

OFFICE OF INSPECTOR GENERAL
U.S. Agency for International Development

U.S. COVID-19 Vaccine Contributions

**USAID Should Consider
Enhancing Oversight to
Mitigate Risk of Fraud,
Waste, and Abuse**

Report E-000-21-002-M
September 1, 2021



Inspections, Evaluations, and Special Projects Division



OFFICE OF INSPECTOR GENERAL U.S. Agency for International Development

DATE: September 1, 2021

TO: USAID, Bureau for Global Health, Acting Assistant Administrator, Jennifer Adams

FROM: Director, Inspections, Evaluations, and Special Projects Division, Alan MacMullin /s/

SUBJECT: U.S. COVID-19 Vaccine Contributions: USAID Should Consider Enhancing Oversight to Mitigate Risk of Fraud, Waste, and Abuse (E-000-21-002-M)

This memorandum transmits the final report on our evaluation of USAID's COVID-19 vaccine strategy. Our objective was to review the status of USAID's effort to develop and implement a COVID-19 vaccine strategy as of May 31, 2021. In finalizing the report, we considered your comments on the draft and included them in their entirety, excluding attachments, in Appendix A.

The report contains two recommendations to improve USAID's oversight associated with ongoing COVID-19 vaccine efforts. USAID agreed with both recommendations. After reviewing information you provided in response to the draft report, we consider one recommendation resolved but open pending additional documentation (recommendation 1) and one recommendation closed (recommendation 2).

For recommendation 1, please provide evidence of final action to the Audit Performance and Compliance Division.

We appreciate the assistance you and your staff provided to us during this engagement.

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Introduction

More than a year after the coronavirus began spreading internationally, the COVID-19 pandemic remained a Public Health Emergency of International Concern requiring a coordinated international response, according to the World Health Organization (WHO), which provides global leadership in public health within the United Nations and is involved in the global coordination for mitigating the COVID-19 pandemic. Over 170 million COVID-19 cases and over 3 million deaths had been reported worldwide as of May 31, 2021.¹ WHO reports that safe and effective vaccines are a critical tool against COVID-19, as they prevent illness and may reduce coronavirus transmission. On December 31, 2020, WHO issued its first Emergency Use Listing (EUL) for the Pfizer COVID-19 vaccine and subsequently listed additional vaccines for emergency use. By issuing the EULs, WHO facilitated regulatory approval in countries seeking to import and administer unlicensed vaccines.²

COVAX

To ensure equitable access to COVID-19 vaccines worldwide, the COVID-19 Vaccines Global Access Facility (COVAX) was established as a global initiative to support the development and manufacturing of safe and efficacious COVID-19 vaccines for participating countries.³ Since its establishment, COVAX has had the support and resources of 191 of the world's economies, including governments and foundations. COVAX is co-led by WHO and Gavi, the Vaccine Alliance (Gavi), whose mission is to increase equitable and sustainable use of vaccines.⁴ Gavi—whose focus is on reaching unvaccinated children—funds global stockpiles for Ebola, cholera, meningitis, and yellow fever. Gavi receives funding from the U.S. government through USAID, and other donor countries, foundations, and persons to support its efforts—including COVAX and traditional vaccination programs.

Gavi also created, coordinates, and provides oversight for the COVAX Facility through which self-financing economies and funded economies can participate in accessing safe and effective vaccines. Within the COVAX Facility sits a separate funding mechanism, the COVAX Advance Market Commitment (AMC), which supports access to vaccines for 92 participating low- and lower-middle-income countries.⁵ With financial support from its donors, the COVAX AMC aims to procure and deliver up to 1.8 billion vaccine doses through the United Nations International Children's Emergency Fund (UNICEF) by the end of 2021.⁶ As of June 4, 2021, UNICEF had procured and delivered more than 50 million COVID-19 vaccine doses to 80

¹ Johns Hopkins University Center for Systems Science and Engineering, "[Novel Coronavirus \(COVID-19\) Cases Data](#)," accessed June 4, 2021.

² The WHO EUL assists interested U.N. procurement agencies and Member States in determining the acceptability of using specific unlicensed products during public health emergencies based on an essential set of available quality, safety, efficacy, and performance data.

³ WHO's EUL is a prerequisite for procurement of unlicensed vaccines by COVAX.

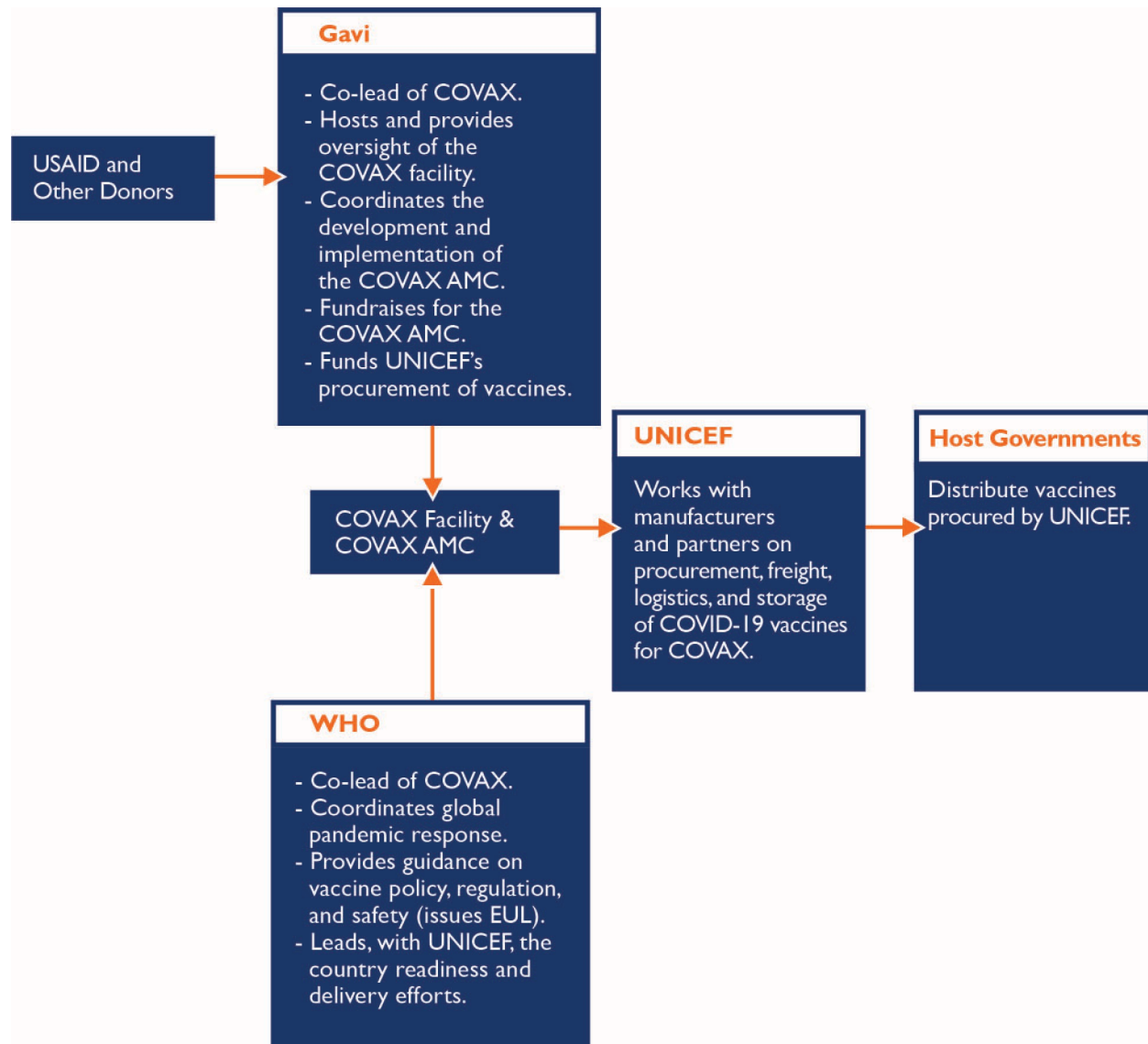
⁴ COVAX is also co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), a global partnership launched in 2017 to develop vaccines to stop future epidemics and now focusing on COVAX research and development across promising vaccine candidates. Our review did not include CEPI.

⁵ The 92 low- and lower-middle-income countries have Gross National Income of less than \$4,000 USD per capita.

⁶ The Pan American Health Organization (PAHO) performs this function in the Americas. Our review did not include PAHO.

countries eligible for COVAX aid.⁷ The flow chart in Figure I shows aspects of the international effort to procure and distribute COVID-19 vaccines through COVAX that are included in our review.

Figure I. Selected Key Players and Roles Associated With COVAX Vaccine Procurement and Distribution



Source: OIG analysis of COVAX roles and responsibilities.

USAID and Missions

USAID is a key player in U.S. international efforts to respond to the COVID-19 pandemic and address its secondary impacts. The Agency administers U.S. government contributions to Gavi and develops strategies to respond to the pandemic. As of May 31, 2021, USAID reported

⁷ Data from UNICEF's COVID-19 Vaccine Market Dashboard.

working with the National Security Council (NSC) and other federal agencies to develop a government-wide COVID-19 response strategy, and USAID's Bureau for Global Health (GH Bureau) was working to develop the Agency's response strategy.

USAID missions support country readiness and delivery, which includes providing technical assistance to host countries preparing to receive COVID-19 vaccines. The missions reported working with other U.S. agencies to help host countries develop and implement National Deployment and Vaccination Plans (NDVPs)—country operational plans to implement and monitor COVID-19 vaccination rollout.⁸ NDVPs are required for countries to obtain eligibility for COVAX-funded vaccines.

About This Evaluation

The objective of this evaluation was to review the status of USAID's effort to develop and implement a COVID-19 vaccine strategy as of May 31, 2021.⁹ Specifically, we (1) determined the status of USAID's COVID-19 vaccine strategy¹⁰ and reviewed the efforts of four USAID missions—Honduras, India, Nigeria and Ukraine—to assist host governments in their vaccination readiness efforts;¹¹ and (2) reviewed USAID's oversight of its contribution to Gavi for the procurement and delivery of COVID-19 vaccines.

Our review focused on views of USAID and global stakeholders regarding challenges and opportunities for USAID strategic efforts given the status to date. We interviewed USAID officials and mission personnel from the GH Bureau, as well as representatives from WHO, UNICEF, and Gavi. We also reviewed USAID policies and guidance related to the global vaccine distribution strategy and documents describing mission engagement on vaccines. Additionally, we obtained USAID's description of oversight for its contribution to Gavi. We conducted our review from December 2020 to June 2021 using the Quality Standards for Inspection and Evaluation from the Council of the Inspectors General on Integrity and Efficiency.

USAID Is Finalizing a COVID-19 Response Strategy Amid Challenges as Missions Support Implementation of Host-Country Plans

At the time of our review, officials from the GH Bureau were working through challenges developing a pandemic response strategy that included support for international COVID-19 vaccination programs. At the mission level, USAID plans to continue supporting host-country strategies for implementing COVID-19 vaccination programs. USAID missions in Honduras,

⁸ NDVPs outline key aspects of vaccination program readiness, including regulatory preparedness, planning and coordination, costing and funding, target populations and vaccination strategies, supply chain and health care waste management, human resources management and training, vaccine acceptance and demand, vaccine safety, and immunization monitoring.

⁹ [OIG COVID brief #3](#) provides information on USAID's response to the COVID-19 pandemic and associated challenges, as well as related oversight plans and activities.

¹⁰ This evaluation did not include the U.S. government's intention to share COVID-19 vaccines.

¹¹ Our judgmental sample was chosen based on geographic diversity, participation of mission country in COVAX, and country use of vaccines that had and had not received WHO emergency use authorization.

India, Nigeria, and Ukraine engaged with host countries on vaccine readiness and distribution efforts varied in the extent and timing of assistance.

USAID is Finalizing a New COVID-19 Response Strategy to Address Shifting Government Priorities

As of May 2021, GH Bureau officials said they were finalizing a USAID strategy that would include international assistance for COVID-19 vaccination programs, with some delays in strategy and funding caused by the change in administration, the need to align with a “whole of government” pandemic response plan across multiple agencies, and the inherent challenges caused by the evolving nature of the worldwide public health crisis. As of August 20, 2021, USAID had not finalized its COVID-19 Response Plan.

While USAID developed a pandemic response strategy in 2020 that included promoting access to COVID-19 vaccines with a roadmap for its rollout, GH Bureau officials stated that the strategy was not finalized and funded before the change in administration in January 2021. Throughout 2020, USAID played a role in U.S. efforts worldwide to prevent and respond to COVID-19 and mitigate its profound public health, economic, social, and development effects. USAID contributed more than \$1.6 billion across more than 120 countries for efforts to improve public health education, protect healthcare facilities, and increase capacity for laboratories, disease surveillance, and rapid response. However, these efforts did not include support for COVID-19 global vaccination campaigns. Under the current administration, GH Bureau officials said they needed time to draft and finalize a new strategy that would align with and help implement a broader, U.S. government-wide pandemic response planning effort led by the NSC.

Systemic Challenges May Complicate Implementation of a COVID-19 Vaccination Strategy

GH Bureau officials said challenges to implementing a COVID-19 vaccination strategy include the evolving pandemic—which requires USAID officials to quickly change focus to address emerging public health crises—as well as the following:

- *Human resources constraints* including hiring and training of surge and support staff at the country level for service delivery of COVID-19 vaccines. Training needs include counseling, adequate supervision, and efforts to monitor and evaluate adverse events following immunization. Additionally, staffing and training is needed for selected tasks, such as community engagement, record-keeping, and maintaining the cold chain.¹²
- *Supply chain and logistics challenges* that could delay the deployment of COVID-19 vaccines, transportation, and distribution of vaccines in country, including hard-to-reach populations.

¹² A “cold chain” is a series of climate-controlled transport and storage facilities that ensure the viability of testing reagents, medicines, vaccines, and blood products from factory to patient.

- *Gaps in systems to monitor and evaluate adverse events following immunization and overcoming hesitation of populations to seek vaccination.*¹³

External stakeholders responsible for the global strategic response to the pandemic—such as WHO—also identified financial resources, human resources, and vaccine supply as key challenges facing the international COVID-19 vaccination efforts.

GH Bureau officials said USAID missions will strive to address these challenges by prioritizing the following areas that align with those outlined by WHO for use by global partners in providing foreign assistance for COVID-19 vaccination programs:

1. *Policy, planning, and coordination.* Technical assistance can help countries establish policies, plans, and coordination arrangements to facilitate the delivery of COVID-19 vaccines.
2. *Pharmacovigilance and monitoring adverse events following immunization and adverse events of special interest.*¹⁴ Technical assistance can help countries develop and tailor guidelines, procedures, and tools for planning and conducting vaccine pharmacovigilance activities. Such activities include detecting, reporting, and investigating adverse events.
3. *Supply chain and logistics.* Technical assistance is needed to strengthen national logistics working groups to support the deployment of COVID-19 vaccines and ancillary products. Support could also include assessments of current cold chain capacity, which is important to identify gaps in existing storage capacity and to understand capacity for maintaining and monitoring the cold chain during transportation and distribution of vaccines in country.
4. *Service delivery.* To reach the target populations (including older populations and those with pre-existing conditions) with COVID-19 vaccines, new and novel service delivery approaches will be required. This starts with identifying the target population based on evidence and country data. Missions can also support the Ministry of Health to engage across sectors to support the design and implementation of varied delivery strategies—for example, engaging the Ministry of Education to implement school-based vaccination for teachers. Service delivery sites will need to be designed and organized for gender and equity considerations.
5. *Human resources for health, including training and supervision.* To ensure high-quality service delivery of COVID-19 vaccines, training materials will need to be developed, incorporating digital-based learning processes where feasible. Training should include counseling, adequate supervision, and efforts to monitor and evaluate adverse events following immunization. Additionally, technical assistance could help countries train surge and support staff for selected tasks, including community engagement, record keeping, micro-planning at the local level, and cold chain maintenance.
6. *Communications and advocacy.* Technical assistance for communications and advocacy will equip decision makers with the information they need to provide sufficient human, financial,

¹³ “Adverse event” means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.

¹⁴ “Pharmacovigilance” is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine/vaccine-related problem. All medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorized for use.

and technical support to COVID-19 vaccine readiness and deployment efforts. Additionally, support for accountability frameworks—which outline clear roles and responsibilities of all stakeholders and identify milestones for country readiness and deployment—can help ensure transparency.

7. *Community engagement and demand.* To generate confidence, acceptance, and demand for COVID-19 vaccines, technical assistance can include coordination support; risk and safety communication; community engagement; and training, monitoring, and responding to misinformation and rumors. Assistance should build on lessons learned from other vaccine introductions to address hesitancy and refusals, as well as increase demand for COVID-19 vaccines and other vaccines in the national schedule.
8. *Monitoring, evaluation, and health information systems.* Technical assistance can help develop or adapt existing data tools and health information systems to support vaccine rollout. This includes information systems that are used for supply chain and logistics, pharmacovigilance, and the human and financial resources required to deploy vaccines. Additionally, information systems should be able to collect and analyze information for tracking vaccination progress, including which populations have been vaccinated and when, as well as information on the ongoing burden of disease and its spread.

Among these priorities, global partners, such as WHO, said that USAID technical assistance has been of value and they welcome USAID's continued support. Global partners also stated that the global community would particularly welcome USAID's assistance in designing and implementing a system for global monitoring and evaluation in the future.

USAID Missions Will Continue to Support Implementation of Host Government Vaccination Strategies

As of March 2021, three of the four USAID missions we reviewed had supported implementation of host-country NDVPs to some extent. Missions had not developed their own vaccination strategies; rather, they supported host governments in implementing NDVPs by reprogramming funds and providing technical assistance. For the missions we reviewed, engagement with host countries on vaccine readiness and distribution efforts varied in the extent and timing of assistance due to uncertainty over the types of program activities that could be supported and funded and how assistance for existing programs could be impacted by COVID-19 vaccination efforts.

Three of the four USAID missions stated that mission staff were engaging at various levels with host governments and in-country implementers on COVID-19 vaccination efforts. One USAID mission we spoke with stated that they were involved early on in assisting the host government develop its NDVP, while the other three missions were not involved in this planning effort. Officials from two of those missions stated that they either were not in a position to assist with international vaccine efforts under the previous administration or were waiting for direction from headquarters on USAID actions that would be approved and funded.¹⁵ The fourth mission

¹⁵ USAID Agency Notice issued February 26, 2021 – “Guidance for USAID Technical Assistance Related to Non-Approved COVID-19 Vaccines.” This notice addresses mission concerns over to what extent and how vaccination program assistance could be provided to countries that distribute a mix of approved and unapproved COVID-19 vaccines.

said that USAID had not been involved in any national efforts for vaccine deployment as the mission did not have the mandate to do so.

Guidance and flexibility to reprogram existing mission funding to support country readiness for COVID-19 vaccination programs started becoming available to missions in February 2021, with the four missions in our sample varying in the extent such funds were available in their foreign assistance portfolio.¹⁶ One reason is that missions reported differences in the extent to which sufficient resources were available for reprogramming without compromising the implementation and sustainability of existing program activities. For example, officials from one mission said they had an extensive and longstanding health program portfolio with enough pipeline funding to reprogram for COVID-19 vaccine readiness without compromising existing health programs, while another mission said that they did not have such a pipeline to allow similar reprogramming actions.

According to GH Bureau officials, as of May 12, 2021, nearly \$23.6 million in funding has been approved for redirection and reprogramming toward COVID-19 vaccine activities. In May 2021, GH Bureau officials stated that the Agency had an additional \$75 million in funding for vaccine preparedness efforts. They also said they did not yet know how this funding would be made available to missions as allocations would be dependent on finalizing the response plans.

Additional Oversight May Be Needed to Mitigate Risk of Fraud, Waste, and Abuse for USAID's Contribution to Gavi

In December 2020, the U.S. Congress appropriated \$4 billion for international COVID-19 vaccine procurement and delivery through a contribution to Gavi.¹⁷ On January 21, 2021, President Biden announced that the U.S. government would join COVAX, thereby allowing Gavi to use the U.S. contribution for COVAX. USAID contributed \$2 billion to Gavi for the procurement and distribution of COVID-19 vaccines through COVAX on March 8, 2021, with another \$2 billion to be provided by September 2022. This \$4 billion contribution will comprise approximately half of the total committed donations to COVAX as of May 2021. USAID and global partners said that the existing fraud oversight process for this contribution may be insufficient to respond to related fraud risks.¹⁸

¹⁶ USAID Agency Notice issued February 1, 2021 – “USAID Process for Programming Resources for Country Readiness and Delivery of COVID-19 Vaccines.” This notice provides guidance on the types of funds that can be reprogrammed for vaccine activities, including Global Health COVID-19 Supplemental funds; Global Health Security funds; Maternal and Child Health funds; Economic Support Fund; and Assistance to Europe, Eurasia, and Central Asia.

¹⁷ The FY 2021 Omnibus and COVID Relief and Response Act H.R. 133. Congressional appropriations language directed the funds be issued as a contribution, which allows USAID to provide funding to a public international organization (PIO)—such as Gavi—for its overall operation and support. The purpose is not to finance specific goods, services, or activities such as monitoring activities. Unique provisions of Federal law and international arrangements enable PIOs to receive Federal funds with less oversight or fewer restrictions than nongovernmental organizations and contractors.

¹⁸ Gavi's traditional oversight process has three lines of defense: (1) Country programs, alliance partners, and implementing countries owning and mitigating risks; (2) Risk, program capacity assessment, grant performance monitoring, finance, operations, legal support, and overseeing risk; and (3) Internal audit, program audit, whistleblower facility and investigations, and counter fraud proving independent assurance.

USAID officials said that, as with other congressionally directed contributions of this type, USAID would not have direct oversight, relying instead on existing oversight mechanisms of Gavi to receive and respond to allegations of fraud, waste, and abuse for vaccine procurement and delivery efforts under COVAX.

Gavi officials, including those responsible for oversight, stated that Gavi's traditional oversight process was developed for vaccination programs that pose a low risk for fraud, including theft and diversion, whereas the COVID-19 program, which poses a high risk, may require more resources than Gavi has in place. Historically, Gavi's risk has been low as traditional vaccines are less expensive and there is more supply. Gavi stated that the fraud risk associated with COVAX is higher due to the cost and limited supply of COVID-19 vaccines. Gavi explained that since COVAX provides vaccines directly to foreign governments, Gavi has had very limited direct engagement with vaccine distribution efforts. As a result, beneficiaries and on-the-ground observers may have difficulty connecting vaccine distribution efforts to Gavi or, more specifically, to USAID. In the case of COVAX, UNICEF procures vaccines, so Gavi would not have full visibility into possible wrongdoing.

GH Bureau officials said that they used standard language in setting the condition of the \$2 billion contribution.¹⁹ However, USAID's policies do not preclude the inclusion of additional oversight clauses to the contribution. At its discretion, USAID may require the inclusion of special audit, financial, geographic, or other provisions in an agreement with a public international organization (PIO) or negotiate the terms to mitigate identified risks.²⁰

USAID policy requires that the agency conduct an Organizational Capacity Review (OCR) of a PIO before entering into an agreement with the organization.²¹ The purpose of an OCR is to conduct a high-level assessment of whether or not a PIO is organizationally capable of adequately safeguarding USAID resources. OCRs should be updated at least every 5 years but may be updated more frequently if specific circumstances warrant earlier reviews. For the current contribution to Gavi, USAID relied on an OCR conducted in June 2020 that stated that "Gavi is organizationally capable of adequately safeguarding USAID resources" and that "Gavi's past performance has been satisfactory." The scale of this vaccine distribution enterprise is beyond the norm for Gavi and its in-country vaccine distribution systems are not accustomed to handling such a high-value vaccine.

Federal Internal Control Standards state that changing conditions often prompt new risks or changes to existing risks that need to be assessed.²² Given the changing conditions that Gavi is experiencing with procuring and distributing high value vaccines, USAID management—in alignment with federal standards—may perform a risk assessment to identify, analyze, and respond to any new risks prompted by the changes. Additionally, existing risks of fraud, waste,

¹⁹ Automated Directives System (ADS) contains the organization and functions of USAID along with the policies and procedures that guide the Agency's programs and operations. ADS Chapter 308 defines a *general contribution* as a mechanism based only on an express statutory authority through which USAID provides contributions to a PIO for its overall operation and support (e.g., annual appropriations for USAID contributions to the Global Fund to Fight AIDS, Tuberculosis and Malaria; and the World Food Program).

²⁰ ADS, Chapter 308, "Agreements with Public International Organizations."

²¹ ADS, Chapter 308, Section 308.3.2.1, "Organizational Capacity Reviews."

²² Principle 9 – Identify, Analyze, and Respond to Change – 9.04 Analysis of and Response to Change.

and abuse for USAID's current \$2 billion contribution may require further assessment to determine whether the defined risk tolerances and risk responses need to be revised.

Given the increased risks associated with COVID-19 vaccines without an assessment of any changes that may be needed to provide adequate oversight, USAID may lack assurance that fraud risks are being identified and mitigated.

Conclusion

At the time of our review, USAID was working through key challenges to finalize and implement a strategy for supporting international vaccination programs, as missions worked to assist host countries based on relative capacity due in part to the size and scope of traditional assistance programs. As Gavi has recognized that the increased risk for fraud, waste, and abuse in COVAX vaccination programs may not be adequately supported by its existing oversight structure, USAID has an opportunity to determine actions the Agency can take to support enhanced oversight to mitigate risk for the past U.S. contribution to Gavi and to proactively preserve the integrity of future U.S. contributions in support of international vaccination programs.

Recommendations

We are making two recommendations to the Bureau for Global Health:

1. Determine whether steps can be taken to mitigate risks associated with the ongoing contribution to Gavi for COVID-19 vaccination efforts.
2. Determine whether future contributions to Gavi for COVID-19 vaccines should include additional oversight clauses to mitigate the higher risk for fraud, waste, and abuse.

OIG Response to Agency Comments

We provided our draft report to USAID on July 13, 2021. On August 20, 2021, we received the Agency's response, which is included as Appendix A of this report. The draft report included two recommendations. The Agency agreed with both recommendations. OIG considers one recommendation resolved but open pending additional supporting documentation (recommendation 1) and one recommendation closed (recommendation 2). While we closed recommendation 2, we encourage USAID to ensure future contributions include oversight clauses to mitigate risks of fraud, waste, and abuse.

Appendix A. Agency Comments



MEMORANDUM

TO: Director, Inspections, Evaluations, and Special Projects Division, Alan MacMullin

FROM: Acting Assistant Administrator, Jennifer Adams, USAID, Bureau for Global Health

DATE: August 20, 2021

SUBJECT: Management Comments to Respond to the Draft Evaluation Report Produced by the Office of Inspector General (OIG) titled, *U.S. COVID-19 Vaccine Contributions: USAID Should Consider Enhancing Oversight to Mitigate Risk of Fraud, Waste, and Abuse* (E-000-21-002-M)

The U.S. Agency for International Development (USAID) would like to thank the Office of Inspector General (OIG) for the opportunity to provide comments on the subject draft report. The Agency agrees with the recommendations, herein provides plans for implementing them, and reports on significant progress already made.

The International Health Regulations (2005) (IHRs) define a Public Health Emergency of International Concern (PHEIC) as “*an extraordinary event which is determined... to constitute a public health risk to other States through the international spread of disease; and to potentially require a coordinated international response.*” The Director-General of the World Health Organization (WHO) has declared six PHEICs since the IHRs entered into force on June 15, 2007: H1N1 Influenza, in 2009; Poliomyelitis, in 2014; Ebola, in 2014; Zika Virus, in 2016; Ebola in the Democratic Republic of Congo in 2018-2020; and COVID-19 in 2020. On January 30, 2020, WHO convened an Emergency Committee under the IHRs and declared the outbreak of COVID-19 a PHEIC. On March 11, 2020, the Director-General of WHO declared the outbreak a global pandemic. Despite vaccines and public health measures, the incidence of COVID-19 cases globally and deaths began accelerating once again in mid-February 2021. As of August 2, 2021, there are 198,234,951 confirmed cases, and 4,227,359 confirmed deaths globally. As of July 29, 2021, a total of 3,839,616,037 vaccine doses have been administered.

The Biden-Harris Administration's National Strategy for the COVID-19 Response and Pandemic Preparedness states that "*U.S. international engagement to combat COVID-19, promote health, and advance global health security is urgent to save lives, promote economic recovery, and develop resilience against future biological catastrophes.*" The Biden-Harris Administration is restoring America's role in leading the world through global crises, advancing global health security and the Global Health Security Agenda, including by supporting the international pandemic response effort, providing humanitarian relief and global health assistance, and building resilience for future epidemics and pandemics. The President has issued a National Security Directive that directs steps to restore U.S. leadership globally and build better preparedness. To support these efforts, USAID has contributed \$4 billion to Gavi, the Vaccine Alliance (Gavi), to support the purchase and delivery of COVID-19 vaccines to 92 low- and middle-income countries. The contribution to Gavi will support COVAX²³ to support equitable access to COVID-19 vaccines for the world's most vulnerable and at-risk populations, including frontline health care workers.

As the world prepares for an unprecedented global rollout of COVID-19 vaccines, governments, donors, and other key stakeholders anticipate challenges in the supply and distribution of COVID-19 vaccines. The programmatic challenges the world is facing in the planning for the rollout and introduction of COVID-19 vaccines include, but are not limited to, human resource constraints, supply chain and logistics challenges, gaps in existing systems to adequately monitor and evaluate adverse events following immunization, and on-going issues of vaccine hesitancy. USAID will strive to address these challenges by prioritizing the following areas of assistance: policy, planning, and coordination; pharmacovigilance and monitoring adverse events following immunization and adverse events of special interest; supply chain and logistics; service delivery; human resources for health, including training and supervision; communications and advocacy; community engagement and demand generation; and monitoring, evaluation and health information systems.

USAID agrees with the underlying premise of the OIG's evaluation that the Agency should consider additional oversight steps to mitigate risks associated with the ongoing COVID-19 vaccine efforts. The Agency has learned an extraordinary amount as a result of the unprecedented, multisectoral battle to contain COVID-19 and is committed to strengthening the aspects of mitigating risks highlighted by the OIG, particularly with respect to our support to improving the supply and delivery of COVID-19 vaccines and our partnership with COVAX. The following are USAID's responses to the OIG's recommendations.

²³ COVID-19 Vaccines Global Access, abbreviated as COVAX, is a global initiative aimed at equitable access to COVID-19 vaccines directed by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations, and the World Health Organization.

COMMENTS BY THE U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT (USAID) ON THE REPORT RELEASED BY THE USAID OFFICE OF THE INSPECTOR GENERAL (OIG) TITLED, *U.S. COVID-19 Vaccine Contributions: USAID Should Consider Enhancing Oversight to Mitigate Risk of Fraud, Waste, and Abuse* (E-000-21-002-M)

Please find below the management comments from the U.S. Agency for International Development (USAID) on the draft report produced by the Office of the USAID Inspector General (OIG), which contains two recommendations for USAID:

Recommendation 1: Determine whether steps can be taken to mitigate risks associated with the ongoing contribution to Gavi for COVID-19 vaccination efforts.

- **Management Comments:** USAID concurs with Recommendation 1, and has taken the following steps to address the issue. USAID has engaged in conversations with Gavi and other donors to the COVAX Facility regarding strengthening Gavi’s oversight processes related to COVID-19 vaccination efforts. Based on those discussions, USAID understands that COVAX is currently considering the implementation of additional risk mitigation strategies including, but not limited to: the potential use of monitoring agents in select countries; using civil society organizations to monitor COVAX implementation, including supply chain risks; strengthen systems to track and trace vaccines throughout the supply chains; and purchasing insurance to cover the costs of vaccines shipped to the 92 COVAX AMC countries.

USAID also participates in the Gavi Audit and Finance Committee, which supports the Gavi Board’s oversight of financial management, risk, audit, and compliance with best practices and norms. In this capacity USAID will monitor the implementation of the best practices and mitigation strategies. Additionally, through the Gavi Board, USAID plays a role in the governance and oversight of COVAX’s performance.

- **Target Completion Date:** USAID recommends closure of this recommendation upon issuance of the final evaluation report.

Recommendation 2: Determine whether future contributions to Gavi for COVID-19 vaccines should include additional oversight clauses to mitigate the higher risk for fraud, waste, and abuse.

- **Management Comments:** USAID concurs with Recommendation 2, and the Agency has taken the following steps to address the issue. As noted by the OIG in the draft report, for Congressionally-directed general contributions such as USAID’s contribution to Gavi for vaccine procurement and delivery, USAID’s standard practice would be to rely on the public international organization’s existing oversight mechanisms to receive and respond to allegations of fraud, waste, and abuse. Although USAID’s standard general contribution agreement template does not contain any provisions regarding fraud, waste, and abuse, USAID proactively included the additional clauses regarding “Financial

Management and Reporting; Fraud, Corruption, and Financial Mismanagement” as well as “Progress Reporting; Review or Evaluation of Activities” in the USAID contribution agreement to Gavi for COVID-19 vaccine procurement and delivery. Although there are no additional planned USAID contributions to Gavi for COVID-19 vaccine procurement and delivery at this time, USAID would continue including similar clauses in any such future contribution agreements.

Furthermore, as USAID continues to serve on the Gavi Board, USAID is participating in discussions with Gavi and other donors regarding mitigation measures being considered by COVAX. USAID will consider adding new language based on those discussions in any future contribution agreements with Gavi for COVID-19 vaccine procurement and delivery that may pose a heightened level of risk for fraud, waste, and abuse.

- **Target Completion Date:** USAID recommends closure of this recommendation upon issuance of the final evaluation report.

In view of the above, we request that the OIG inform USAID whether it agrees or disagrees with the management comments.

COMMENTS BY THE U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT (USAID) ON THE REPORT RELEASED BY THE USAID OFFICE OF THE INSPECTOR GENERAL (OIG) TITLED, *U.S. COVID-19 Vaccine Contributions: USAID Should Consider Enhancing Oversight to Mitigate Risk of Fraud, Waste, and Abuse* (E-000-21-002-M)

Recommendation 1: Determine whether steps can be taken to mitigate risks associated with the ongoing contribution to Gavi for COVID-19 vaccination efforts.

Documentation: USAID concurs with Recommendation 1, and the Agency is providing the following documentation to close this USAID recommendation upon issuance of the final evaluation report. The Gavi Alliance Board Meeting report from 24-25 June 2020, notes that a USAID employee has been appointed to the Gavi Audit and Finance Committee. (see attachment) In this capacity USAID will monitor the implementation of the best practices and mitigation strategies. Additionally, through the Gavi Board, USAID plays a role in the governance and oversight of COVAX's performance.

In addition, the following Gavi documents that address risk policy:
<https://www.gavi.org/sites/default/files/document/risk-policy.pdf>

Recommendation 2: Determine whether future contributions to Gavi for COVID-19 vaccines should include additional oversight clauses to mitigate the higher risk for fraud, waste, and abuse.

Documentation: USAID concurs with Recommendation 2, and the Agency is providing the following documentation to close this USAID recommendation upon issuance of the final evaluation report.

The March 5, 2020 Contribution to the Gavi Alliance for the COVAX Facility Advanced Market Commitment (Gavi COVAX AMC) (7200GH21IO00002) demonstrates how the Agency included additional oversight clauses to mitigate the higher risk for fraud, waste, and abuse. (See attachment) As noted above, a USAID employee has been appointed to the Gavi Audit and Finance Committee. In this capacity USAID will monitor the implementation of the best practices and mitigation strategies. Additionally, through the Gavi Board, USAID plays a role in the governance and oversight of COVAX's performance.



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