



Project Information Document (PID)

Appraisal Stage | Date Prepared/Updated: 15-Jan-2021 | Report No: PIDA31131



BASIC INFORMATION

A. Basic Project Data

Country Ethiopia	Project ID P175853	Project Name Ethiopia COVID-19 Emergency Response Project Additional Financing P175853	Parent Project ID (if any) P173750
Parent Project Name Ethiopia COVID-19 Emergency Response	Region AFRICA EAST	Estimated Appraisal Date 16-Feb-2021	Estimated Board Date 26-Mar-2021
Practice Area (Lead) Health, Nutrition & Population	Financing Instrument Investment Project Financing	Borrower(s) Democratic Republic of Ethiopia	Implementing Agency Ministry of Health

Proposed Development Objective(s) Parent

To prevent, detect and respond to the threat posed by COVID-19 and strengthen national systems for public health preparedness in Ethiopia.

Components

Medical Supplies and Equipment
Preparedness, Capacity Building and Training
Community Discussions and Information Outreach
Quarantine, Isolation and Treatment Centers
Project Implementation and Monitoring

PROJECT FINANCING DATA (US\$, Millions)

SUMMARY

Total Project Cost	207.00
Total Financing	207.00
of which IBRD/IDA	207.00
Financing Gap	0.00

DETAILS

World Bank Group Financing



International Development Association (IDA)	207.00
IDA Credit	103.50
IDA Grant	103.50

Environmental and Social Risk Classification

High

Other Decision (as needed)

B. Introduction and Context

Country Context

The Ethiopia COVID-19 Emergency Response Project (P173750) for US\$ 82.6m was approved on April 2, 2020 and prepared under the Fast Track COVID-19 Facility (FTCF). The project comprises an IDA Credit (US\$ 41.30 million equivalent) and IDA Grant (US\$ 41.30 million equivalent) from the Crisis Response Window (CRW) Resources to support response activities for COVID-19 and strengthen the health system both at national and sub-national level. Since then, COVID cases and deaths have dramatically increased in Ethiopia (as of January 10, there were 128,316 cases and 1994 deaths reported in Ethiopia with a population of 109 million), as has COVID's economic and social impact given the closures of schools and businesses. Flooding and a locust outbreak have exacerbated the humanitarian impact. The Project has been instrumental in mobilizing critical resources for the country to rapidly strengthen its preparedness and response to the pandemic.

Providing access to COVID-19 vaccines will be critical to accelerate economic and social recovery in Ethiopia. The Government of Ethiopia has decided to gradually ease or lift restrictions to facilitate the resumption of economic activity. Considering the significant public health threat posed by COVID-19 To avoid an exponential rise in COVID-19 morbidity and mortality following this decision, mitigation strategies and measures need to be implemented. Hence, supporting health system improvements and providing access to COVID-19 vaccines will be critical to accelerate economic and social recovery in Ethiopia. The proposed AF presents an opportunity to increase the development effectiveness of the operation and response to COVID-19 in Ethiopia by expanding the scale and scope of the parent Project.

While progress is being made in the development and production of vaccines against COVID-19, there are immediate actions that countries can take to prepare for the implementation and deployment of COVID-19 vaccines. Though much information on the potential vaccines is still unknown, such as cold chain needs, number of doses to administer for adequate protection, administration route as well as vaccine safety



and effectiveness etc.; with the information currently available and with the assumption that vaccines will be available in the countries during the first quarter of 2021, it is essential to start preparing the infrastructure and key components of the vaccine implementation plan, prioritizing areas in which progress can be made. The Ethiopia **vaccine implementation** plan will address the allocation policy, capacity development, communication and community engagement, infrastructure and IT needs and coordinated management.

This AF is being proposed at a crucial juncture in the Government of Ethiopia response to COVID-19. Recently published results from the trials of two vaccines show that they are safe and produce desired immune responses. Consequently, they have been approved by Stringent Regulatory Authorities for use in vaccination. **Two vaccines (Pfizer and Moderna) have received Emergency Use Authorization from a stringent regulatory authority (SRA). Other pharmaceutical companies are confident they also will soon have sufficient data from Phase III trials to apply for SRA approvals.** Given the centrality of limiting the spread of COVID-19 to both health and economic recovery, providing access to COVID-19 vaccines will be critical to accelerate economic and social recovery in Ethiopia. This AF will enable affordable and equitable access to vaccines and play a critical role in further strengthening the health system.

The AF will form part of an expanded health response to the pandemic. The activities will build on COVID-19 MPA-Program's Ethiopia COVID-19 Emergency Response Project (P173750), as well as the Ethiopia Health SDGs Program for Result (P123531), and Africa CDC Regional Investment Financing Project (P167916). A number of development partners (including Global Fund and GAVI), international and local private sectors, and Associations have been supporting the government's efforts in fighting against COVID-19 pandemic.

Sectoral and Institutional Context

The need for additional resources to expand the COVID-19 response was formally conveyed by the Government of Ethiopia to the World Bank on October 16, 2020 to support procurement and deployment of a COVID-19 vaccine. Subsequently, the GoE sent a letter to the World Bank on November 27, 2020 requesting US\$ 207million AF to support COVID-19 vaccination. The proposed AF will form part of an expanded health response to the COVID pandemic. The Government of Ethiopia is leading donor coordination in close consultation with the Bank. Overall, the World Bank is providing a substantial share of total funding for Ethiopia's COVID-19 health response (as of October 2020, 40% is from WB, 47% government and 13% from other partners). Therefore, continued Bank engagement is essential to enable an expansion of a sustained and comprehensive vaccination effort in Ethiopia.

Ethiopia has conducted a vaccine readiness assessment to identify gaps and options to address them, as well as to estimate the cost of vaccine deployment, with the support of international organizations (**WBG, WHO, UNICEF, GAVI**). COVID-19 vaccine deployment will be an unprecedented effort for Ethiopia, but the country has established the appropriate coordination mechanisms for successful vaccine deployment. Ethiopia's immunization scores as per the Global Health Security Index report are high (94 percent out of 100 percent) showing a robust immunization system. However, as many countries,



Ethiopia, is used to vaccinating infants/children which represent around only five percent of the country's population.

Ethiopia plans to vaccinate at least 20 percent of the population for the calendar year of 2021 and 2022. Ideally and depending on the manufacturer's production capacity Ethiopia aims to get to at least 60 percent vaccination coverage. This would depend on the epidemiology of the pandemic in the world and in Ethiopia as well as the success, effectiveness and safety of the vaccine. Regarding human resources capacity, Ethiopia's preliminary quantification results have shown that the country has enough human resource for health who can quickly be trained and engaged in the deployment of the COVID19 vaccine in the country. For the tracking and monitoring system for the deployment of the COVID19 vaccine, the country has a logistics and supply electronic management tool (SMT) which has appropriately been tracking the activities of the routine immunization program. This tool is being adapted and tailored to the anticipated needs for the COVID-19 vaccine. For vaccine deployment, Ethiopia is putting in place the institutional framework for the safe and effective deployment of vaccines, including: (i) ensuring voluntary and informed vaccination practices; (ii) regulatory standards for vaccine quality; (iii) guidelines for acceptable minimum standards for vaccine management, including cold chain infrastructure; and (iv) policies to ensure robust governance, accountability, pharmacovigilance, and citizen engagement mechanisms.

The government has followed and contextualized WHO SAGE's roadmap for the prioritization of the target population. The roadmap recognizes that many countries' prioritization decisions will be tied, in part or in whole, to vaccine distribution through the COVAX Facility.

C. Proposed Development Objective(s)

Original PDO

To prevent, detect and respond to the threat posed by COVID-19 and strengthen national systems for public health preparedness in Ethiopia.

Current PDO

To prevent, detect and respond to the threat posed by COVID-19 and strengthen national systems for public health preparedness in Ethiopia.

Key Results

PDO Indicator:

1. Percentage (%) of priority population vaccinated, based on the targets defined in national plan by sex. Target: 100%

Intermediate Result indicators



1. **Component 1:** (i) Percentage of vaccine stockout rate, (ii) management tools and operating procedures updated to reflect the needs for deployment and management of COVID-19 vaccines.
2. **Component 2:** (i) Potential numbers of target populations estimated who will be prioritized for access to vaccines stratified by target group and gender, (ii) Guidelines, documented procedures and tools for planning and conducting vaccine pharmacovigilance activities are established and available.
3. **Component 3:** Number of key COVID19 vaccine messages disseminated through various media outlets (radio, TV, social media, print media, etc.)
4. **Component 4:** Number of vaccine laboratories renovated and equipped.

Component 5: Gender-based indicators

5. Increase in share of women-owned firms involved in deployment logistics
6. Increase in share of women in pandemic response oversight agencies and/or managerial level

D. Project Description

Project Components

Proposed New Activities

Component 1. Medical Supplies and Equipment [current allocation US\$ 51.4 million; proposed AF allocation US\$ US\$132.1 million]: The support for vaccines when available, which was anticipated in the initial Global COVID-19 MPA, will be added as part of the containment and mitigation measures to prevent the spread of COVID-19 and deaths under Component 1: Emergency COVID-19 Response. Ethiopia will utilize the COVAX AMC facility for vaccine purchase and financing mechanisms. The AF under this component will finance: (i) the procurement of vaccines; (ii) Procurement of vaccination supplies needed for activities outlined in the vaccine deployment plan such as diluents, syringes, and all medical supplies associated with the vaccination response; (iii) cold chain inputs, (iv) maintenance of existing cold chain equipment; (v) infection prevention and waste management; and (vi) vaccine storage and transportation.

Component 2. Preparedness, Capacity Building and Training [current allocation US\$16 million; proposed AF allocation US\$63.2 million]: The AF will finance: (i) the development of a COVID-19 vaccination card, COVID registry, report and analytical tools; training plan for vaccine introduction; (ii) deployment of health professionals; and training on surveillance, supply chain and others as needed; (iii) iterative development of micro-level deployment plans at national and sub national levels; (iv) establishment of regulatory measures for the procurement/ importation of COVID-19 vaccine and related supplies; vaccine safety, licensure pharmacovigilance; (v) trainings of front line health personnel on vaccine inoculation; (vi) supervision on vaccine safety and Adverse Event Following Immunization (AEFI) monitoring for regulators and EPI officers; (vii) strengthening of regional AEFI investigation task force and support for AEFI case investigations through provision of technical assistance for AEFI; (viii) data protection guideline, draft consent forms, developing SOP; (ix) developing innovative registries for key vaccine target groups, identification of target populations; monitoring and evaluation including establishment of a mechanism to track adverse reactions to vaccines. The AF will further strengthen the testing capacity for COVID-19 at the subnational (regional/state) level; develop/adapt existing vaccine surveillance and monitoring



frameworks; strengthen existing national and sub national coordination committees and technical working group for EPI to support the vaccine procurement and deployment; and enhance the existing electronic information system/data and monitoring system used by the EPI Program.

Component 3. Community Discussions and Information Outreach [current allocation US\$6.5million; proposed AF allocation US\$2.4 million]: The AF will finance: i) the development of social mobilization and community engagement strategies (using local languages) to increase vaccine acceptance and COVID-19 prevention behaviours; ii) monitor vaccine acceptance /hesitancy; iii) establish compliant handling mechanisms at all levels (Federal MOH, Regional Health Bureau, Woreda Health Office and Facility). It will further strengthen activities in the parent project including deployment of risk communication officers and other human resources to expand and accelerate vaccine deployment efforts.

Component 4. Quarantine, Isolation and Treatment Centers and regulatory infrastructure [current allocation US\$ 7.3 million; proposed AF allocation US\$ 7.3 million]: The AF will finance the regulatory infrastructure and capacity for safety surveillance of the COVID-19 vaccine which include refurbishing and equipping vaccine laboratory under Ethiopia Food and Drug Authority. Ethiopia is currently contracting out the vaccine laboratory testing undertaking which has its own limitation in terms of selecting independent laboratory, establishing and reviewing selection criteria, assembling a list of possible qualified laboratories and carrying out the contracting process which will normally be undertaken by the procurement entity responsible for purchasing vaccines and other biological products. The absence of vaccine laboratory in the regulatory body of the health sector has a negative implication on the quality, timelines and cost of the operation. Given that COVID 19 vaccine research and development and vaccine improvement will be the major and critical assignment for the upcoming years, this laboratory will have significant importance in terms of facilitating licensing and registering any potential COVID 19 candidates in the future.

Component 5. Project Implementation and Monitoring [current allocation US\$ 1 million; proposed AF allocation US\$ 2.0 million]: Proposed new activities: The AF will finance: i) the operating costs of mobilizing additional short-term consultants who support vaccine deployment; and ii) Covid-19 hazard pay /risk allowance for staff who will be involved in vaccine deployment efforts. It will further finance additional operating costs to strengthen the existing GMUs.

The AF will finance technical assistance to support Ethiopia to establish institutional frameworks for the safe and effective deployment of vaccines. These will include: a) establishment of policies related to ensuring that there is no forced vaccination; b) acceptable approved policy for prioritized intra-country vaccine allocation; c) regulatory standards at the national level, including pharmacovigilance; d) appropriate minimum standards for vaccine management including cold chain infrastructure (with financing as well for the investment to meet those standards as described below); and e) the creation of accountability, grievances, and citizen and community engagement mechanisms. In addition, the AF will finance upfront community mobilization and advocacy to increase vaccine acceptance.



Legal Operational Policies

	Triggered?
Projects on International Waterways OP 7.50	No
Projects in Disputed Areas OP 7.60	No

Summary of Assessment of Environmental and Social Risks and Impacts

E. Implementation

Institutional and Implementation Arrangements

The Ministry of Health (MOH) through its Grant Management Unit (GMU) is the implementing agency for the project as the Partnership and Cooperation Directorate (PCD) has been moved from the State Ministers office to the Minister’s Office. A National and Sub National Inter-Agency Coordinating Committee (ICC) for COVID-19 vaccine introduction has established five Technical Working Groups to serve as its technical wing, namely Planning, Monitoring and Evaluation & Service Delivery; Communication, Demand, and Community Engagement; Logistics, Supply Chain and Vaccine Forecasting; Safety, Vaccine Licensing and Pharmacovigilance and Infection Prevention; and Surveillance and Research & Development. The ICC is the highest COVID 19 vaccine technical coordination committee and coordinates the overall planning, implementation, and monitoring of COVID 19 vaccine introduction and resource mobilization activities. The existing research and advisory committee as well the Ethiopian National Immunization Technical Advisory groups are also engaged in the overall vaccine deployment strategy development and implementation.

The Grant Management Unit (GMU) of the MoH’s PCD in collaboration with MCH Directorate (MCHD) and ICC is responsible for the day-to-day management of activities supported under the project, as well as the preparation of a consolidated annual workplan and a consolidated activity and financial report for the parent and AF project. In addition, MOH- respective directorates, the regional health bureaus, and other key agencies implement some of the project activities based on their functional capacities and institutional mandates. The MCHD and Ethiopia Public Health Institute (EPI), Ethiopia Pharmaceutical Supply Agency (EPSA) and Ethiopia Food and Drug Authority (EFDA) will also continue to serve as the key technical entity for this project. MCHD, EPI, EPSA and EFDA will both support the PCD and directly implement certain activities under the original and AF for activities outlined in the National COVID vaccine rollout plan. The EPI and MCHD will report directly to the Minister and Program State Minister respectively, and they will share the project’s technical and financial updates with the MoH PCD GMU.



Ethiopia has developed a comprehensive COVID-19 vaccine deployment strategy and plan. The country has established the National Coordination Committee that will work as the National Immunization Technical Advisory Group (NITAG). Within such coordination mechanism, several sub-committees have been established and focus on: (i) service provision; (ii) vaccine cold chain and logistics; (iii) demand and communication generation; (iv) COVID-19 prioritization, guidance and surveillance; (v) monitoring and evaluation: determination and proof of eligibility, proof of vaccination, monitoring of coverage in risk groups, and monitoring of vaccine impact; and (vi) safety, including injury prevention and detection and response to Adverse Events Following Vaccination (AEFI).

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APPROVAL

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