centers in big cities.

Mobile teams will be created and equipped to coordinate the work of medical orgasnisations and medical centers at all district levels to vaccinate residents and staff of long-stay facilities, as well as people with reduced mobility. The leadership of the municipality will be instructed to prepare lists of this contingent, which must be provided to mobile teams in a timely manner.

8. Organizing COVID-19 vaccination service delivery

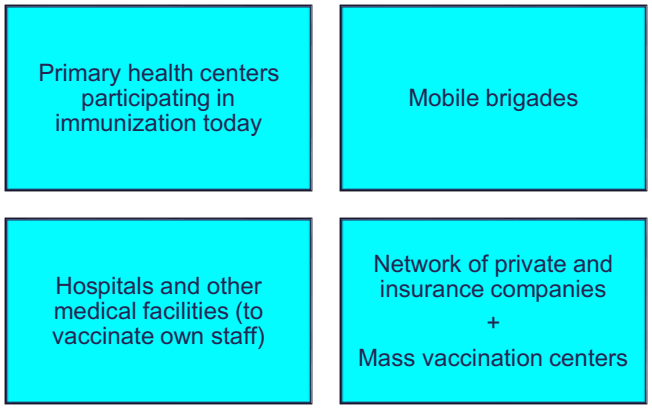
By 2021, 60% of the country's adult population will need to quadruple the capacity of the network of immunization providers. If today the system accepts an average of one million vaccination visits over

[23] On a weekly basis because the maximum shelf life after thawing of vaccines at 2-8 ° C is 5 days.

[24] Of these 5 days, one day is needed for the distribution of vaccines to vaccination sites, leaving only 4 days for vaccination.

12 months for immunization against COVID-19, only in about 7-8 months of 2021, 3.4 million more vaccination visits must be made (as routine immunizations continue). As of today, 351 legal entities and 929 individuals, mainly rural doctors, participate in the immunization programme (see Figure 3). Therefore, in order to increase existing capacities and at the same time use them efficiently, it is planned to:

Figure 1. Immunization network expansion plan



(a) In the first phase of immunization, all healthcare facilities will be involved in the vaccination of medical personnel, regardless of their participation in the immunization programme (unless Pfizer vaccine is administered only in selected municipal hospitals and in more than one facility in large cities). Institutions that do not participate in the immunization programme will register as immunization service providers.

(b) At the same stage, mobile brigades will be formed through the joint efforts of public healthcare centers and selected medical facilities to vaccinate residents and staff of long-term care facilities (at the first stage) and vaccinate a non-mobile contingent staying at home in parallel with the expansion and by the expansion phase of the programme. In total, it is planned to create 70 brigades (for each municipality and 5 cities of Tbilisi). The mobile team will be staffed with a doctor, nurse and driver and will be equipped with the appropriate equipment (see Resources for Details).

(c) In the next phase of the expansion of the COVID-19 immunization programme, health facilities located in municipal centers and participating in routine immunization (excluding village doctors) will be mostly responsible for the vaccination of the population and other target groups. To cope with the increased volume and if requested by an organization, additional vaccination teams and vaccination rooms will be established in these facilities, as well as a network of private and insurance healthcare companies, which are not currently participating in the immunization programme. Finally, high-capacity mass vaccination centers will be established in major cities, organized in accordance with the guidelines of the US Centers for Disease Control[25].

Vaccinations, including for medical staff, will be voluntary. Before vaccination, a person must be fully informed about the risks and benefits of vaccination, and informed consent must be obtained from this person.

The NCDC will also procure services from participating institutions. A visit fee for vaccination was determined separately for both the health facility and the mobile team and reflected in the budget calculations. The principle of payment for services provides for the conduct of 2 vaccinations necessary for the vaccination of one person in order to obtain an adequate immune layer in the population. Accordingly, 30% of the total 2 visits will be reimbursed after the first vaccination and 70% after the second vaccination. The existing immunization information system is fully adapted to the implementation of this principle and adequate monitoring.

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

Medical waste associated with vaccination is considered hazardous waste, and its handling is regulated by the relevant technical regulations[26]. The financial costs associated with the management of waste resulting from the increase in vaccinations are calculated and reflected in the accrued benefits.

Table 8. Assessment of technical needs for organizing vaccination services

Sphere	Change/Action	Responsible	Status
regulatory framework	Approval of the National Vaccination Introduction Plan.	Government of Georgia	Approved
Involvement of health care providers in the programme and compensation for services provided	Change in the state programme (Target State Programme for Reduction of Harm Caused by Infection (COVID-19) with a Novel Coronavirus (SARS-COV-2))	GoG/Ministry	Developed[27]
Trainings	For local government (details in the section "Personnel and training")	NCDC	Conducted
	On provision of services (details in the section "Personnel and training")	NCDC	Conducted
Electronic systems	Adapting the system to the specific requirements of COVID-19 vaccination	NCDC Ministry	Modified
Standard operating procedures / guidelines / Instruments	Operational plan for vaccination (General plan and municipal plans)	NCDC Municipal healthcare centers	Developed
Budget estimate	Service and Waste Management Assessment	Work group	Completed
	Addressing organizational and financial issues necessary for the creation of mass vaccination centers	Work group	To be developed

9. Cold chain

The cold chain and logistics team has developed various vaccine import and distribution scenarios and related specifications for these scenarios.

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

The choice and implementation of a specific scenario will depend on the availability of vaccines and the organization of the import.

The specifications for each scenario presented include the following information:

- the vaccine used for immunization;
- target groups, characteristics of the group, number and percentage of the group in relation to the population of the country;
- the readiness of the cold chain system to receive, store and distribute vaccine at different levels of the system;
- the volume and weight of medical waste accumulated as a result of vaccination.

Scenario I

Vaccine used: -70^{0}C temp. control (Pfizer) and +2+8^{0}C temp. control (AstraZeneca)

Scenario Description: immunization of **healthcare workers, organized groups with Pfizer** vaccine, while the rest of the high-risk population with-AstraZeneca.

Vaccine logistics:

[26] Ordinance №294 of the Government of Georgia of 16 June 2017 on the Approval of the Technical Regulation – "Medical Waste Management".

[27] Ordinance № 43 of the Government of Georgia of 2 February 2021 on the Approval of the Ordinance № 828 of the Government of Georgia of 31 December 2020 on the Approval of the State Health Care Programmes for 2021.

In the case of using the Pfizer vaccine, there will be three warehouses in total, where the temperature control required for the Pfizer vaccine is ensured:

- Tbilisi Central Warehouse, which will serve as both a National Central Warehouse and a Regional Warehouse and will serve Eastern Georgia;
- Kutaisi Regional Warehouse, which will serve western Georgia;
- Batumi Regional Warehouse, which will serve the population of Ajara.

The scenario will be implemented in two stages:

Stage 1 – Temperature control -70^{0}C vaccine immunization (Pfizer)

Stage 2 – Temperature control +2+8^{0}C vaccine immunization (AstraZeneca)

In total, according to Scenario I, 717,982 people will be immunized.

Conclusion Scenario I

- The existing volume of the cold chain is sufficient to obtain AstraZeneca vaccine and does not require additional investment.
- The existing cold chain system does not require additional investment to store and distribute Pfizer vaccine in line with current regulations (-700 ° C temperature) if vaccines are only stored in regional warehouses and vaccinations are carried out on a tight schedule.
- The volume of Pfizer vaccine is 1,384 liters and the available volume is 3,205 liters. Details are provided in the corresponding table in a separate document.

Scenario II

Vaccine used: **-20^{0}C temp. control** (Moderna) და **+2+8^{0}C temp. control** (AstraZeneca)

Scenario description: **immunization of healthcare workers, organized groups with MODERNA** vaccine, while the rest of the high-risk population with **AstraZeneca** vaccine.

The scenario will be implemented in two stages:

Stage 1 – Temperature control -20^{0}C vaccine immunization (MODERNA)

Stage 2 – Temperature control +2+8^{0}C vaccine immunization (AstraZeneca)

In total, according to Scenario II, 717,982 people will be immunized.

Conclusion Scenario II

- The existing volume of the cold chain is sufficient to receive the AstraZeneca vaccine and does not require additional investment.
- The volume of the existing cold chain system is adequate and does not require additional investment to store and distribute the MODERNA vaccine in accordance with the current regulation (subject to a temperature of -20 ° C).

Scenario III and Scenario IV

Vaccine used: **+2+8^{0}C temp. control** (AstraZeneca fully or partially and other vaccines of the same temperature control)

Scenario description: Vaccination of the high-risk population with the vaccine at +2+8 ^{0}C.

The scenario will be implemented in one stage:

Implementation – immunization with the vaccine(s) of the temp.control +2+8^{0}C

Target group (number): 717,982 people;

Target group (description): all groups

Scenarios III and IV- Conclusion

- The existing cold chain system does not require additional investments to ensure the storage and distribution of the vaccine in accordance with the existing vaccine regulations (temperature control + 2 + 80C). See a supplementary document.

In the case of vaccination of 60% of the adult population (with additional doses of vaccine with + 2 + 8 ° C), the volume of the cold chain system does not require additional investment, provided that the vaccine is delivered on time and used adequately.

10. Distribution of vaccines

Transportation at the regional level will be carried out by special vehicles – "vaccine carriers". These vehicles enable to transport vaccines with a temperature control of +2+8^{0}C and -20^{0}C.

Current practice is that "vaccine carriers" are used throughout the country to replenish a three-month regular vaccine supply at the municipal level. Stocks are replenished regularly - once every 2 months.

It should be noted that when transporting a vaccine corresponding to a temperature control of -70^{0}C, the same transport will not be able to transport other consumables and a diluent (solvent).

Detailed information on the distribution of vaccines, in particular, assessment and calculation of the needs of transport equipment at each level of the facility, in particular cold chain transport boxes and the appropriate number of ice elements, as well as "vaccine carriers" will be detailed and calculated at a later stage, taking into account the characteristics of the vaccine.

Vaccine distribution and transportation with temperature control of +2+8^{0}C may be based on normal vaccine distribution practices, but with a different route schedule.

With regard to distribution of vaccines corresponding to other temperature control, the corresponding route, the number of routes and other details of the distribution of vaccines from the central to the municipal level will be planned, during the development of the operational plan, taking into account the the characteristics of the vaccine.

While planning vaccination, rapid and quality training of specific personnel, involved in immunization against COVID-19 and responsible for cold chain in logistics and cold chain issues will be provided (see Chapter 13. Human Resource Management and Training, page 23).

11. Waste management

Waste generated from the COVID-19 vaccination campaign will be handled in accordance with the rules and mechanisms applicable in the country that are used by facilities during other scheduled or unscheduled vaccinations. However, at each level of the cold chain system, additional waste disposal needs are identified depending on the vaccine specification and the requirements for additional ancillary materials and consumables.

12. Electronic module for stock management

Depending on the specification of the selected vaccine, the vaccine will be managed in the existing electronic module for stock management, where all standard stock and shipment reports are generated at the central, regional, municipal or institutional level.

The stock management module is integrated with the e-immunization module and the balances are recorded automatically at the time of vaccination registration. Vaccines will be registered in the stock module in accordance with the batches and / or serial numbers that will appear on the secondary packaging.

WHO has already developed a model for the harmonization of secondary packaging for labeling vaccines (see 4. Regulatory framework, p. 7). WHO is also considering the use of 2D barcodes on secondary packaging - to electronically track the application process - in the presence of primary and

secondary packaging, although this is not mandatory and does not replace the obligation to comply with national requirements.

A 2D barcode indicates the serial number of a specific batch. Registration of vaccines under serial numbers is performed in the electronic module of stock management. Accordingly, there is no need to introduce an additional bar coding system.

In parallel with the registration of vaccines and costs in the e-stock management module, real-time stock information is generated at national, regional and municipal levels.

Table 9. Assessment of cold chain needs

Sphere	Change/Action	Responsible	Status
Regulatory framework	Not required		
Trainings	Om cold chain and logistics (see section Human resource management and training)	NCDC	Conducted
	On the use of electronic module for stock management (see section on Human resource management and training)	NCDC	Conducted
Electronic systems	Clarification of reporting requirements	NCDC	Developed
Budget estimate	No additional need for a cold chain		
	The need for logistics is in the process of determination and the financial need will be also identified	Work group	Determined

13. Human Resource Management and Training

For the introduction of the COVID-19 vaccine, it is important to define human resources and their quantity, and then provide them with knowledge and skills that meet the relevant standards.

For the training of human resources, a specific training plan, design and methodology have been developed; The target audience has been identified; Training modules should be translated and adapted, based on training materials developed by WHO and other global immunization partner organizations, and the so called supportive monitoring should be enhanced as well.

In the process of introducting the COVID-19 vaccine in Georgia, the framework of specialized trainings will cover the following:

- Training plan, design, methodology, training modules - NCDC / Department of Communicable and Noncommunicable Diseases, Division of Information Technology Services, other stakeholders;
- Target audience – a circle of nationwide service provider (doctors, nurses, managers of provider clinics); a circle of cold chain and logistics (persons responsible for the cold chain and logistics of regional and municipal healthcare centers); Media, speakers;
- Subsidiary Monitoring – appropriate Departments of the NCDC;

Workout design:

- Online format;
- Mixed format if required;

Training topics:

- Practical immunization;
- Cold chain and logistics;

- Adverse events following immunization (AEFI) and monitoring;
- Communication;
- Service organization;
- Reporting.

Modules	Topics	Learners (Number)	Duration of the modul
Module 1: Practical immunization	Vaccination rules	Persons responsible for immunization of state healthcare centers, service provider doctors, nurses	4-6 h
	Vaccine characteristics		
	Contraindications		
	Storage conditions		
	Enter data into the electronic module		
	Drug-related reactions Reactions related to a defective quality of the vaccine Reactions associated with an immunization error (so-called programmatic) Reactions associated with the sensation of immunization Coincidental event Notice, registration and research rules	Persons responsible for immunization of state healthcare centers, Provider Clinic Managers, Service provider doctors, nurses	
	Preventing the unauthorized use of vaccines		
Module 2: Cold chain and logistics	Vaccine transportation and storage	Persons responsible for the cold chain and logistics of regional and municipal state healthcare centers	2-3 h
	Electronic Module for Stock Management		
	Medical waste management		
Module 3: Communication and crisis communication	Fundamentals of behavioral science determining vaccine acceptance interventions	Persons responsible for immunization of state healthcare centers, Service eprovider doctors, nurses (Quantity to be specified) Heads of state healthcare centers HJeads of service provider institutions Local government representatives	4-6 h
	Interpersonal communication (including AEFI communication)		
	Advocating the importance of the vaccine, developing and disseminating messages on behavioral changes		
	Working with active anti-vaccine groups		
	Infodemia and misinformation		
	Social media engagement and interaction		
	Principles of Public Health Crisis Management and Risk Communication		

	Advocating the importance of the vaccine, developing and disseminating messages on behavioral changes		
	Media Relations		
	Social media envolvement and engagement		
	Infodemia and misinformation		
	Working with active anti-vaccine groups		
	Media trainings	Media representatives	4 h
Module 4: Service organisation	Planning Contingent mobilization Mobile teamwork Monitoring and evaluation	Heads of state healthcare centers HJeads of service provider institutions Local government representatives	4 -6 h
Module 6: Issues on immunization safety	AEFI issues	Members of the National Committee of Experts on Immunization Safety	2 h

Table 10. Assessment of training needs

Sphere	Change/Action	Responsible	Status
Regulatory framework	Not required		
Trainings	For the six modules mentioned above	NCDC	Conducted
Mpodules	To be developed	NCDC	Developed
Electronic systems	Highlighting a web portal for virtual supply of trainings	NCDC	Highlighted
Budget estimate	Budget to be estimated	Work group	Completed

14. Demand creation and communication

Years of experience and evidence of new vaccine introductions prove that clear and effective communication is essential for the successful implementation of the COVID-19 vaccination programme, which must be launched before vaccines are available.

In addition to raising public awareness, vaccine acceptance is influenced by three factors that need to be considered in order to understand the problem and determine strategies: an supportive environment, social impact, and motivation[28].

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

Purpose

Increasing confidence, increasing acceptance and creating demand for the COVID-19 vaccine.

To achieve the goal, the following approaches will be used: advocacy, communication, social mobilization, communication on risk and safety issues, community involvement, trainings, as well as communication in crisis situations.

Tasks:

- Mobilizing and engaging key partners and communities;
- Dialogue with internal and external partners regarding the implementation of the COVID-19 vaccination programme to understand their main views and needs;
- Media awareness, mobilization and media advocacy;
- Developing and implementing an action plan for anti-crisis communication;
- Preparation of daily / weekly dashboards / development of a standard form;
- Developing detailed guidance on the technical nature and effective communication of COVID-19 vaccination and providing training for local healthcare managers, medical staff and other stakeholders;
- Providing the public with constantly updated information on the development, authorization, introduction, distribution and use of vaccines against COVID-19;
- Ensuring public confidence in the safety, efficacy and implementation process of the COVID-19 vaccine;
- Disseminating proactive, timely, accessible and effective information on community consolidation, management of expectations, public health, and safety issues;
- Mobilization of the target group of COVID-19 vaccine, effective communication for invitations to vaccination with both the first and second dose;
- Infodemia management and taking steps against disinformation;
- Possibility of using vaccines for communication purposes to vaccinate famous people;
- Monitoring the strategy implementation process, supervisory support and impact assessment.

Target audience

1. Parties involved in the introduction of the Covid-19 vaccine:
    - Coordination Council;

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

- NITAG members;
- Ministry and the NCDC;
- Municipal Public Health Centers;
- Local government;
- Local and international partners;

2. Health care providers and staff (health sector in general).
3. Representatives of high-risk groups:
   - Beneficiaries and staff of long-term care facilities;
   - Persons of the appropriate age;
   - Persons with some chronic diseases (18-49 years old);
   - Essential service providers, etc.
4. Part of the population not included in the groups defined for the first stages (management of expectations).
5. Stakeholders / Influencial parties:
   - Policy makers and politicians;
   - Civil society;
   - Scientific Society, Academy;
   - Non-governmental organizations;
   - Critical and negative groups;
   - Business sector.
6. Media and social networks:
   - Central and regional television (including television channels broadcasting in the language of national minorities);
   - Radio;
   - Print media;
   - Social media groups and "influencers":
     - STOPCOV.ge;
     - MOH.gov.ge;
     - NCDC.ge;
     - Facebook, Instagram pages.

Strategic directions

International experience and research confirms that information alone or individual interventions are ineffective in overcoming barriers to vaccination and that it is necessary to integrate and combine different strategies and approaches[29], such as, for example, interventions[30,31] to schedule reminders[32] and guidelines[33], educate and build confidence in health care providers. It is also possible to involve volunteers (for example, students, civil servants) for the purpose of social mobilization of the target population and physical mobilization (attraction) for vaccination.

[29] 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.

30 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.

31 Gagneur A. Motivational interviewing: a powerful tool to address vaccine esitancy. Can Commun Dis Rep. 2020;45(4):93-97. doi:10.14745/ccdr. v46i04a06.

[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.

The communication action plan is based on four interrelated strategic elements of an integrated approach to the creation of vaccine demand:

1. Social Listening, media participation and disinformation management:
   - Listening to and understanding target populations, developing targeted communication strategies by collecting behavioral and social data on key factors;
   - Creation of a supportive and transparent information environment and neutralization of misinformation through social listening and assessment to plan further interventions.
2. Risk communication and community participation:
   - Increasing confidence in vaccine and acceptance by engaging civil society.
3. Professional development of medical workers:
   - Raising awareness and knowledge among medical personnel of COVID-19 vaccination as the first vaccination target group, trusted source of information, influencer and vaccinator; It is necessary to strengthen the interpersonal skills of the target population and the community with the medical staff.
4. Anti-crisis communication:
   - Preparedness of the country for crisis management, rapid and coordinated response at all levels in case of possible further complications of immunization.

Implementation stages and priority actions:

Use timely notifications of the current phase of the COVID-19 vaccination programme.

- Before vaccination
- The vaccine is available to a limited number of the general population.
- Vaccine availability is increasing for critical / priority populations and the general population.
- The vaccine is widely available to the adult population.

Resources on issues are currently being sought according to priorities.

Table 11. Assessment of demand creation and Communication Needs

Sphere	Change/Action	Responsible	Status
Regulatory framework	Not required		
trainings	For healthcare personnel (including public healthcare), local government	NCDC	Conducted
	For media	NCDC	Active
Modules	To be developed	NCDC	Developed
Electronic systems	Highlighting a web portal for virtual supply of trainings	NCDC	Allocated
Budget estimate	Budget to be estimated	Work group	Completed

15. Vaccine safety monitoring, AEFI management, vaccine safety

AEFI (Adverse Events Following Immunization) surveillanceis an integral part of the National Immunization Programme, and its effective operation enhances the safety of all vaccines in the country and, at the same time, helps maintain public confidence in the immunization programme for a long term.

The AEFI surveillanceunder the State Immunization Programme is active more than two decades, the last update was in 2019[34]. The current surveillancesystem is fully in line with WHO recommendations. The vaccine safety system in Georgia includes the production of vaccine pharmacovigilance, which is carried out by the personnel of the relevant authority. This is a well-established system, and monitoring

[34] Order № 01-193/ო of the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia.

of adverse effects from the introduction of covid vaccine does not require fundamental changes or revision of approaches. Information will flow in the prescribed manner.

However, the new technologies used to create the COVID-19 vaccine and the urgency of using the vaccine pose some challenges to the system. To effectively address these issues, in addition to existing regulations, additional regulations should be developed in order to apply for introduction of covid vaccine, which will include adjustments based on the urgency of the vaccine introduction. In the current situation, the availability of the software is very important both before the introduction of the vaccine and during the delivery of the vaccine. Within the existing surveillancesystem, efforts need to be scaled up in all five areas of the AEFI related to specific causes (see Annex 3.3 for details).

1. Reactions associated with vaccines
2. Reactions to the violation of the quality of the vaccine
3. Reactions associated with the error of immunization (the so-called software).
4. Reactions associated with the sensation of immunization.
5. Random event.

16. National Committee of Experts on the Safety of Immunization

The National Expert Committee on the Safety of Immunization was established in 2014[35] and is based on WHO recommendations. It is an independent body with 14 different experts. The committee was created in the context of routine vaccination and is mainly staffed by pediatricians. In the target population of the elderly, the specifics of the patients change due to the campaign production, the novelty of the vaccine and the theoretically expected number of AEFI (14,000 cases in 7-8 months, about 60 cases per day) [36] and the workload on the committee increases. To ensure the effective and timely work of the commission, the composition of the commiittee was expanded by specialists (family doctor, therapist-cardiologist, pulmonologist, nephrologist, allergist) and an updated procedure was approved[37].

Table 12. Assessment of technical needs associated with vaccination safety

Sphere	Change/Action	Responsible	Status
Regulatory framework	Vaccine safety monitoring and AEFI issues in the Ministry's Order on Vaccination against COVID-19	Ministry, NCDC (Development and approval)	Approved
	Updating the National Committee of Experts on the Safety of Immunization	Ministry	Approved
Trainings	On monitoring vaccine safety and AEFI issues for medical personnel, Covid-19 vaccination and Covid-19 epidemiological surveillance	NCDC	Conducted
	On the issue of establishing a causal relationship of the new composition of the UEC	NCDC	Conducted
Electronic systems	Adapting an Electronic Integrated Disease Surveillance System for registration of AEFI of Covid-19 vaccines	NCDC	Adapted
	Online adaptation of the electronic immunization and stock management module for registration of AEFI of Covid-19 vaccines	NCDC	Adapted

[35] Order № 01-185 / ო of the Minister of Labour, Health and Social Affairs of Georgia of 30 July 2014.

[36] The calculations are based on the upper limit 1/100 of the expected frequency range of unusual complications of the Moderna and AstraZeneca vaccines.

37 Order № 01-35 / ო 1 of the Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia, 1 February 2021.

Standard Operating Procedures / Manual	Contraindications and warnings for covid vaccine (preliminary) Control over AEFI with special interests National and subnational baseline indicators of existing conditions and nosologies of particular interest Introducing monthly reports on AEFI Reflection of particularly interesting events in the form of emergency notifications Reflection of Covid-vaccination and nosologies of special interest in the form of an epidemiological survey of AEFI	NCDC	Developed

17. Information system, monitoring, epidemiological surveillance

Surveillance, monitoring and evaluating the process from the outset of COVID-19 vaccination is critical to managing the vaccination process and adapting the strategy. Standardized tools will enable the country to conduct processes in a transparent and accessible manner to ensure that the set goal is achieved through interim reporting and problem identification.

Reporting

The reporting model takes into account country practice and includes: reporting on immunization / vaccination, vaccine administration, unusual adverse events and complications following immunization, as well as on vaccine status in cases of COVID-19.

Registration and reporting of vaccinations will be done through the existing **electronic immunization management module**.

The electronic immunization management module was developed and used since 2013 and was fundamentally updated in 2020 as a tool to improve immunization programme management and vaccine logistics. The module is part of the Health Management Information System (HMIS), which, in turn, is integrated with the childbirth module, stock management system, state register and is based on the identification of a citizen using his/her unique personal number.

As of today, vaccination against Covid-19 is recommended for populations other than the target group for routine vaccination (see 7. Priority groups and vaccination strategies).

The electronic immunization management module provides for the registration of other additional vaccinations, therefore the Covid-19 vaccination will be registered in the immunization module in an already tested manner.

All legal and natural persons who vaccinate must be provided with adequate access to the immunization module (including all facilities not previously involved in the immunization process) in order to ensure that vaccines are not delivered to a service provider that does not have such access. It is the responsibility of local (municipal) public health centers to check the availability of passes and readiness for registration of vaccinations in the module. During the planning and implementation phase while adding vaccination sites, the training of the personnel of vaccination sites/points/mobile brigades must be pre-determined on the issues of module usage, access to it and technical support.

In the electronic immunization management module, used in Georgia, through integration with the stock module, serial vaccine codes are registered and tracked in the prescribed manner (see 12. About the use of barcodes in the stock management package).

Along with the integration into the Vaccination and Cold Chain Registration System, the immunization reporting system was updated so that to make possible, in real time, at the national, regional and municipal levels, to report: a) individual list of vaccines in doses; b) cumulatively - about the number of vaccinated – by age group, priority category, as well as simultaneously by priority and age groups in this subdivision - at the municipal, regional and national levels.

Stock Management part of the same Module, in turn, provides the creation of standard stock reports at the level of NCDC.

A standard format has been developed to generate other additional non-standard operational reports (coverage) that will be aggregated by priority groups, age groups and geographic units (municipality, region, national). At the municipal level, a denominator was determined by the national level, which was split into municipal / regional public healtcare centers. The target denominator will be reviewed by the municipal / regional public healthcare centers and updated information or agreement with the reality of values will be returned to the national level. The processing of vaccination data is the responsibility of the public healthcare centers at the municipal level. The reporting frequency and format of the templates developed are under consideration.

The described part of the registration-reporting has been reflected in operating systems since February 2021.

To ensure a call for a second dose of vaccination, a possible date of vaccination will be determined after the first dose has been received, and a warning will be given immediately after the first dose has been injected. This is made possible by the existing immunization module (adapted to a specific vaccine). The module allows a beneficiary to receive a short text message (sms) about the next vaccination. The same will be convidered in the immunization web application. The mobile application was originally intended for parents as a source of information about ongoing and planned vaccinations. The application allows users to receive information about vaccines and the diseases in Georgia against which the vaccine protects (Vaccine-preventable diseases).

At the initial stage of vaccination, an electronic queue management system will be launched (https://booking.moh.gov.ge). This will, on the one hand, help medical institutions manage the flow of citizens, as well as help citizens to make an appointment for vaccinations in a medically accessible medical institution at a predetermined time. A hotline will be created to assist citizens in booking vaccinations through the electronic queue management system.

A recipient's vaccination card is generated by the electronic immunization management system. The document meets internationally recognized requirements and has anti-counterfeiting mechanisms.

International reporting on AEFI will be in accordance with the requirements of the World Health Organization (WHO), the European Center for Disease Control and Prevention (ECDC) and / or the European Union (EU).

Monitoring

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

- Monitoring the supply of vaccines;
- Monitoring the process of immunization service;
- Monitoring the cumulative growth of coverage;
- Comparison of the coverage index with the planned index;
- National vaccination coverage indicators will be posted on the Center's webpage and updated weekly. The Center is responsible for updating.

Vaccine logistics are monitored by the Center and public healthcare centers on an ongoing basis - when vaccines are placed in these locations and at vaccination sites - by local public healthcare centers before vaccines are received and should include an assessment of the unit capacity and readiness and later, in the process of vaccination, periodically. This monitoring phase will combine the monitoring of the vaccine logistics and the immunization process and will be carried out at least once a week.

Comparison of the coverage index with the planned index will occur continuously, at the end of each round of vaccination.

The target coverage of certain groups of the target population is determined in the list of priority groups of the document. The indicator used for monitoring purposes includes the achievement of the goal in a timely manner and is developed at the municipal, regional, and national levels.

COVID-19 cases are reported through the National Electronic Disease Surveillance System (NEDSS), a flexible structure of which allows vaccine status to be recorded after vaccination has been introduced. This update in the NEDSS will take place as soon as the vaccine is introduced into the country.

The same system records any adverse events following immunization (AEFI) found across the country, including the AEFI cases caused by the new vaccine.

Cases of COVID-19 in the country are subject to single registration, epidemiological study and reporting.

Trainings will include up-to-date information on standard AEFI case definitions, COVID-19 and AEFI reporting, vaccination registration, format and timing of reporting for service providers and public health professionals.

Surveillance

Influenza-like illnesses (ILI) and severe acute respiratory infections (SARI) are part of national surveillance by support bases in the country.

SARI caused by ILI and other respiratory viruses have similar symptoms and often share a common case definition. In Georgia, as in other countries, COVID-19 is being integrated into the syndromic sentinel surveillance system for influenza-like illness (ILI) and severe acute respiratory infections (SARI) to monitor the spread of COVID-19, which will continue to function even after the spread is complete. An integrated system is of particular importance when the seasons of pandemic and influenza coincide. Laboratory testing of samples taken from the ILI and SARI support bases are carried out on a regular basis by the Influenza Laboratory of the National Center for Disease Control and Public Health. Due to the increased load of the COVID-19 pandemic, this function is planned to be transferred to the NCDC's regional research laboratories (Kutaisi, Batumi, Zugdidi) for influenza, SARS-CoV-2 and other respiratory viruses (PCR diagnostics).

Sentinel surveillance typically collects information on separate case studies for influenza vaccination in the most recent, current season. With the introduction of the COVID-19 vaccine, the collection of information on the latest vaccination will begin as well.

Special studies will be carried out at the stage of introduction and implementaion of vaccination against COVID-19, subject to the availability of adequate needs and funding sources. The country is ready to participate in the study of the effectiveness of the vaccine – by the priority groups, the type of manifestation of the type of vaccine, representative data will be collected taking into account international research practice, adapted procedures and relevant basic infrastructure.

Table 13. Assessment of technical needs related to information systems

Sphere	Change/Action	Responsible	Status
Regulatory framework	Registration of a vaccination document Minister's order on vaccination against COVID-19	Ministry (Approval) NCDC (Drafting)	Approved
Electronic systems	Providing access to the online e-immunization management module for all service providers	NCDC	Provided
	Providing covid-specific reporting in the online e-immunization management module	NCDC	Integrated
	Registration, reporting	NCDC	Completed
	Providing short text messaging function	NCDC	Completed

	Ensuring the creation of a vaccination document with protection mechanisms	NCDC	Completed
	Adapting an Electronic Integrated Disease Surveillance System for registering AEFI of covidvaccines	NCDC	Completed
	Managing queues and online registration of population to get vaccinated	NCDC	Developed
Standard Operating Procedures / Manual	Integrating COVID-19 surveillance into the sentinel system	NCDC	Developed

Corruption Prevention Measures

In the context of a global vaccine shortage, when domestic access to vaccines is limited and demand is high, there are potential corruption risks, therefore the table below presents measures to prevent these risks based on four main instruments: (a) legislative regulation; (b) providing the immunization process with digital information technologies and the use of these technologies; (c) disseminating information on immunization; and finally, (d) giving feebback to the population through a hotline. The combination of these tools serves to identify a problem in the materialization of a possible risk, as well as response mechanisms.

Risks of potential corruption	Prevention measures
- Corrupt transactions in the process of purchasing vaccines and consumables, services	- The transparency of the terms of the global procurement of vaccines may ensure the prevention of these risks, however, when the plan is formed at the request of the manufacturers, the disclosure of the terms of the procurement is limited by the terms of the contract between the manufacturer and the state. - Contracts for the purchase of consumables are transparent - The budget estimate and conditions for the procurement of services are regulated by the Ordinance N828 of the Government of Georgia of 31 December 2020 and the Order N01/11-6 of the Minister for Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Protection of Georgia of 3 February 2021.
- Distribution of counterfeit product	- The sale of counterfeit vaccines is limited under the governmental procurement conditions. - With regard to private procurement, the state also regulates the quality of the product in accordance with the rules for the registration of pharmaceutical products, which are regulated by law and by-laws (Law of Georgia on Medicines and Pharmaceutical Activities; Order N327 / N of the Minister of Labour, Health and Social Protection of Georgia of 13 October 2009).

Risks of potential corruption	Prevention measures
- Involvement of stakeholder groups in the identification of priority groups	- Priority groups based on the recommendations of WHO/ SAGE were determined by a working group with the participation of different experts, reviewed by the Council of Experts on Immunization and Multi-sectoral Board and was made public.
- Nontransparency of the selection process and the involvement of priority groups	- This plan is available to public, and each stage of vaccination will be widely announced. - The results of vaccinations (number of vaccinated persons, the used doses) will be communicated to the public on a daily basis.
- Unfair use of vaccines	- The electronic system of immunization management provides the registration of vaccine supplies, distribution and vaccination at the individual level and in real-time. Vaccination is possible only for registered persons from the priority groups, and the algorithm, used in the programme, excludes the delivery of vaccinations to those for whom it is not intended ა a specific stage of vaccination. - Safe storage of vaccines will be strictly supported at a central, regional, municipal and institutional level. A special protocol of safe storage of vaccines for warehouses and recommendations for service providers have been developed that are controlled by public healthcare services. - Informing about response actions in case of dishonest use of vaccines in the training process

Response actions:

Violations associated with the immunization process will be revealed thanks to a hotline, where the anonymity of informants will be fully protected.

The information received will be studied and transferred to the Interagencyl Commission, and appropriate actions will be taken to correct any violations.

Monitoring of the implementation of the plan

The implementation of the National Plan for Vaccine Introduction will be monitored by the Interagency Coordination Commission for the Introduction of COVID-19 Vaccination in Georgia, in accordance with the selected indicators.

Annex 1. Methodology for calculating the financial resources required for the introduction of the COVID-19 vaccine and cost according to scenarios

Methodology

The methodology and approaches for calculating the financial resources required to introduce the COVID-19 vaccine are based on the WHO Guidelines for estimating costs of introducing new vaccines into the national immunization system, [38] the common approaches developed by the Bill and Melinda Gates Foundation for the costing and financing analysis of routine immunization and new vaccine introduction, [39] and the methodology developed by the Harvard School of Public Health to cost immunization programmes[40].

The calculations take into account only the additional financial costs that accompany the introduction of a novel COVID-19 vaccine in the country, and do not take into account such general costs as capital construction costs, operating costs, etc. Therefore, only fiscal (capital and current) costs are calculated, which must be allocated by a state or additionally attracted from donor and partner organizations.

Financial calculations were made for the following components:

Monovalent COVID-19 vaccine

1. Vaccines, syringes, additional safety containers, personal protective equipment.
2. Storage of vaccines, the cold chain.
3. Distribution of vaccines
4. Additional time for additional human resources and available staff.
5. Trainings
6. Social mobilization, advocacy, social media campaigns
7. Improvement / maintenance of the information system (registration, reporting, inventory management, surveillance)
8. Remuneration for the work of medical institutions involved in vaccination by a state purchaser, including the payment of mobile teams.

Vaccines were calculated by the target groups identified for each stage. The total cost of vaccines takes into account the vaccine wastage rate, which is calculated using the following formula 1 / (1-w), where w is the percentage of vaccine wasted. In our calculations, the loss rate is assumed to be 15% for all vaccines[41], therefore, the loss rate is 1.176. Prices per dose of different vaccines are taken from the webpage https://www.unicef.org/supply/covid-19-vaccine-market-dashboard as of 22 December 2020. Calculations were made for each vaccine, taking into account both the minimum and maximum prices of the corresponding vaccine. We've also added the cost for Procurement Supply Management (PSM) to the price of the vaccine dose, which amounts to 23% and includes UN handling fee, freight and insurance[42].

[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; Harvard School of public Health; How to cost immunization programs; 2020

[41] This figure is expected to be updated by NCDC at a later date when the vaccine is introduced and the country-specific figure is available.

[42] Source: National Center for Disease Control and Public Health; Latest data of Global Fund Projects on Drugs and Diagnostic Means during Procurement.

To calculate the financial resources needed for the vaccine, the target population was multiplied by 2 (since a two-doze vaccine is reported to be required for a full course of vaccination), as well as the vaccine wastage rate and the vaccine price per dose, which includes PSM costs.

The cost of the syringes was calculated by multiplying the number of syringes required by the unit price and taking into account the 1.05 loss rate as provided by the UNICEF Sizing Tool for syringes.

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

Vaccine Logistics - the financial resources required to distribute vaccines from the central warehouse to the regional and district warehouses were calculated according to the average mileage and fuel consumption. The financial resources needed to distribute the vaccines also covered the cost of vehicle maintenance, which was calculated as 15% of the cost of fuel as defined in the WHO cMYP costing guideline. Vaccine logistics costs also include staff travel expenses.

Surveillance- monitoring / surveillancecosts of the vaccination process were calculated according to the number of planned follow-up visits.

The financial resources required for conducting trainings were also calculated according to the training plan, together with the cost of social mobilization, advocacy, communication and media campaign.

To convert the prices expressed in USD, the exchange rate at 1 GEL -3.3 USD is used[43].

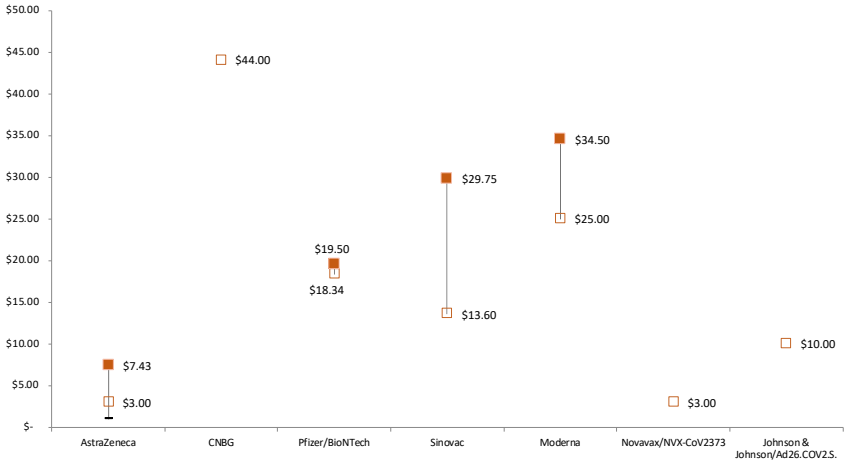
Financial calculations

Vaccines

The price of vaccine per dose, depending on the type of vaccine, is shown in Figure N1. The figure shows the minimum and maximum prices for vaccines. There is only one price for several vaccines.

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

Figure 1. Minimum and maximum prices of a vaccine per dose



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

The doses of vaccines required by priority groups taking into account the loss rate are given in Table 14.

Table 5: The doses of vaccines required by priority groups

Phase	Target group	Target group size	Coverage indicator	Groups yet to be vaccinated	Number of necessary doses	Loss indicator %	Loss factor	Number of necessary doses including losses
1ა	Health care sector in full	71 415	65%	46 420	2	15%	1,176	109 223
1ა	Beneficiaries and caregivers of long-term care facilities	2 600	60%	1 560	2	15%	1,176	3 671
1ა	>75 years old population	226 800	60%	136 080	2	15%	1,176	320 188
1ბ	65-74 years old popilation	329 183	60%	197 510	2	15%	1,176	464 729
2ა	Essential services	180 373	60%	108 224	2	15%	1,176	254 644
2ა	55-64 years old population	478 400	60%	287 040	2	15%	1,176	675 389
2ბ	18-54 years old population with a chronic disease	89 400	60%	53 640	2	15%	1,176	126 212
3	Other groups of the population	1 434 567	60%	860 740	2	15%	1,176	2 025 271
	In total	**2 812 738**	60%	**1 691 214**				**3 979 327**

As described in the document above, a total of 3,979,327 doses are needed to protect 60% of the adult population, taking into account the wasted vaccines. As of today, the COVAX platform has guaranteed 1,484,400 doses of vaccine for Georgia by 2021, but financial resources have been calculated for 3,979,327 doses of vaccine, provided that the country will be able to import additional 2,494,927 doses from alternative sources.

According to the scenarios, the financial resources required to purchase vaccines (as of today, according to the minimum and maximum prices of the vaccine available) are shown in Table 15.

Table 6: The minimum and maximum prices of vaccines by scenarios

Scenario	Minimum price of vaccines $	Maximum price of vaccines $	Minimum price of vaccines (GEL)	Maximum price of vaccines (GEL)
Scenarion 1				
COVAX 1,484,400 doses	**5 477 436**	**13 565 783**	**18 075 539**	**44 767 084**
Additional doses required for vaccination of the priority groups in full	5 506 669	7 261 355	18 172 007	23 962 471
Subtotal	**10 984 105**	**20 827 138**	**36 247 546**	**68 729 555**
Additional doses required for vaccination of 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**
Scenarion 2				
COVAX 1,484,400 doses	**5 477 436**	**13 565 783**	**18 075 539**	**44 767 084**
Additional doses required for vaccination of the priority groups in full	7 145 029	10 951 355	23 578 595	36 139 471
Subtotal	**12 622 465**	**24 517 138**	**41 654 134**	**80 906 555**
Additional doses required for vaccination of 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**
Scenarion 3				
COVAX 1,484,400 doses	**5 477 436**	**13 565 783**	**18 075 539**	**44 767 084**
Additional doses required for vaccination of the priority groups in full	3 528 829	9 780 395	11 645 135	32 275 303
Subtotal	**9 006 265**	**23 346 178**	**29 720 674**	**77 042 387**
Additional doses required for vaccination of 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**
Scenarion 4				
COVAX 1,484,400 doses	**5 477 436**	**13 565 783**	**18 075 539**	**44 767 084**
Additional doses required for vaccination of the priority groups in full	1 733 029	4 292 135	5 718 995	14 164 045
Subtotal	**7 210 465**	**17 857 918**	**23 794 534**	**58 931 129**
Additional doses required for vaccination of 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 can be seen from the table, the financial resources required for vaccines are the largest for the Scenario II, and the minimum cost is approximately 66.3 million GEL which is 1.4 times as much as the minimum financial resources required for the Scenario IV. Detailed calculation tables for each scenario in separate tables are given below:

Table 16: Price of vaccines provided in Scenario I

Contingent to be vaccinated	Number of doses required	Loss indicator %	Loss rate	Number of doses required including losess	Vaccine	Minimum price of a single-dose vaccine	Maximum price of a single-dose vaccine	Minimum price of a single-dose vaccine including all costs	Maximum price of a single-dose vaccine including all costs	Total (minimum) price of required vaccine $	Total (maximum) price of required vaccine $
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: Value of vaccines provided in Scenario II

Contingent to be vaccinated	Number of doses required	Loss indicator %	Loss rate	Number of doses required including losess	Vaccine	Minimum price of a single-dose vaccine	Maximum price of a single-dose vaccine	Minimum price of a single-dose vaccine including all costs	Maximum price of a single-dose vaccine including all costs	Total (minimum) price of required vaccine $	Total (maximum) price of required vaccine $
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: Value of vaccines provided in Scenario III

Contingent to be vaccinated	Number of doses required	Loss indicator %	Loss rate	Number of doses required including losess	Vaccine	Minimum price of a single-dose vaccine	Maximum price of a single-dose vaccine	Minimum price of a single-dose vaccine including all costs	Maximum price of a single-dose vaccine including all costs	Total (minimum) price of required vaccine $	Total (maximum) price of required vaccine $
85 000	2	15%	1.176	200 000	Sinovac/CoronaVac/China	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: Value of vaccines provided in Scenario IV

Contingent to be vaccinated	Number of doses required	Loss indicator %	Loss rate	Number of doses required including losess	Vaccine	Minimum price of a single-dose vaccine	Maximum price of a single-dose vaccine	Minimum price of a single-dose vaccine including all costs	Maximum price of a single-dose vaccine including all costs	Total (minimum) price of required vaccine $	Total (maximum) price of required vaccine $
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, safe boxes, personal protective equipment and other consumables

The financial resources required to purchase syringes, safe boxes, personal protective equipment (surgical masks, face shields, gloves, disposable coats) and other consumables (alcohol swabs, sealing tapes and vaccination cards) were also calculated according to the scenarios since as mentioned above, different scenarios consider the introduction of different types of vaccine.

As you know, introducing a Pfizer / BioNTech vaccine requires in addition a syringe (to open the diluent) in comparison with all other vaccines, the diluent itself, dry ice and special glasses / safety goggle for working with dry ice. In addition, special gloves / insulated gloves and a temperature monitor / a temperature data logger are required for Pfizer and Moderna vaccines. The financial resources required for all scenarios are summarized in Table 20.

Table 7: Cost of consumables by four scenarios

Scenarios	Price of consumables $	Price of consumables (GEL)
Scenarion 1		
Consumables required for COVAX 1,484,400 doses	**559 874**	**1 847 586**
Additional doses required for vaccination of the priority groups in full	189 391	624 991
Subtotal	**749 266**	**2 472 577**
Additional doses required for vaccination of other groups of population	763 876	2 520 791
Total	**1 513 142**	**4 993 367**
Scenarion 2		
Consumables required for COVAX 1,484,400 doses	**559 874**	**1 847 586**
Additional doses required for vaccination of the priority groups in full	217 927	719 158
Subtotal	**777 801**	**2 566 744**
Additional doses required for vaccination of other groups of population	763 876	2 520 791
Total	**1 541 677**	**5 087 534**
Scenarion 3		
Consumables required for COVAX 1,484,400 doses	**559 874**	**1 847 586**
Additional doses required for vaccination of the priority groups in full	179 305	591 705
Subtotal	**739 179**	**2 439 291**
Additional doses required for vaccination of other groups of population	763 876	2 520 791
Total	**1 503 055**	**4 960 082**
Scenarion 4		
CConsumables required for COVAX 1,484,400 doses	**559 874**	**1 847 586**
Additional doses required for vaccination of the priority groups in full	179 305	591 705
Subtotal	**739 179**	**2 439 291**
Additional doses required for vaccination of other groups of population	763 876	2 520 791
Total	**1 503 055**	**4 960 082**

As you can see from the table, the cost of consumables required for the Scenario II is the highest. The financial resources required for the third and fourth scenarios are the same.

Cold chain

An assessment of the existing cold chain capacity (as described in the cold chain section below in the document) showed that the country's cold chain capacity is sufficient for all four scenarios and there is no need to purchase additional refrigerators and freezers. Consequently, the country does not need financial investments in this direction for additional capital.

Service delivery

As described in the document above, various types / models of service delivery are discussed. The financial resources required for service delivery were calculated for both a single vaccination visit and full (2 doses) coverage. These calculations were made for both medical institutions (hospitals and clinics) and mobile brigades. The cost of providing the service for mass vaccination centers will be calculated later.

Table 8: Unit price of service delivery

Type of service delivery	Service price for a single 1 vaccination visit (GEL)	Service price for a full 2-dose vaccination visit (GEL)
Hospitals and clinics	2.5	5
Mobile brigades	6.7	13.4

The unit price includes both direct and indirect costs. It also includes the cost of waste disposal. In addition, the unit cost of a mobile brigade includes the cost of the shockproof package, travel costs and investment costs required for the operation of mobile brigades: for example, tablets, 4.4 L cold boxes, cold box thermometer and internet package for tablets.

Logistics / distribution of vaccines

The operational costs of distributing vaccines from central vaccine levels to regional and district warehouses include fuel costs, vehicle maintenance costs and travel costs.

It was necessary to hire additional staff (1 person) for the proper functioning of the vaccine logistics and distribution system. The remuneration of the staff was also determined and, therefore, these costs were added to the operating costs of the logistics. The full financial resources required for this component are indicated above.

Surveillance/Oversight

Visits were planned from the center to the regions, as well as from the regional level to the district level to supervise / observe the vaccination process. The financial resources required for surveillanceinclude travel, accommodation and transportation expenses. The required financial resources are indicated above.

Information system

At the moment, the financial resources of the information system component include only the costs of additional personnel required for the smooth operation of the hotline. (See).

Trainings

The financial resources required for trainings were calculated according to the training plan (as described in the Training Chapter above). The training budget includes all modules, including crisis communication, interpersonal communication and training for media representatives (see).

Demand creation and communication

According to the detailed plan prepared for the creation of the request and communication, the financial resources required for the implementation of this component were calculated, which amounted to 1,662,800 GEL / 503,879 USD. The country will have to work actively with donor and partner organisations to mobilize the necessary financial resources.

Annex 2. Principles for the selection of priority groups

The WHO / SAGE value system is based on the core principles of determining priority groups for vaccination against COVID-19.[44]

Tasks

1. Reduction of severe cases of illness and mortality.
2. Reduction of the risk of infection for vulnerable groups.
3. Sustainability of essential services.

When determining the priority of groups, the following are taken into account:

- Global and National Epidemiological Picture: Widespread scenario as of December 2020.
- Availability of vaccines depending on the stages of delivery.
- Possibility of implementation - technical possibility of parallel / simultaneous vaccination.
- Ethical aspects - maximum benefit and minimum harm, fairness, equality, and transparency.

Stages of vaccine delivery

I Stage: very limited access to vaccines (1-14% of the adult population)
I a - 1-6%; I b - 7-14%

II ეტაპი: Vaccine supply is increasing, but availability is limited (14-26% of the adult population);
Iა – 1-6%; Iბ – 7-14%;

II Stage: Vaccine supply is increasing, but availability is limited (14-26% of the adult population);

III Stage: Moderate availability of vaccines (27-60% of the adult population).

Gradual introduction of the vaccine in the context of the tasks

- The supply of vaccines will be limited at the beginning of vaccination, therefore prioritization is aimed at achieving the set goal with maximum effect. As the vaccine supply increases, vaccinated groups will expand by prioritizing and then expanding the adult population. It is important to note that based on the data accumulated about the vaccine, recommendations for different populations may vary depending on the characteristics of each vaccine, the epidemiology of the disease, and other contextual factors.

Reduction of severe cases and mortality

- To stop the transmission of COVID-19 infection, it is necessary to vaccinate a large part of the population, which is highly effective in preventing the spread of infection[45]. In the early stages of vaccination, there is no high level evidence of the effect of vaccination in reducing transmission of the virus, and in addition, access to vaccines is limited. Therefore, the best strategy for reducing morbidity and mortality in the early stages of vaccination is to directly protect those at increased risk of morbidity and mortality from infection.

Reduction of the risk of infection for vulnerable groups

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

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

- **Medical personnel** are considered one of the high risk groups in terms of infection and, in turn, pose a danger to vulnerable groups to whom they provide medical care[46] [47]. Protecting healthcare workers from infection will reduce transmission of infection to vulnerable groups and help maintain the health system during an epidemic. WHO/SAGE recommends vaccinating health personnel of very high and high risk groups first. In the case of access to a limited amount of vaccine in the first phase (<1.0%), it is according to this principle that priority is given to those employed in the health sector (see details below). When the vaccine becomes available to 3% of the population, it is recommended to vaccinate all persons employed in the health sector during the first stage of vaccination (Ia), in addition, one-stage vaccination will facilitate the vaccination processes (planning, recruitment, vaccination logistics, registration, and monitoring).
- Beneficiaries **in houses, long-term care facilities** are at high risk of infection due to the rapid spread of infection in the facility, and staff working in the facility pose a risk of transmission to beneficiaries. Given these risks, vaccination of this contingent is planned at stage Ia. At the same stage, it is planned to vaccinate people with disabilities who are members of organized groups (communities, family-type organisations).
- International evidence and analysis of the epidemic situation in Georgia show that the greatest risk of mortality from COVID-19 is associated with **age**, and this risk increases exponentially with age. As of 2 December 2020, the age structure of the total number of deaths from COVID-19 in Georgia is as follows (> 75 years old - 39.2%, 65-74 years old - 33.2%, 55-64 years old - 18.8% , 50-54 years old - 4.1%, 18-49 years old - 4.6%)[48]. The strategy in relation to age-related risk provides for the gradual vaccination of age groups (in descending order of older age), regardless of comorbidities. In particular, at the first stage (Ia - availability 6.5%), the population aged 75 and over will be vaccinated, while at the next stage (Ib - vaccine availability 7-13.5%), the population aged 65-74 will be vaccinated. At the II stage of vaccination (vaccine availability is 14–26%), the population aged 55–64 is vaccinated. As the analysis of mortality from COVID-19 shows, the risk of death is significantly reduced in the under 55-year-old age group, so the next step is to cover the remaining adult age group (18-54 years old) by concomitant chronic diseases. Vaccination by age group also helps to attract the population to vaccination, thereby ensuring higher coverage and speeding up the process.
- Evidence (international as well as local epidemiological analysis) indicates that certain **chronic conditions** increase the risk of severe morbidity and mortality from COVID-19[49] [50]. In general, the risk of comorbid chronic diseases increases with age. Since the proposed vaccination strategy ensures that the vaccine is offered to populations over 55 years old regardless of comorbid conditions, this will reduce the risk of serious complications and death from chronic diseases in vulnerable populations. Given the availability of the vaccine, vaccination will be available to people between the ages of 18 and 54 with the following co-morbid conditions:
- Diabetes (type I and II)
- Cardiovascular diseases:

[46] Transmission of SARS-CoV-2: implications for infection prevention precautions: scientific brief, 09 July 2020 [Internet]. Geneva: World Health Organization; 2020. (https://apps.who.int/iris/handle/10665/333114,accessed 5 December 2020)

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

[48] National Center for Disease Control and Public Health

[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

- Ischemic heart disease, all clinical forms with and without revascularization
- Cardiomyopathy
- Valve pathology, congenital malformations of adulthood
- Atrial fibrillation (permanent)
- Idiopathic long QT syndrome (high risk of fatal arrhythmias and sudden cardiac death)
- Chronic heart failure stage B, C, D (ACC / AHA) and functional class II-IV (NYHA)
- Deep vein thrombosis
- History of pulmonary artery thromboembolism.

Note:

Arterial hypertension is considered in the age group over 55 years old.

- Chronic respiratory diseases
  - Chronic obstructive pulmonary disease
  - Asthma
  - Cystic fibrosis
  - Idiopathic pulmonary fibrosis
- Oncohematological diseases
- Cancer (given the contraindications for a specific vaccine)
- Chronic renal failure
  - Individuals on dialysis
- Chronic liver pathology
  - Liver fibrosis stage 3 and 4
- Stroke suffered
- Post-transplant status
- Immunosuppressive patients
- Extremely obese (estimated BMI> 40 kg / m^2).

Sustainability of essential services

- The operation of basic services is essential to maintain public health, safety and educational management. Phase I vaccinations will help remove the burden of disease on staff from the health system. Personnel involved in the operation of other essential services will be covered in Phases II and III. The main services include:
  - Front headquarters of the Ministry of Internal Affairs (including the Emergency Management Service)
  - Defense Ministry system and representatives of NATO mission in Georgia
  - Long-distance transport operators (drivers, persons employed in sea / air / rail transport)
  - Full staff of pharmacies and pharmaceutical sector
  - Maintenance staff of preschool and educational institutions (kindergartens), as well as teachers and maintenance staff of educational institutions (if necessary, give priority to grade 4, and then high-quality staff)
  - Public transport personnel (driver, driver, conductor, dispatcher)
  - Taxi and minibus drivers.

- In Phase III, other high-risk groups will be vaccinated (prisoners / convicts, with the same approach as the age groups of the population, including those with a chronic condition and persons in direct contact with them; miners).
- Vaccination of representatives of diplomatic missions will be carried out with the same priority as the population of Georgia.
- Additional groups include people with disabilities (the possibility of vaccination with a mobile service if there are restrictions on movement) and athletes who participate in planned international tournaments.
- Target coverage indicator is provided for each priority group (those employed in the health sector - 65%, age and essential groups of the population - 60%). These target indicators exceed the evidence available at the coverage level of the first year of the new vaccine introduction. However, in the case of the COVID-19 vaccine, we are expected to have a different context in comparison with other vaccines, and coverage will largely depend on the acceptance of the vaccine in general and in certain groups (for example, medical personnel) at the beginning and din the course of vaccination. As of today, evidence shows that adoption of the COVID-19 vaccine ranges from 55% (Russia) to 99% (China) [51], and according to a December WHO / UNICEF survey in Georgia, 56% of the population would agree to vaccination if a vaccine is available and recommended[52].
- Coverage of priority groups will be monitored during the vaccination process. In case of excessive demand, if the coverage of a certain priority group exceeds the predicted rate, the groups will be reprogrammed.
- Based on the available evidence, transmissible infection is not a contraindication to vaccination, the current recommendation will be revised as soon as new evidence becomes available.
- Pregnant women and children under 16 years old are not included in COVID-19 immunization groups due to the lack of conclusive evidence of safety.
- After covering 20% of the population, the remaining adult population will be vaccinated based on the number of vaccinations. The definition of the contingent (age groups or other approach) is determined by the number of vaccinations.

[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] WTO/ UNICEF, preliminary data, 7 December 2020.

- When calculating the timeframes for the stages of vaccination, the quantity of doses to be supplied must be taken into account. At the first stage-Ia, vaccination of the older age group can be started in parallel (or after a certain period of time) with the vaccination of representatives of the health sector.

For maximum coverage of the vaccinated population, a person who wants to be vaccinated but is not eligible for vaccination during this period, may not be denied vaccination if the vaccine stock in the country includes coverage for a certain population.

All priority groups are listed below, depending on vaccine availability:

- Phase 1a (1-6.5% of the adult population).
  - People employed **in the health sector** are divided into the following subgroups by priorities:
    - **Very high and high risk:** *Personnel at risk of exposure to SARS-Cov-2 aerosol, through close contact with infected or suspected persons, through contact with infected objects:*
      - All persons working in active Covid clinics (medical and non-medical).
      - Physicians working in other (non-covid) clinics (including assistant physicians, residents), nurses, nursing assistants, caregivers working in the following areas: anesthesia-resuscitation, critical care medicine, emergency medicine, ambulance (including drivers), medical radiology X-rays, computed tomography), infection control / epidemiology / public healthcare (involved in testing, contact search), laboratory specialists (involved in testing / analysis), as well as security guards.
      - All individuals working in potential (currently inactive) Covid clinics.
    - **Medium risk:** *personnel in contact with the public who do not need to contact sick or suspected persons; Work is associated with crowded places where it is difficult to maintain distance or require close and frequent contact with employees.* All other medical and non-medical persons employed in the health sector.
    - **Low risk**: *personnel not required to have frequent and close contact with the public or suspected patients.* For example, only persons engaged in telemedicine, persons engaged in administrative activities remotely.
  - Beneficiaries and caregivers of long-term care facilities and community and family-type organizations for persons with disabilities
  - > 75 years old population
- Phase 1b (7-13.5% of the adult population)
  - Population aged 65-74
  - Essential services (Group 1)
- Front Line Office of the Ministry of Internal Affairs (including the Emergency Management Service)
- Long-distance transport operators (drivers, persons engaged in sea / air / rail transportation)
- System of the Defence Ministry
- Phase II (11-20% of the total population, 14-26% of the adult population)
  - 55-64 years old population
  - 18-54 years old with a chronic illness.
- Phase III (over 20% of the total population, 26-60% of the adult population)
  - Essential services and other high risk groups (Group II)
    - Pharmaceutical sector including pharmacy staff

- Public transport personnel (drivers, machine operators, conductors, dispatchers)
- The team of preschool and educational institutions
- Teachers and other staff of educational institutions (if necessary, giving preference to the 4th grade, and after – staff of high grades)
- Prisoners / convicts (> 55 years old, 18-54 years old with a chronic condition) and persons in official contact with them
- Miners
- Taxi and minibus drivers

- Other groups of population.

The following data sources were used to determine the vaccination contingent of priority groups: Healthcar sector - National Center for Disease Control and Public Health; Long-term care facilities - Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Healthcare and Social Protection of Georgia; Population groups - National Statistics Office of Georgia; The essential services - the relevant ministries, local authorities, the National Statistics Office of Georgia. Diplomatic Corps - Ministry of Foreign Affairs.

Annex 3. Monitoring and Reporting on AEFI related to COVID-19 vaccination

Issues to consider before introducing Covid-19 vaccination and while providing immunization services

Monitoring of AEFI associated with vaccines and vaccine quality defects

Action	Status	Responsible
Identifing and maintaining a list of health conditions of particular interest, along with the post-vaccination status subject to surveillance, registration and reporting applicable in the country	Determined	NCDC Subnational
Determination of national and subnational background indicators for nosologies of particular interest	Determined Sampled in 2019 To be improved	NCDC Subnational

Error-related reactions in immunization

It is impossible to insure against error-related reactions in immunization, and timely detection and correction of such errors is very important. The AEFI of this class can be minimized by improving software elements, which implies:

Action	Status	Responsible
Determining Service Provider Resources	See Service Delivery	Ministry of Healthcare/ NCDC
Determining Service Delivery Methods	See Service Delivery	Ministry of Healthcare/ NCDC/Municipal healcare centers
Identifying the need of volumes of the cold chain, its provision and supply	See Cold Chain	NCDC
Identifying and meeting the need for safe vaccine supplies for immunization (AD syringes, needles, safe disposal containers, appropriate reconstitutions, vaccine carriers), and their supply	See Cold Chain	Ministry of Healthcare/ NCDC
Identifying contraindications and warning conditions for covid vaccine.	To be determined according to the vaccines to be introduced	Ministry of Healthcare/ NCDC
Preparing training materials and training of service providers on the following issues: 1. Cold chain storage mode and management for Covidvaccine; 2. Treatment with Covidvaccine; 3. Covidvaccine vaccination technique; 4. Contraindications and warnings about Covidvaccine; 5. Expected AEFI for Covidvaccine; 6. Management of the vaccination service delivery process at the primary healthcare level.	See section Human Resources	NCDC

Immunization anxiety-related reactions

Action	Status	Responsible
Informing the population	See Section Communication	National Subnational
Information campaign before and during the immunization process;	See Section Communication	National Subnational
Preparation and delivery of an informational commemorative booklet.	See Section Communication	NCDC/ Municipal healthcare services
Ensuring proper management of the vaccination process by minimizing stress between injection recipients by reducing waiting times, maintaining a comfortable room temperature, hiding from view of a recipient the preparatory process, with the observance of confidentiality.		National municipal healthcare services Administration of institutions selected as service providers
Giving a clear and understandable explanation about immunization from a service provider to reduce the level and spread of injection-related anxiety and maintaining balance.	See Section Communication	National vaccination medical staff
Having a crisis communication plan	See Section Communication	Ministry of Healthcare/ NCDC

AEFI surveillance in connection with coincidental events

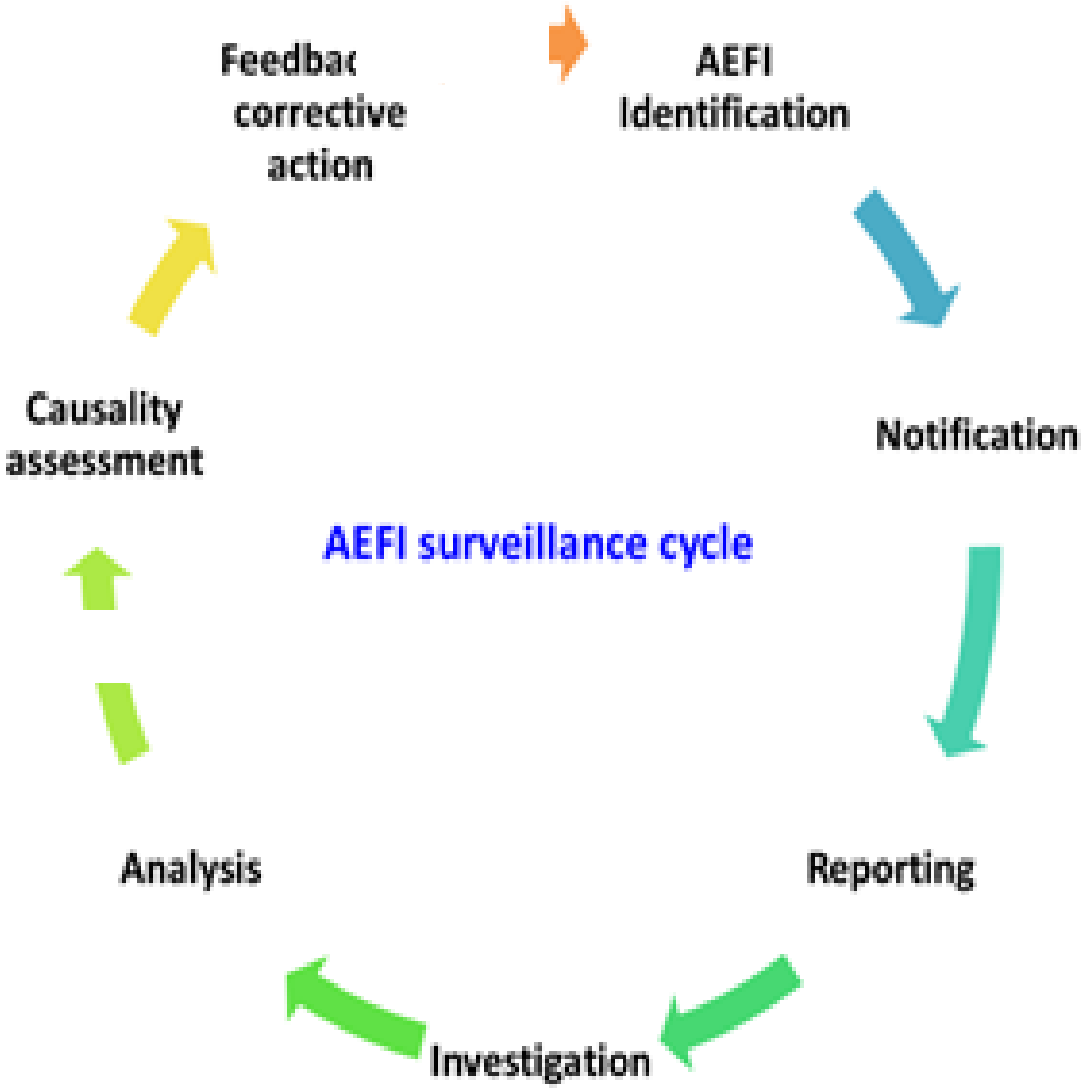
The assumption of an increase in the number of coincidental events caused by vaccination is logical when campaigning for a target population of older people. In chronic comorbidities, it is very difficult to make a differential diagnosis between an accidentally coincidental in time event and AEFI. Minimizing these incidents will allow the state programme to save resources and focus more on managing other specific AEFI. To prevent these events:

Action	Status	Responsible
The assessment of the health status of the vaccinated person should be carried out in accordance with the pre-vaccination procedure.		Service Provider Medical Staff
Determining the national background of existing conditions and nosologies of particular interest under surveillance	Adopted in 2019	NCDC

Registration and reporting on AEFI

The AEFI susurveillance system in the country is well functioning and adaptable, so the principles of passive surveillance and reporting channels for possible AEFI in Covidvaccine do not require major changes and are carried out in the prescribed manner.

Existing information flows on the AEFI:



The AEFI surveillance system applicable in the country is aimed at:

- Rapid detection of AEFI and timely response to its origin;
- Identifying, correcting and preventing error-related reactions in immunization;
- Facilitating causality assessment of the AEFI;

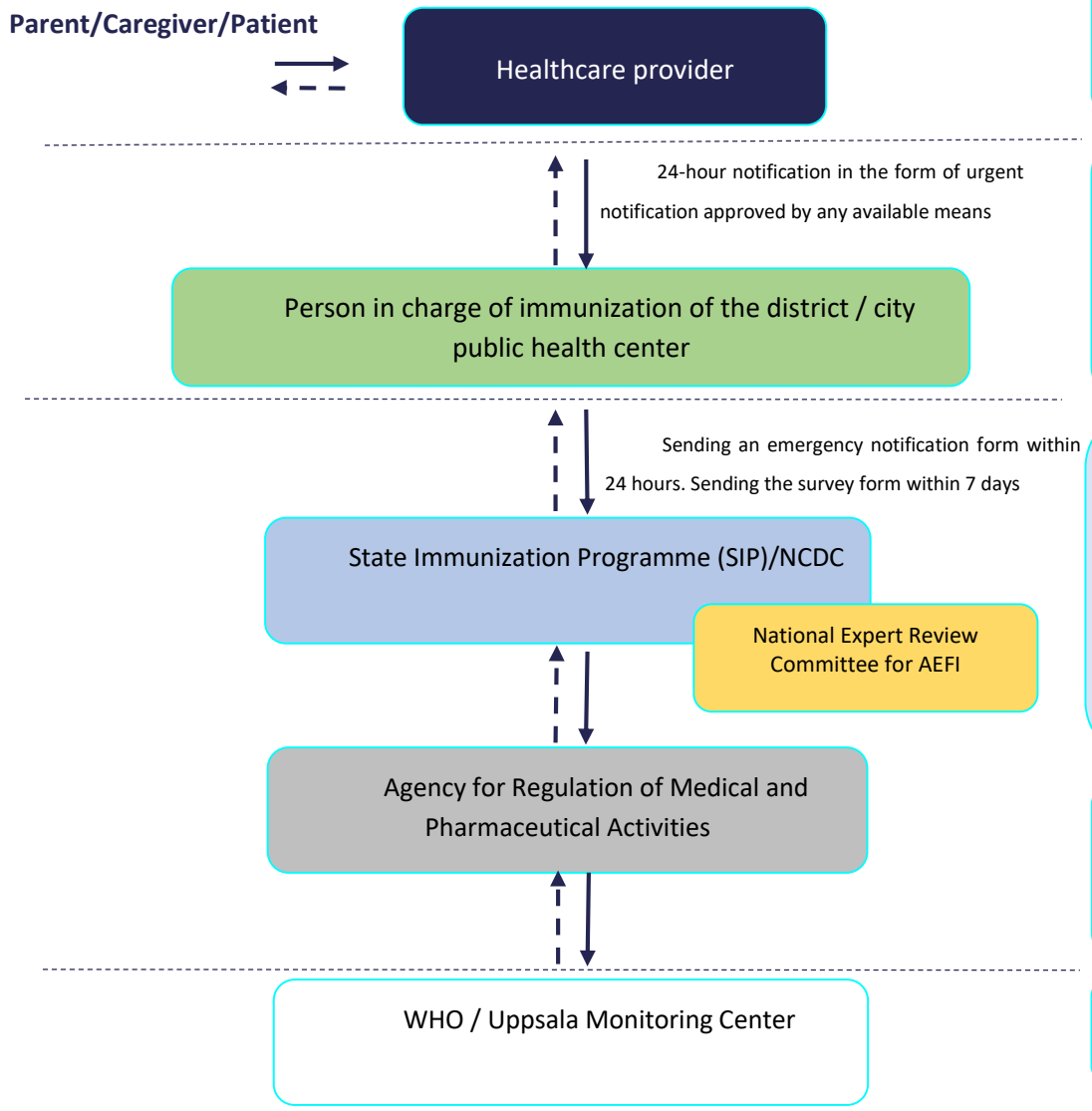
- Perceiving an AEFI cluster or an unusually high indicator;
- Identifying potentially dangerous signals (including previously unknown reactions to vaccines) and developing hypotheses that may require further research;
- Generating information on the safety of vaccines used in Georgia that enables effective communication with stakeholders.

The parties involved in the reporting and research of AEFI are:

At the subnational level: medical personnel, persons responsible for immunization of municipal health services, republican / regional public health services;

At the national level: State Immunization Programme of Georgia, Agency for the Regulation of Medical and Pharmaceutical Activities, National Committee of Experts on Immunization Safety.

Actions for AEFI detection, flow and timing for notifications



- Complete and submit an emergency message form (Attachment 1)

- Assisting the District Public Health Centers to investigate the AEFI case and collect laboratory materials as needed.

- Check a notification form and determine the need for assistance at the national level in the AEFI case study;
- Start collecting appropriate laboratory material;
- Conducting an AEFI survey within 48 hours;
- collect additional evidence (e.g. reports) related to the event;
- Submit an epidemiological survey form (Appendix 3) and related evidence (e.g. reports) to the State Immunization Programme.

Assisting a district public health center in investigating a case and, if necessary, in obtaining laboratory materials.

-View reports and epidemiological forms to determine if there have been similar cases from other regions.

Make sure all available evidence is collected for submission to the AEFI National Expert Committee.

- Provide results of the causality assessment to relevant stakeholders.

-Complete causal assessment and reporting of results to the SIP

Issuing recommendations to the National Technical Council of Immunization Experts/Interagency Coordination Committee, based on cause-and-effect assessment results.

-Annual submission of AEFI case data to VigiBase, a copy to the SIP
-Complete the relevant actions of the regulations

The introduction of the Covid-vaccine requires an adjustment of the applicable registration and reporting procedure, which requires:

Action	Status	Responsible
Additionally introducing monthly reporting on AEFI	Developed	Ministry/NCDC
Adding events of special interest to the AEFI emergency notification form;	Developed	Ministry/NCDC
Modifying an AEFI Epidemiological Study From by adding Covid-vaccination and nosologies of special interest.	Developed	Ministry/NCDC
Adapting the electronic integrated disease surveillance system for Covid-vaccine AEFI registration.	See Section Information Systems	NCDC
Adapting the online immunization and stock module for Covid-vaccine AEFI registration	See Section Information Systems	NCDC
Implementing AEFI case coding and data conversion for international notification	Developed	Ministry/NCDC
Encoding AEFI Cases in the NEDSS	See Section Information Systems	NCDC

Availability of readiness regulations

1. Development of draft rules for the surveillanceof the AEFI before and during the introduction of Covid vaccination.
2. Description of key issues related to post-epidemic surveillance, AEFI requirements and problem management.
3. Detailed information to support AEFI assessments at the National Committee for the Safety of Immunization (involving the scientific community, regulatory agencies and the immunization programme)
4. Description of steps to ensure injection safety.
5. Accountability, roles and responsibilities of staff.