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USAID Had Limited Control Over COVID-19 Ventilator Donations, Differing From Its Customary Response to Public Health Emergencies

AUDIT REPORT 4-936-21-002-P
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MEMORANDUM

DATE: February 24, 2021

TO: USAID, Bureau for Global Health, Deputy Assistant Administrator, Carol Chan

FROM: Africa Regional Office, Director, Robert Mason /s/

SUBJECT: USAID Had Limited Control Over COVID-19 Ventilator Donations, Differing From Its Customary Response to Public Health Emergencies (4-936-21-002-P)

This memorandum transmits the final report on our audit of the role of ventilators in USAID's response to COVID-19. Our audit objectives were to (1) describe USAID's plans to respond to the COVID-19 public health emergency and (2) determine the extent to which the practices employed to determine the use and allocation of ventilators during the COVID-19 pandemic differed from USAID's customary practices for responding to public health emergencies. In finalizing the report, we considered your comments on the draft and included them in their entirety, excluding attachments, in appendix D. We are not making any recommendations.

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

CONTENTS

INTRODUCTION

The emergence of the novel coronavirus SARS-CoV-2 (COVID-19) in Wuhan, China, created the greatest public health crisis the world has faced in over a century. On January 30, 2020, the World Health Organization (WHO) declared COVID-19 a Public Health Emergency of International Concern, and later declared COVID-19 as a pandemic on March 11, 2020. With cases being reported in 223 countries, territories, and areas as of February 2021, there have been 107 million cases and 2.3 million deaths reported worldwide, according to WHO.

As the lead U.S. agency for international development and humanitarian assistance, USAID has played a key role in the United States' international efforts to prevent and respond to the COVID-19 pandemic and mitigate its profound public health, economic, social, and development effects. One of USAID's main interventions in the fight against COVID-19 has been the provision of ventilators to over 40 countries at an obligated amount of approximately $204 million.

The ventilator donation program has been one of the most publicized and controversial aspects of USAID's COVID-19 response, attracting both media and congressional scrutiny. Multiple embassy and USAID press releases and social media announced the delivery of ventilators to recipient countries. The media has questioned the decisions surrounding which countries received ventilators. Some in Congress have also questioned how decisions regarding the use and level of funds for ventilators, and which countries would receive them, were made, as well as how the involvement of other U.S. Government (USG) actors affected USAID's pandemic response.

Due to the publicity, media attention, and congressional inquiries, and because ventilators constituted a significant portion of USAID's COVID-19 response to date, we sought to provide a review of the way decisions were made for the provision of ventilators. Specifically, our audit objectives were to (1) describe USAID's plans to respond to the COVID-19 public health emergency and (2) determine the extent to which the practices employed to determine the use and allocation of ventilators during the COVID-19 pandemic differed from USAID's customary practices for responding to public health emergencies.

To conduct our work, we reviewed U.S. supplemental appropriation laws and USG strategies for responding to COVID-19 abroad; analyzed key USAID strategy, guidance, and policy documents related to responding to public health emergencies in general and COVID-19 specifically; interviewed USAID officials and staff with knowledge of the subject under review; and analyzed documentation from the Bureau for Global Health and the Agency's COVID-19 Task Force.

We did not review the Agency's COVID-19 response in its entirety; conduct procedures to determine the allowability of payments made for ventilators; confirm that ventilators were delivered; or verify that ventilators were being used as intended.

We conducted our work in accordance with generally accepted government auditing standards. Appendix A provides more detail on our scope and methodology.

SUMMARY

Prior to the start of the ventilator donation program in April 2020, USAID followed its customary practices in determining how it would respond to COVID-19 in accordance with the Department of State (State)-USAID joint strategy. USAID established internal coordination groups consisting of medical doctors, public health and disaster response experts, supply chain specialists, and other subject matter experts on staff to contribute to its COVID-19 response. The Agency designated the Bureau for Global Health as the technical lead office and coordinated with WHO and other Federal agencies, including the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services (HHS), the Department of Defense (DoD), and State. USAID relied on WHO guidance, interagency input, and lessons learned from prior health crises to assess needs and allocate resources. The Agency proposed countries to prioritize for key interventions it determined would have the greatest impact in alleviating the burden of COVID-19 while strengthening health systems and promoting global health security.

The ventilator donation program significantly differed from USAID's customary practices for responding to public health emergencies. Specifically, the decisions for donating ventilators abroad—including National Security Council (NSC) decisions for determining recipient countries, how many ventilators to send, and which suppliers and models to use—did not align with the Agency's initial COVID-19 response planning. The joint State-USAID strategy did not specifically mention ventilators and stated that COVID-19 interventions should have the potential for broad impact. According to WHO, only the sickest patients—the 5 percent designated as critically ill—may possibly need assisted ventilation. Overall, the recipient countries and number of ventilators donated through the program indicated that USAID's early analysis was not the primary means used by the NSC to make such decisions. For example, most of the countries that USAID had proposed to support in response to COVID-19 were categorized as low- or lower-middle income by the World Bank, but well over half of all ventilator donations were made to upper-middle- or high-income countries, as directed by the NSC. The Agency obligated approximately $204 million implementing the ventilator donation program—leaving less funds available to support the preventative measures that were the cornerstone of USAID's COVID-19 response planning. In addition, USAID waived routine congressional notification requirements and used some non-health funds to expedite funding for ventilators.

We are making no recommendations because the ventilator donation program has been completed and there are no current plans to donate more ventilators abroad.

BACKGROUND

USAID's Customary Approach in Responding to Public Health Emergencies

USAID plays an essential role in the USG effort to protect Americans by combating emerging threats to public health. The Agency's primary focus in this effort is to "limit the potential for the emergence of a pandemic by containing new diseases … minimizing the number of human cases, and ensuring adequate and appropriate response to a pandemic should it occur."[1]

USAID's activities to assess need and identify appropriate interventions are key in shaping how it responds to public health emergencies. When faced with a public health emergency, USAID's customary approach is to conduct an assessment to determine countries' needs and then tailor an appropriate response given available resources. Although each public health emergency poses unique challenges, USAID can draw upon a collection of resources to guide its efforts:

- *International guidance.* Internationally, WHO determines whether an event should be categorized as a Public Health Emergency of International Concern and recommends measures to prevent or reduce the spread of the disease. The Global Health Security Agenda—launched in 2014 by nearly 30 countries and international organizations, including the United States—complements WHO by facilitating the sharing of best practices and lessons learned among global partners.
- *Agency protocols.* In 2019, USAID issued guidance for responding to infectious disease outbreaks under four different scenarios, identifying technical lead offices and assigning roles and responsibilities.[2] In scenario B, for example, when the Agency responds to a WHO-declared Public Health Emergency of International Concern that does not constitute a humanitarian response, the Bureau for Global Health serves as the Agency's technical lead. In this role, the bureau sets up a technical working group, liaises directly with WHO and USAID's headquarters and regional offices, and is responsible for continuously monitoring the situation. Conversely, in scenario C, in which the outbreak has the potential for humanitarian consequences, the Bureau for Humanitarian Assistance serves as lead.
- *Institutional knowledge.* The Agency has employees across its functional and regional bureaus with backgrounds and expertise in the medical field, including practitioners and specialists in infectious diseases, public health, disaster response, public health emergencies, and supply chain logistics. Their collective experience in responding to emergencies in developing countries contributes to an extensive knowledge base from which the Agency can draw. USAID's internal technical expertise also benefits

[1] USAID, "Pandemic Influenza and Other Emerging Threats," ADS chapter 201 mandatory reference (201mau), "Guidance on the Definition and Use of the Global Health Programs Account," December 2014.

[2] USAID Agency Notice, "USAID Infectious Disease Outbreak Scenarios A-D," "USAID Response to Infectious Disease Outbreaks," October 2019.

from data collected from missions, which is used to inform needs-based, bottom-up decisions and capture good practices to inform its work. USAID has responded to past public health emergencies, such as the 2009 H1N1 influenza pandemic, the 2014 West Africa Ebola virus outbreak, and the 2015 Zika virus epidemic.[3] To develop lessons learned for future use, USAID conducted reviews and developed after-action reports from prior disease outbreaks, such as Ebola and Zika, and referred to audits conducted by OIG, the U.S. Government Accountability Office (GAO), and other sources.

- *Interagency coordination.* During public health emergencies, USAID typically coordinates with other Federal agencies, such as State, CDC, and DoD, sometimes under the leadership of the NSC, in a whole-of-Government effort. At the national level, USAID contributed to the development of a guide, commonly referred to as the NSC pandemic playbook, after the 2014 West Africa Ebola outbreak. The playbook aimed to standardize USG coordination in response to emerging infectious diseases, even to the magnitude of pandemics such as COVID-19, by specifying the responsibilities of each agency playing a major role. It was "meant to identify key questions, USG interagency partners, and decisions to guide possible response measures" for how the USG assists countries without the capacity to properly respond, setting the foundation for analytic work and decisions based on disease epidemiology. The playbook states that the NSC will coordinate and leverage the expertise within USG agencies to respond to an emergency. The playbook was not intended to replace national or pre-existing USG response structures, but rather to serve as a guide based on existing authorities, guidance, and response frameworks for those monitoring and responding to the outbreak. According to both the NSC pandemic playbook and USAID staff that we interviewed, the NSC typically serves as a coordinating body, utilizing the technical capacities and comparative advantages of various agencies for different aspects of the USG response.

The State-USAID Strategy To Respond to COVID-19

To support USG efforts to stem the further transmission and re-emergence of COVID-19, in March 2020 the U.S. Congress passed, and President Donald J. Trump signed, two bills that contained funding for USAID programming related to COVID-19: the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Public Law 116-123) of March 6, 2020, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Public Law 116-136) of March 27, 2020. The two bills appropriated approximately $1.93 billion to State and USAID via distinct funding accounts. As required by Public Law 116-123, USAID and State jointly released the "Strategy for Supplemental Funding to Prevent, Prepare for, and Respond to Coronavirus Abroad." This strategy served as the primary document to guide USG efforts and use of supplemental funding to prevent, prepare for, and respond to the COVID-19 pandemic

[3] While USAID responded to these public health emergencies prior to the release of the "USAID Response to Infectious Disease Outbreaks" guidance, each of these emergencies would have triggered one of the four scenarios for responding to infectious disease outbreaks under the current guidance.

abroad. It outlined four pillars of response, with USAID playing a role in Pillars 2, 3, and 4 (figure 1).

Figure 1. USAID and State COVID-19 Response Strategy Framework

	Goal: To accelerate the U.S. Government's global effort to stem the further transmission and re-emergence of COVID-19 and to mitigate the impact			
Objective	**PILLAR 1** Protect American citizens and the USG community overseas, and facilitate the continued work of the USG overseas, and communicate effectively	**PILLAR 2** Prevent, prepare for, respond to, and bolster health systems to address COVID-19 and re-emergence	**PILLAR 3** Prevent, prepare for, and respond to COVID-19 in existing complex emergency responses and address potential humanitarian consequences of the pandemic	**PILLAR 4** Prepare for, mitigate, and address second-order economic, civilian security, stabilization, and governance impacts of COVID-19, in part to prevent development backsliding
Agencies	State	USAID and State	USAID	USAID and State
New Funding	Operational Funds	Emergency Reserve Fund (ERF); Global Health Programs (GHP)	International Disaster Assistance	Economic Support Fund (ESF)
	$264M	$200M; $235M	$300M	$250M

Source: State-USAID, "Strategy for Supplemental Funding to Prevent, Prepare for, and Respond to Coronavirus Abroad."

Note: The funding amounts in this figure reflect only appropriations under Public Law 116-123. Public Law 116-136 appropriated an additional $258 million in International Disaster Assistance funds, and $95 million in operational expenses for USAID and $324 million in operational expenses for State.

To support the ventilator donation program, the Agency obligated funds available under Pillar 2 to include both the GHP and ERF accounts, totaling $435 million in appropriated funds. The program was also partially supported by the ESF account under Pillar 4. While activities funded under Pillar 2 with GHP and ERF funds would focus on responding to, preventing, and reducing the burden of disease abroad, activities funded under Pillar 4 with ESF funds would "have a longer time horizon" to address second-order economic, civilian security, stabilization, and governance impacts that arise from the pandemic.

Given the worldwide impact of COVID-19, as opposed to localized outbreaks such as Zika and Ebola, the State-USAID strategy stated that GHP funds under Pillar 2 would be used to prioritize interventions with the greatest "potential for broad impact" and that countries would be prioritized based on seven key factors (see figure 2).

Also, under Pillar 2, the strategy emphasized three areas of focus: emergency health response, strengthening health security in affected countries, and supporting health institutions. The strategy noted eight critical areas in which the United States would address gaps in affected and at-risk countries through its emergency health response (see figure 2).[4] In USAID's notifications to Congress about the Agency's planned use of COVID-19 funding, USAID listed 23 interventions that aligned to these eight critical areas.[5]

Figure 2. Key Elements of USAID's Plans To Respond to COVID-19 Under Pillar 2

Key Factors for Prioritizing Countries

1. Confirmed caseload of COVID-19
2. Connectivity to a COVID-19 hotspot
3. Vulnerability
4. Particularly weak or fragile health systems
5. Ability to leverage existing health institutions
6. Diplomatic considerations
7. Political will of host-country government

Critical Response Areas

1. Strengthening laboratory diagnostics
2. Promoting risk communications and community engagement
3. Preventing and controlling infections in health facilities
4. Supporting surveillance, rapid response, and emergency operations
5. Bolstering capacities at ports of entry
6. Improving COVID-19 case management
7. Planning for the availability and delivery of future vaccines and treatments
8. Accelerating innovative and market-based approaches

Source: State-USAID "Strategy for Supplemental Funding to Prevent, Prepare for, and Respond to Coronavirus Abroad."

State and USAID also provided guidance outlining the process the agencies would use for programming, approving, and reporting on the $1.93 billion of supplemental funding Congress appropriated to State and USAID for their COVID-19 response. The guidance specified the funding approval process and stated that after internal reviews within USAID, State and USAID leadership would decide the use and allocation of supplemental funds.

Ventilator Donation Program

COVID-19 is the disease caused by the new coronavirus SARS-CoV-2. Coronaviruses are a family of viruses which can have a range of symptoms, from mild like the common cold, to more severe, similar to severe acute respiratory syndrome (SARS). According to WHO, the most common symptoms are fever, dry cough, and fatigue, while the most severe symptoms include confusion, shortness of breath, and chest pain. While the

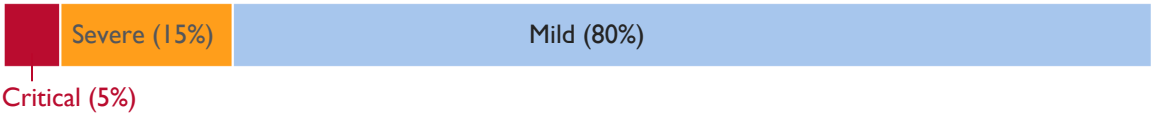
[4] These eight critical areas are reflected in the WHO guidance, "Strategic Preparedness and Response Plan," February 2020, and "Operational Planning Guidelines to Support Country Preparedness and Response," February 2020.

[5] See appendix C for a list of the 23 interventions.

majority of those infected with the COVID-19 virus recover without hospitalization, roughly 20 percent of patients are hospitalized. The illness severity among COVID-19 patients falls into three categories (see figure 3).

Figure 3. Categories and Percentages of Illness Severity in COVID-19 Patients

Category	Outcome	Percentage of Patients
Mild	Recover without requiring hospitalization	80%
Severe	Require oxygen support	15%
Critical	Require intensive care and possibly assisted ventilation	5%



Source: Data published by WHO and CDC, cited in USAID's submitted congressional notifications.

Current clinical management for COVID-19 includes infection prevention and supportive care. According to WHO and CDC, COVID-19 prevention measures include washing hands, wearing a mask, social distancing, and self-isolating if experiencing symptoms. Due to the respiratory impact of the disease, supportive care includes supplemental oxygen and mechanical ventilation support when indicated. Supplemental oxygen is oxygen therapy or treatment that provides extra oxygen typically delivered through nasal prongs or a face mask. Ventilators are highly technical machines that support patients who are experiencing extreme respiratory distress. According to WHO, ventilators provide temporary respiratory assistance to patients who cannot breathe on their own due to illness, trauma, or other reasons. Ventilators should only be used by physicians or other trained medical staff.

According to WHO, optimal supportive care for severely ill patients includes oxygen. For critically ill patients at risk for severe disease, optimal supportive care includes more advanced respiratory support such as ventilation. Early in the pandemic as countries around the world tried to mitigate the impact of COVID-19—both in preventing its spread and managing reported cases—the demand for ventilators to treat the critically ill surged.

As a result, and soon after declaring a national emergency, on April 2, 2020, President Trump invoked the Defense Production Act to meet the demand for ventilators to treat COVID-19 patients in the United States. Under the act, USG ordered almost 200,000 ventilators from 10 different suppliers for the Strategic National Stockpile under contracts administered by HHS.[6] Decisions surrounding ventilators generated controversy among some members of Congress. For example, in separate letters to the USAID Acting Administrator and President Trump, the ranking member of the Senate Foreign Relations Committee at the time, Senator Robert Menendez, expressed

[6] The Strategic National Stockpile is the nation's largest reservoir of supplies for use in public health emergencies when state and local supplies run out. The supplies, medicines, and devices in the stockpile can be used as a buffer when the immediate supply of these materials may not be available.

concerns about the decision-making process and the absence of clear guidelines for providing ventilators to foreign countries.

On April 19, 2020, President Trump announced that the United States would provide ventilators to other countries as part of the USG's international response to COVID-19. Some ventilators initially slated to be manufactured and delivered to the Strategic National Stockpile were instead sent to foreign countries for emergency diplomatic purposes using an "excusable delay" by HHS, which allowed for the delayed delivery of ventilators to the stockpile for diplomatic or emergency reasons. Foreign countries could either directly purchase or receive a donation of ventilators facilitated by USAID. Three suppliers—Medtronic, Vyaire, and Zoll—manufactured the ventilators for the donation program.

The NSC and two Federal agencies each had a role in the ventilator donation program (see figure 4). These agencies coordinated with the governments of recipient countries to carry out their respective roles.

Figure 4. Federal Entities With Key Roles in the Ventilator Donation Program

NSC	HHS	USAID
Determine the recipient country and number of ventilators and communicate HHS's matching results to USAID	Match recipient country to ventilator supplier	Facilitate procurement and logistics

Source: OIG analysis of USAID documentation.

Upon notification that a country would receive a ventilator donation, USAID worked with recipient governments on determining the necessary technical specifications to properly customize the devices according to country norms and configurations.[7] Since these machines were new to some recipient countries, USAID tried to obtain regulatory approval in the host country for the ventilators. If approval was not obtained, the Agency instead secured a waiver for registration, which required approval from the ministries of health.

USAID also undertook actions beyond the NSC's direction in order to promote the long-term beneficial aspects of the ventilator donation program. USAID conducted oxygen ecosystem surveys to support ventilator-planning efforts, critical care facility assessments to determine future resources needed to support ventilator use and identify needs for technical assistance, and provided "wraparound" support to accompany ventilator donations. This support included consumables such as oxygen hoses and monitors, a 1-year service agreement, and technical assistance. USAID ultimately delivered 8,722 ventilators to 43 countries and the North Atlantic Treaty

[7] These specifications were only for color coding for oxygen tubing, language preferences for manuals and controls, electrical plug types, and import registration waivers. These specifications ensured the equipment could function properly within the unique country context and in accordance with established health systems and norms.

Organization (NATO) at an obligated amount of approximately $204 million.[8] The majority of ventilators were delivered through arrangements made by Chemonics, Inc., the Bureau for Global Health's primary implementer for supply chain and logistics of health commodities through the Global Health Supply Chain – Procurement and Supply Management project (GHSC-PSM).[9]

USAID'S INITIAL COVID-19 RESPONSE PLANNING FOLLOWED ITS CUSTOMARY PRACTICES FOR RESPONDING TO PUBLIC HEALTH EMERGENCIES WHILE FOCUSING ON PREVENTATIVE MEASURES

Prior to the start of the ventilator donation program in April 2020, USAID followed its customary practices in determining how it would respond to COVID-19 in accordance with the State-USAID strategy. USAID established internal coordination groups, designated the Bureau for Global Health as the technical lead office, coordinated with other Federal agencies, applied lessons learned, and conducted needs assessments to guide Agency response efforts.

USAID Established Internal Coordination Groups and Designated a Technical Lead Office

Shortly after WHO determined that the COVID-19 outbreak was a Public Health Emergency of International Concern on January 30, 2020, USAID initiated its protocols for responding to infectious disease outbreaks and designated the Bureau for Global Health as the technical lead for the COVID-19 response. In addition, and over the course of the response, USAID stood up multiple internal coordination groups, including the:

- Administrator's Crisis Action Team (activated in January)
- Technical Working Group (February)
- COVID-19 Task Force (March)
- Sustained Crisis Response Team (April)

These internal coordination groups consisted of subject matter experts, including medical doctors, public health and disaster response experts, and supply chain specialists on staff, to contribute to USAID's COVID-19 response. The staff we interviewed also had experience in prior public health emergencies and disaster responses.

[8] See appendix B for a full list of countries receiving ventilators through the donation program.

[9] USAID arranged with DoD to deliver ventilators to two countries—Indonesia and Russia—using U.S. military transport. While the USG may use DoD resources for public health emergencies, a State Department Disaster Declaration cable for COVID-19 stated that DoD's resources would be used "as a last resort in an international humanitarian response."

The Bureau for Global Health was designated as the technical lead for the COVID-19 response and has extensive technical expertise in combating infectious diseases, one of the bureau's three strategic priorities. For example, the bureau's Office of Health Systems provides technical leadership and direction in strengthening country health systems and its Office of Infectious Disease supports Agency efforts to combat infectious diseases by managing prevention, mitigation, and control for emerging threats in global health security. According to USAID officials, when responding to a Public Health Emergency of International Concern, the Bureau for Global Health reaches out to impacted missions; coordinates with the Bureau for Humanitarian Assistance; and looks at the disease epidemiology, strength of in-country health systems, and the supply chain for resources.

USAID Coordinated With Other Federal Agencies, Applied Lessons Learned, and Conducted Needs Assessments To Focus on Preventative Measures in High-Priority Countries

In late January 2020, USAID initiated outreach in preparation for COVID-19 response efforts to CDC, HHS, and WHO. The Agency coordinated with internal and interagency points of contact, including from DoD, CDC, HHS, State, and other Federal agencies. While the NSC pandemic playbook was designed to guide the USG response to an emerging infectious disease, according to USAID officials and media reports, it was not used to coordinate USG efforts for responding to the COVID-19 pandemic.

In early February, USAID coordinated externally and internally to conduct needs assessments to identify and fund high-priority countries. USAID coordinated initial global COVID-19 response planning with other agencies such as State and CDC to assess the needs of affected countries. Through an interagency country prioritization exercise that was also used during the West Africa Ebola outbreak, the Bureau for Global Health determined that USAID should fund 10 high-priority countries, mostly in Asia.[10] The three-stage prioritization and selection process considered three factors and leveraged the Global Health Security index and Joint External Evaluation points-of-entry scores.[11] In order to move quickly, USAID headquarters identified a list of existing central and bilateral mechanisms that COVID-19 funds could support and asked missions in each priority country to select the mechanisms that it endorsed for COVID-19 supplemental funding. Funding was obligated for these 10 countries by late February. This level of coordination with USAID missions allowed for a bottom-up approach to its COVID-19 response.

[10] The 10 countries were Bangladesh, Burma, Cambodia, Ethiopia, Indonesia, Laos, Nepal, Philippines, Thailand, and Vietnam.

[11] The Global Health Security index is "a measure of the sufficiency and robustness of the health system to treat the sick and protect health workers." The index considers health capacity in health facilities, medical countermeasures, healthcare access, and other considerations. The Joint External Evaluation is a "voluntary, collaborative, multisectoral process to assess country capacity to prevent, detect, and rapidly respond to public health risks occurring naturally or due to deliberate or accidental events. The purpose of the evaluation is to assess country-specific status and progress in achieving targets." In this case, the Agency focused on scores related to passages for international exit or entry of travelers.

As the pandemic worsened and more countries were affected, the Agency continued to conduct needs assessments and gather comprehensive data from its missions to understand countries' needs and better inform decisions on the use of COVID-19 supplemental funds. In early April, missions that were interested in COVID-19 funding were asked to identify known gaps in COVID-19 readiness in existing USAID health programs and propose their requests for funding. By the end of April, the Bureau for Global Health expanded its list and proposed an additional 38 priority countries for its COVID-19 response. Additionally, in late May, the Agency used a country planning tool to collect in-country data from many of its USAID missions. The framework for this tool included the WHO critical areas for COVID-19 response and country readiness. The objective of this exercise was to again identify priority countries, ranked using evidence-based modeling that identified countries via three lenses: burden, vulnerability, and protecting and leveraging USG investments. USAID staff described this bottom-up approach as the most data-driven response the Agency has ever used.

Relying on WHO guidance, interagency input, and lessons learned from prior health crises to assess needs and allocate resources, USAID prioritized a number of key interventions that would have the greatest impact in alleviating the burden of COVID-19 while strengthening health systems and promoting global health security.[12]

Based on our analysis of eight congressional notifications USAID submitted before the start of the ventilator donation program in April, planned COVID-19 interventions focused on preventative measures.[13] These measures included supplying personal protective equipment (PPE) and disinfectants, and supporting infection prevention, case diagnostics, and risk communication (see callout box below). Across the 8 congressional notifications that USAID submitted to Congress from February 2020 to April 2020 before the ventilator donation program began, the Agency listed 23 different interventions it would implement for its response, which generally aligned with the State-USAID strategy.[14]

Common COVID-19 Interventions in USAID's Congressional Notifications Before the Ventilator Donation Program Began

1. Purchase of key commodities (i.e., diagnostics, PPE, disinfectants)
2. Prevention and control of infections in health facilities
3. Readiness to rapidly identify, diagnose, and treat cases
4. Awareness-raising in the population through risk-communication and community engagement

[12] CDC defines global health security as the existence of strong and resilient public health systems that can prevent, detect, and respond to infectious disease threats, wherever they occur in the world.

[13] Congressional notifications are intended to provide information to congressional and intergovernmental stakeholders on agency activities. For this audit, OIG reviewed a total of 14 USAID congressional notifications, which were submitted to Congress from February 2020 through July 2020—both before and after the ventilator donation program began—and which cited 27 different COVID-19 interventions.

[14] See appendix C for a list of interventions prior to the ventilator donation program. Ventilators were first listed as an intervention in a congressional notification dated May 18, 2020.

5. Country-level readiness and response

Source: OIG analysis of USAID's submitted congressional notifications from February 2020 to April 2020.

In USAID's response letter to Senator Menendez regarding its "science-based public health actions and interventions to bend the curve of COVID-19 infections," USAID stated that it aligned supplemental appropriations for COVID-19 with identified public health and development needs. The Agency listed the interventions it had prioritized in developing countries affected by, and at-risk of, COVID-19.[15] USAID stated that "these interventions are best practices in public health that can help slow the spread of COVID-19, care for those affected by the disease, and equip local communities with the tools needed to fight it." The Agency also stated it was "coordinating with national and global implementing partners to provide science-based subject matter expertise in the clinical management of COVID-19 patients."

THE NSC, RATHER THAN USAID, MADE KEY DECISIONS ON THE ALLOCATION OF VENTILATORS, DIFFERING FROM USAID'S CUSTOMARY PRACTICES FOR RESPONDING TO PUBLIC HEALTH EMERGENCIES

The ventilator donation program marked a departure from USAID's customary practices for responding to public health emergencies. The decisions to send ventilators, the particular models to send, and which countries to send them to, did not align with the Agency's initial COVID-19 response planning. In addition, USAID waived routine congressional notification requirements to expedite funding for some ventilators and used second-order impact funds to procure some ventilators.

The NSC Made Key Decisions About the Use of Ventilators, Selection of Countries, Suppliers and Models, and the Amount of Funding for Ventilators

The NSC, rather than USAID, made key decisions about the ventilator donation program. This included the use of ventilators, the recipient countries, the suppliers, and the particular models to send. These decisions differed from USAID's initial COVID-19 plans and shifted resources from preventative measures.

The NSC Decided To Prioritize the Use of Ventilators and Determined Which Countries Would Receive Them

The NSC directed USAID to fund ventilator donations as part of its COVID-19 response. This differed from USAID's customary approach to public health emergencies. In late April 2020, the NSC met with USAID and other Federal agencies to discuss the

[15] See items 1-10 in appendix C.

ventilator donation program. In early May, USAID told its mission directors that the administration's assessment of domestic ventilator supply and demand showed that, as production ramped up for the Strategic National Stockpile, there would be ventilators in excess of the number needed to meet immediate domestic stockpile requirements; as a result, President Trump was making ventilator commitments to heads of states. According to one USAID official, the NSC stated that the ventilator donations would serve public health and national security purposes and generate good will. According to another USAID official, the ventilator donations showcased USAID's commitment to assist other countries.

The NSC's direction put USAID in an unusual role in a portion of its own public health emergency response. USAID staff we interviewed said that while the NSC usually plays a coordinating role in USG responses, its influence during the COVID-19 response for the provision of ventilators was atypical.

In its response letter to Senator Menendez, the Agency noted that for the ventilator donation program, "USAID follows direction from the NSC" and "USAID does not determine the vendors from which we purchase ventilators, nor the countries for which we procure them." Also, in communication from headquarters to field missions about the ventilator donation program, USAID stated that "the NSC is making all decisions on USAID's provision of ventilators." Specifically, the NSC determined recipient countries and their priority, quantities of ventilators, and informed the Agency of the assigned manufacturer and ventilator model.

The provision of ventilators was not included in the joint State-USAID strategy. Oxygen was mentioned parenthetically as a possible treatment, and ventilators were not mentioned at all. The strategy stated that COVID-19 interventions using GHP funds should have the greatest "potential for broad impact." According to WHO, only the sickest COVID-19 patients—the 5 percent designated as critically ill—are admitted to intensive care and possibly need assisted ventilation. Although the strategy parenthetically referred to oxygen as one of those interventions, USAID staff we interviewed said that reference meant the range of oxygen needs and not specifically, or exclusively, ventilators.

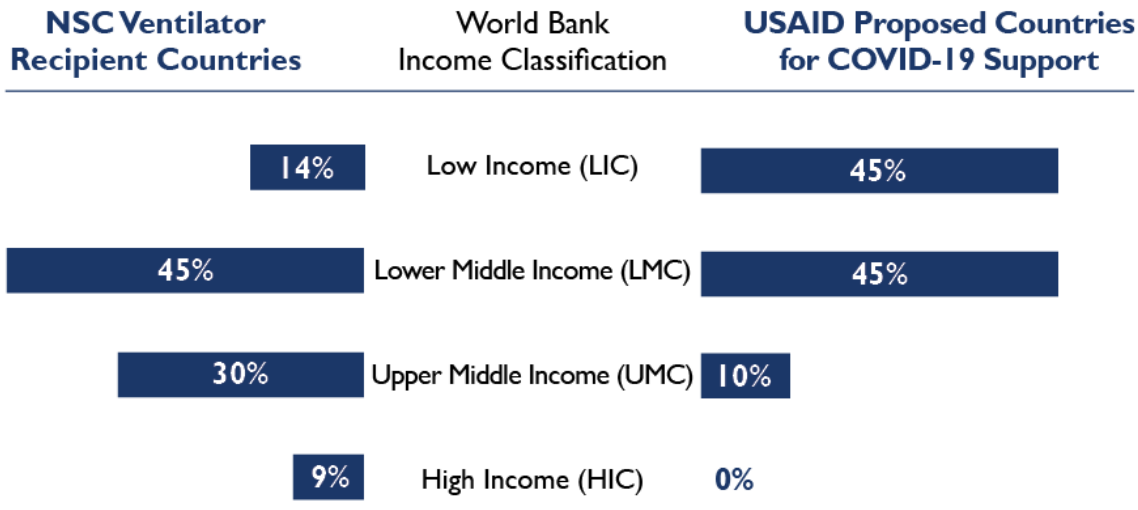
Some USAID officials stated they did not know what analysis or data the NSC used to inform decisions about ventilator donations. Several USAID officials we interviewed did not know whether the data collected from missions before the establishment of the ventilator donation program were considered by the NSC. Moreover, the Agency told us it was unable to determine whether the NSC used any of USAID's needs assessments performed as part of its initial COVID-19 response planning to inform ventilator decisions.

The NSC decided which countries would receive ventilators and how many they would get, while USAID's role was largely restricted to procurement and delivery. This process differed from the joint State-USAID strategy for use of COVID-19 supplemental funding, which stated that USAID and State would make decisions about country-level allocations in close consultation with other USG agencies, donors, the governments of

partner countries, and other stakeholders. While OIG determined that the Agency followed the State-USAID strategy to initially prioritize countries, according to USAID staff, they did not know the specific factors that influenced the NSC's selection of ventilator donation recipient countries but assumed that the countries ultimately selected by the NSC had been chosen more for political agreements and diplomatic considerations than for being most affected by COVID-19. While foreign policy considerations are not uncommon, these considerations were only one element among several in the joint State-USAID strategy.

USAID and the NSC had different priority countries that each identified as needing COVID-19 support. The NSC allocation of a proportion of ventilators to higher income countries differed from USAID's traditional approach in responding to public health emergencies. After USAID's initial COVID-19 support to the 10 high-priority, mostly Asian countries in February 2020, the Bureau for Global Health continued to collect and analyze data from the pandemic and updated its recommendations to reflect the changing circumstances of the pandemic. In April, the bureau identified an additional 38 countries it proposed providing COVID-19 support to, in line with its listed 23 interventions, and ranked 10 of those countries as being the highest priority, all in Africa.[16] Yet, of the 43 countries that received ventilators, only 12 had been included in the Bureau for Global Health's proposal.[17] As figure 5 shows, 59 percent of the countries that received ventilator donations were categorized as low- or lower-middle income by the World Bank, while 90 percent of the countries that USAID had proposed supporting fell in those two categories.

Figure 5. Distribution Comparison of Prioritized Countries by Income Classification



[16] The 10 countries were Cameroon, Côte d'Ivoire, Democratic Republic of the Congo (DRC), Ethiopia, Kenya, Mozambique, Nigeria, South Africa, Tanzania, and Uganda.

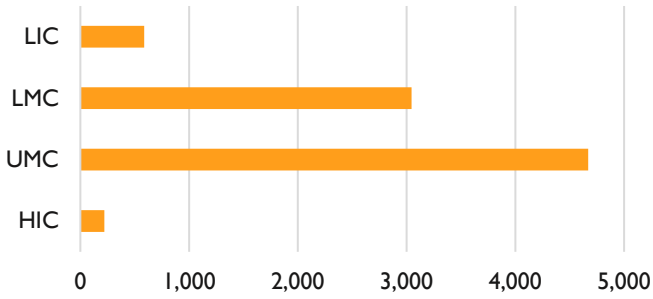
[17] The 12 countries proposed by the Bureau for Global Health that received ventilators were DRC, Ethiopia, Ghana, Guatemala, Haiti, Kenya, Mozambique, Nigeria, Papua New Guinea, Rwanda, South Africa, and Zimbabwe.

Source: OIG analysis of ventilator recipient countries and Agency-proposed COVID-19 countries' income classification.
Note: This figure does not reflect the 200 ventilators donated to NATO. NATO represents 2% of NSC ventilator recipient countries.

Furthermore, of the 8,722 donated ventilators, over half (4,890, or 56 percent) were donated to upper-middle- or high-income countries, as directed by the NSC (see figure 6).[18]

Figure 6. Number of Ventilators Donated, by Income Classification of Country

Of the donated ventilators, more than half—**56%**—were donated to upper-middle- or high-income countries.



Source: OIG analysis of ventilator recipient countries and Agency-proposed COVID-19 countries' income classification.
Note: This figure does not reflect the 200 ventilators donated to NATO.

During OIG interviews, some bureaus and USAID staff questioned the selection of certain countries to receive ventilators. Specifically:

- Some countries receiving ventilators reported a low number of COVID-19 cases.
- Some countries did not have enough intensive care unit (ICU) beds or knowledgeable staff to properly use the machines.
- Some countries where USAID does not have a physical mission presence received ventilators.

According to OIG's analysis of ventilator donation recipient countries:

- 15 countries reported having less than 1,000 cases per 1 million people, or a rate of infection less than 0.1 percent.[19]
- 9 countries received more ventilators than they had ICU beds.[20]
- 5 countries did not have a USAID mission or presence.

[18] This includes 200 ventilators donated to NATO, which does not have a World Bank income classification.
[19] According to a WHO weekly COVID-19 situational report dated December 7, 2020.
[20] ICU bed data were sourced from an HHS/National Institutes of Health (NIH) analysis titled "Critical care capacity during the COVID-19 pandemic: Global availability of intensive care beds," April 23, 2020.

Some of these decisions could create oversight challenges. Staff we interviewed raised concerns that the Agency was delivering ventilators without mechanisms in place to know where they were going or how they were being used. According to USAID staff, donating to countries where USAID does not have a presence impedes oversight.[21] In addition, the State-USAID strategy stated that all programming for COVID-19 resources would contain a monitoring component to ensure continuous assessment of programs. As mentioned above, five countries, or roughly 12 percent of recipient countries plus NATO, did not have a USAID presence, accounting for 815 donated ventilators and approximately $26.6 million.

USAID provided limited input to the NSC. Early in the program, the NSC twice formally requested input from USAID: once about 26 countries' capability to self-finance or purchase ventilators, and once to inquire whether 6 countries were allocated the appropriate number of ventilators. USAID stated it was unaware whether its responses to these requests influenced NSC decisions. USAID determined that 12 of the 26 countries that the NSC inquired about had the ability to self-finance ventilators, and USAID advised against procuring ventilators for these countries. According to OIG analysis, however, 2 of those 12 countries, Colombia and Italy, still received a ventilator donation. Regarding the six countries flagged by the NSC to advise on allocation of ventilators, USAID recommended reduced ventilator numbers for four countries, and ultimately two of those countries did not receive a donation.

The NSC Selected Which Ventilator Suppliers and Models To Use

The NSC also made decisions regarding the ventilator supplier and model that USAID was to procure and deliver to the selected country, following results of HHS's matching exercise that matched recipient country to supplier. This differed from normal circumstances during public health emergencies. According to USAID staff, when providing commodities during a rapid response, USAID typically would decide which commodities to procure—in consultation with partner countries—and would solicit bids to choose which suppliers would provide those commodities through its own procurement process. USAID's typical process for rapidly selecting vendors consisted of determining whether the vendor is qualified; submitting an open solicitation via the GHSC-PSM contract; attempting to receive at least three bids; and comparing cost, product availability, expected delivery timeframe, and other included services and maintenance. In May 2020, when USAID provided guidance to its missions for ordering COVID-19-related commodities through the Chemonics GHSC-PSM contract, the Agency explained that missions must "concentrate on allowable PPE, sanitation, and respiratory support that would have the largest impact." However, USAID did not use this guidance for the ventilator program, due to the NSC conveying the decisions on suppliers and ventilator models.

In addition, according to USAID officials, recipient countries generally did not have a say in the supplier chosen or the ventilator model received. Instead, these decisions were made through a country-to-supplier matching exercise led by HHS. Two suppliers each

[21] The Agency is currently awaiting approval of a 3-year, $800,000 contract to monitor all ventilators post-donation, except in Russia, called a traceability plan.

manufactured one ventilator model for the donations, while the third supplier manufactured two models. Countries that were matched to the third supplier could choose from the company's two ventilator models; however, one model was on back-order for a period, which limited countries matched with this supplier to the only available model.

The way in which ventilator suppliers were determined limited USAID's ability to make adjustments when it encountered challenges with performance and meeting production goals. USAID leadership expressed concerns to NSC regarding manufacturing delays, stating the Agency was having timeliness issues with one of the three suppliers, and appealed to the NSC for changes to be made to the allocation of ventilator donations across the three suppliers. The GHSC-PSM contractor, Chemonics, also expressed concern in continuing to purchase ventilators from this same supplier. Despite USAID's appeal to address these challenges, this supplier received 63 percent of the obligated funding and manufactured 58 percent of the donated ventilators, as directed by the NSC.

The NSC's Decision to Fund Ventilators Differed From USAID's Initial Focus on Preventative Measures

The NSC's decision to fund ventilators shifted the level of resources away from other COVID-19 interventions and was not in line with USAID's initial focus on preventative measures. Before the introduction of the ventilator donation program and as listed in appendix C, USAID cited 23 different interventions to respond to COVID-19, none of which included ventilators. While ventilators were not part of USAID's planned interventions, according to the Agency, the ventilators have further utility by also building resilience into the health systems of recipient countries and are already being used for purposes other than supporting COVID-19 patients. The ventilators were obligated for $204 million, which included nearly half of the $435 million in the total Pillar 2 funds available to USAID under the COVID-19 supplemental funding, leaving less funds available to support the preventative measures that remained the cornerstone of USAID's COVID-19 response planning.

USAID staff expressed concern about the level of resources allocated to ventilators. According to some Agency staff we interviewed, GHP funds focused on ventilators to the exclusion of other interventions that would have been mission-led proposals and, had USAID made decisions about COVID-19 interventions from a public health perspective, the decisions would have been different. Some USAID staff did not think the level of resources devoted to the donation of ventilators was appropriate. In addition, during OIG interviews some USAID bureaus questioned the decision to prioritize ventilators, raising several points, including:

- In-country challenges vary, and the Agency should weigh in on a broader ecosystem to determine if ventilators are the optimal intervention.
- Prevention measures, not treatment, should be the backbone of any COVID-19 response, especially given there is no cure.
- Ensuring proper use of ventilators is key.

After the 2014 Ebola outbreak in West Africa, when the NSC pandemic playbook was developed, it recognized that asking key questions about a disease, including how it can be treated, may affect the design of a response. The playbook also noted that early observations would likely be based on limited and incomplete information and would need to be continually reassessed as new information evolved. However, because USAID did not make decisions about which health interventions to provide in response to the COVID-19 pandemic with the funds used for ventilators, USAID did not have authority to modify decisions based on emerging medical evidence. For example, USAID medical professionals we interviewed noted that around the time the Agency was directed to donate ventilators, the medical opinion on the efficacy of ventilators to treat COVID-19 was being questioned. In April 2020, reports of the grim statistics of COVID-19 patients treated with ventilators started surfacing. A number of medical journals and articles suggested alternatives to invasive ventilation, including oxygen therapy and proning.[22] These less invasive alternatives have proven effective in keeping COVID-19 patients off ventilators.

USAID Waived Routine Congressional Notification Requirements and Used Some Second-Order Impact Funds to Expedite Funding for Ventilators

In a letter to President Trump dated June 24, 2020, Senator Menendez expressed concern over transparency and accountability of the ventilator donation program. Section 7015(a) of the 2020 State and Foreign Operations Appropriations Act requires that the Committees on Appropriations be notified 15 days in advance of any obligations of funds.[23] The supplemental funding for responding to COVID-19 falls under this act. Section 7015(e) provides a waiver to this provision if "failure to do so would pose a substantial risk to human health or welfare." In the letter, the Senator noted that "the administration has not provided an adequate rationale for the use of special authorities pursuant to Section 7015(e) of the State and Foreign Operations Appropriations Act to waive congressional notification requirements for providing this assistance" and requested a full justification for using the provision to waive congressional notification for ventilator assistance.

To expedite the obligation of funds in support of ventilator donations, USAID twice used its authority under section 7015(e) to obligate funds before notifying Congress. The waiver was enacted in two submitted congressional notifications. In May 2020, USAID notified Congress that $5.6 million from the Pillar 4 – ESF fund was used to purchase ventilators and related support for the Russian Federation. In June, USAID notified Congress that $24 million from the Pillar 2 – GHP fund was used to purchase ventilators and related commodities, training, and consumables for 19 countries. USAID staff with whom we spoke and who were knowledgeable about the topic said this authority was rarely used in the past and that Congress raised concerns over its use.

[22] Proning is a technique whereby the patient is placed on their stomach to improve lung capacity.

[23] The annual Department of State, Foreign Operations, and Related Programs Appropriations Act appropriates funds to the State Department, USAID, and other USG programs. Title VII (section 7000s) contains the general provisions for the appropriate funds.

Several staff said that USAID "felt pressure" by the NSC to procure and deliver the ventilators as quickly as possible. As the USAID Acting Administrator approved the Agency to use its authority pursuant to section 7015(e), OIG concluded this was one method USAID utilized to do so.

Although USAID has the authority under section 7015(e) to waive this notification requirement, it can only be used when following normal procedures "would pose substantial risk to human health or welfare." In the June 2020 congressional notification for ventilators that cited the 7015(e) waiver, USAID stated that two countries had no reported COVID-19 cases (Kiribati and Nauru), one country reported only 8 cases (Papua New Guinea), and another country reported 18 cases (Fiji). These four countries accounted for 90 ventilators and approximately $3.3 million of Pillar 2 – GHP funds. For each of these four countries, USAID cited similar justification: "observational data suggest a higher vulnerability for severe morbidity and mortality for Asians and Pacific Islanders," external analysis suggested the countries faced an uncertain future or high risk for a serious outbreak, and potential vulnerability from a 2019 measles outbreak in Polynesia. By December 2020, the case numbers for these countries had only minimally increased.[24] Additionally, Tajikistan was included in this congressional notification but rejected the offer of ventilators and requested alternative COVID-19-related support—which similarly raised questions around whether the country needed ventilators to avoid a substantial risk to human health.

The Agency used second-order impact funds to expedite some ventilators. In the congressional notification submitted in May 2020 in which USAID also used its authority under 7015(e), USAID informed Congress it used approximately $5.6 million in ESF funding to purchase and distribute 200 ventilators for Russia. Russia was one of the first countries to receive donated ventilators, shipped via U.S. military transport, and USAID has not had a presence there since 2012. While the Coronavirus Preparedness and Response Supplement Appropriations Act provided a broad purpose for ESF resources, the State-USAID strategy, developed as required by the act, specified that ESF resources were intended for Pillar 4 activities to mitigate second-order impacts of the pandemic by supporting economic, security, and governance initiatives, and intended to have a longer time horizon. [25]

Waiver justifications were not in line with the joint strategy for use of some supplemental funds. In the congressional notification submitted in May 2020, USAID noted it was responding to requests from national governments to support the highest level care, as governments were currently underprepared to save the lives of their

[24] By December 2020, Nauru and Kiribati still had no reported cases. Also, Fiji had 44 reported cases, and Papua New Guinea had 671 reported cases, representing 0.0049 percent and 0.0075 percent cases per 1 million people, respectively.

[25] The USAID-State strategy identified seven key factors to prioritize countries for ESF resources: economic reliance on affected sectors; level of need to prepare and prevent or mitigate negative second-order impacts; impact on U.S. strategic priorities; state fragility; high population density; proximity and/or significant transportation to countries with large outbreaks of COVID-19; and commitment by governments and societies to self-reliance and willingness to share the burden of responding to the pandemic.

COVID-19 patients. The congressional notification stated that Russia reported 11,600 cases in a single day and the country had more than 221,000 total cases, the second-highest number in the world at the time. USAID found this warranted an urgent need for assistance to address the pandemic in Russia. However, in reviewing the State-USAID strategy, the ESF account for COVID-19 supplemental funds was not meant to be used to implement immediate, critical life-saving measures. Furthermore, USAID provided limited information in the congressional notification as to why ESF resources were used. While the strategy was developed to provide operational flexibility, it was specific about how the funds were to be used for various purposes across the pillars. According to the Agency, one reason USAID used ESF funds was because it could obligate them faster.

CONCLUSION

As the lead U.S. agency for international development and humanitarian assistance, USAID has guidance and robust institutional knowledge and expertise in place to help the Agency respond to public health emergencies. While USAID initially drew on these resources to develop data-driven plans and proposals for responding to the unique global nature of the COVID-19 pandemic, and followed the State-USAID strategy, the USG's foreign response that focused on the ventilator donation program was primarily shaped by decisions made by other Federal agencies, as directed by the NSC. We are making no recommendations, because the ventilator donation program has been completed and there are no current plans to donate more ventilators abroad. The intent of this report was to provide insights on the decision-making and coordination roles played by USAID and the NSC. This information can be considered as the new administration and the newly appointed USAID Administrator, who will also be a formal member of the NSC, determine what health interventions will figure into the Agency's COVID-19 response and future global health emergencies going forward.

OIG RESPONSE TO AGENCY COMMENTS

We provided our draft report to USAID on January 30, 2021, and on February 5, 2021, received its response, which is included as appendix D. USAID also included technical comments with its response, which we considered and incorporated into the final report as appropriate.

APPENDIX A. SCOPE AND METHODOLOGY

We conducted our work from August 2020 through January 2021 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Our audit objectives were to (1) describe USAID's plans to respond to the COVID-19 public health emergency and (2) determine the extent to which the practices employed to determine the use and allocation of ventilators during the COVID-19 pandemic differed from USAID's customary practices for responding to public health emergencies.

The audit scope was limited to USAID's customary practices for responding to public health emergencies, the Bureau for Global Health's plans for responding to COVID-19 as USAID's designated lead office for Agency response efforts, and USAID's provision of ventilators to foreign countries as part of the Agency's response to COVID-19. Our audit period was January 30, 2020, to December 15, 2020 (the date the World Health Organization declared the COVID-19 outbreak a Public Health Emergency of International Concern to the date the last recipient country received its ventilator donation). Included in our review of the role of ventilators in USAID's COVID-19 response were the COVID-19 Task Force and the Bureau for Global Health, both based at USAID headquarters in Washington, DC.

We requested and received from USAID (1) policies and procedures for responding to public health emergencies; (2) plans and assessments for addressing COVID-19; and (3) a list of all ventilator donation recipient countries, the number of ventilators donated for each country, the suppliers that manufactured the ventilators, and the ventilator models. USAID procured and delivered donated ventilators to 44 entities (43 countries and NATO) between May 2020 and December 2020.

To support USG efforts to stem the further transmission and re-emergence of COVID-19, in March 2020, the U.S. Congress passed, and President Trump signed, two bills that contained funding for USAID programming related to COVID-19: the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Public Law 116-123) of March 6, 2020, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Public Law 116-136) of March 27, 2020. The two bills appropriated approximately $1.93 billion to State and USAID via distinct funding accounts (see figure 7).

Figure 7. Congressional Funds Appropriated to State and USAID for COVID-19

Fund Account	P.L. 116-123	P.L. 116-136	Total
State Operational Expenses	$264M	$324M	$588M
Emergency Reserve Fund (ERF)	$200		$200
Global Health Programs (GHP)	$235		$235

Fund Account	P.L. 116-123	P.L. 116-136	Total
International Disaster Assistance (IDA)	$300	$258	$558
Economic Support Fund (ESF)	$250		$250
USAID Operational Expenses		$95	$95
Total			**$1.93 billion**

Note: This table does not reflect additional appropriations including $350 million in Migration and Refugee Assistance funds.

Source: OIG analysis of USAID's COVID-19 supplemental funding.

To support the ventilator donation program, the Agency obligated funds available from the GHP, ERF, and ESF accounts.[26] According to the Agency, it obligated approximately $204 million to procure and deliver ventilators and provide complementary support to include related consumables, service agreements, and technical assistance. Of the funding used for the ventilator donation program, most ($186.4 million, or 91 percent) was obligated from GHP and ERF funds, and $17.4 million (9 percent) was obligated from ESF funds.

To address the audit objectives, we reviewed publicly available information on USG's ventilator donations, including relevant congressional notifications and letters about USAID's response to COVID-19, media articles, social media announcements, and USAID and U.S. embassy press releases about USAID's donated ventilators. We reviewed guidance from WHO and the Global Health Security Agenda addressing COVID-19 in affected countries. We identified, reviewed, and analyzed U.S. supplemental appropriation laws and key USG strategies for responding to COVID-19 abroad. We analyzed key USAID documentation for responding to public health emergencies in general, such as USAID's "Response to Infectious Disease Outbreaks" and other relevant documentation received from the Bureau for Global Health and the Agency's COVID-19 Task Force. We also reviewed relevant past reports from USAID OIG. We interviewed USAID officials and staff with knowledge of the subject matter under review from the Bureau for Global Health and USAID's COVID-19 Task Force to obtain an understanding of USAID's customary practices during public health emergencies, plans and activities to address COVID-19, and the ventilator donation program.

We did not select a sample and focused our review on decisions made and activities performed at USAID's headquarters in Washington, DC. We did not review the Agency's COVID-19 response in its entirety; conduct procedures to determine the allowability of payments made for ventilators; confirm that ventilators were delivered; or verify that ventilators were being used as intended.

The team conducted audit procedures with staff based in Pretoria, South Africa, and Washington, DC, from which we interviewed USAID officials and staff. Due to travel

[26] Public Law 116-123 appropriated $435 million for the GHP fund, but further stated that of these funds, not less than $200 million shall be made available for the ERF fund.

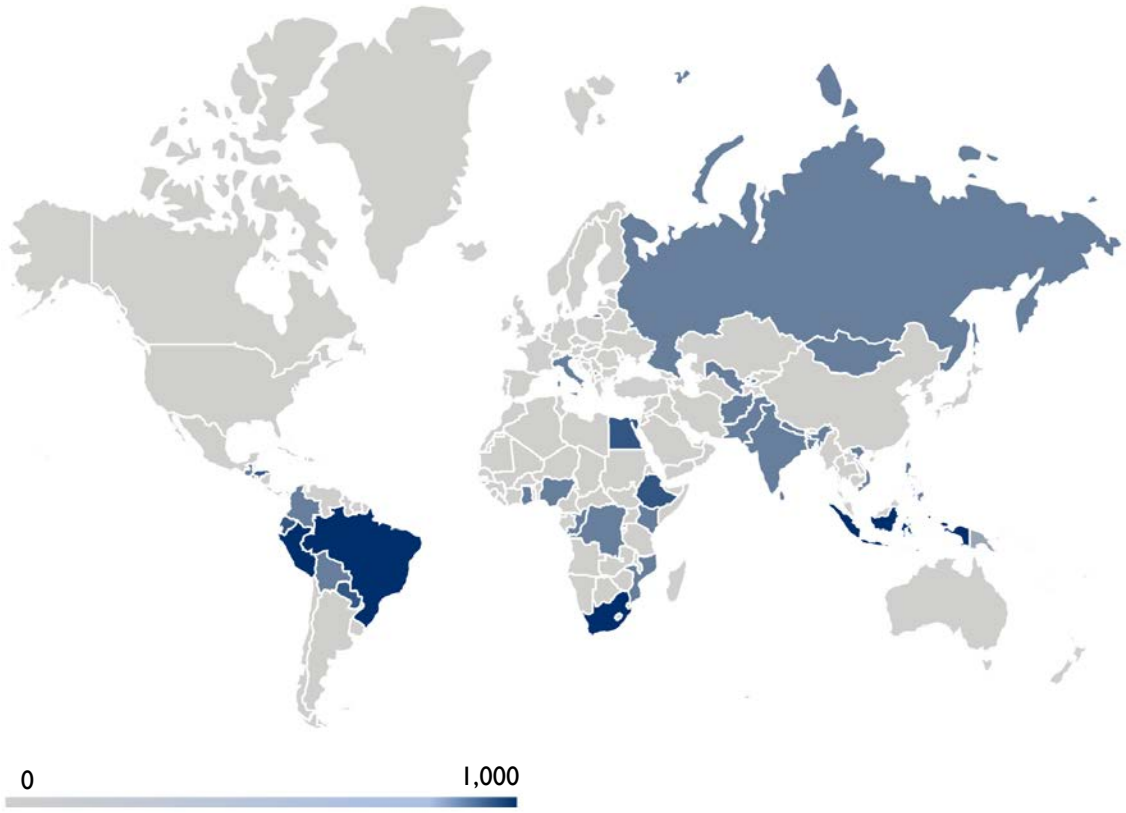
restrictions during the COVID-19 pandemic, all interviews were held virtually, and we did not conduct any site visits.

To answer the first objective, we reviewed USAID strategies, policies and procedures, and guidance to respond to COVID-19, such as the State-USAID joint "Strategy for Supplemental Funding to Prevent, Prepare for, and Respond to Coronavirus Abroad"; the State-USAID joint "Guidance on the Process for Investing Supplemental Foreign Assistance Resources"; the "Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents," also known as the NSC Pandemic Playbook; and "USAID's Response to Infectious Disease Outbreaks" to obtain an understanding of specific strategies and processes relevant to responding to the COVID-19 pandemic. We reviewed and analyzed USAID's submitted congressional notifications to understand how the Agency used COVID-19 supplemental funds, including prioritized interventions and affected countries to which it would provide support for the COVID-19 pandemic. We reviewed and analyzed documentation related to USAID's COVID-19 response, including documents related to establishing internal coordination groups and designating a technical lead office, coordinating with U.S. Federal agencies, and conducting needs assessments to prioritize interventions and affected countries. We interviewed staff from the Bureau for Global Health and USAID's COVID-19 Task Force to obtain an understanding of USAID's practices and activities for responding to public health emergencies in general and COVID-19 specifically.

To answer the second objective, we reviewed and analyzed USAID's submitted congressional notifications for use of COVID-19 supplemental funds on the provision of ventilators. We reviewed and analyzed documentation related to USAID's ventilator donation program, including documents related to updates between the NSC and USAID on ventilator recipient countries, quantities, and suppliers as well as communication from USAID headquarters to recipient country missions on what to expect when receiving a ventilator donation. We interviewed staff from the Bureau for Global Health and USAID's COVID-19 Task Force to obtain an understanding of USAID's role in the ventilator donation program, the decisions made, and the activities performed to carry out its role. In addition, we reviewed and analyzed notes from weekly meetings the COVID-19 Task Force held with USAID leadership, USAID mission directors, and other representatives to gain an understanding of USAID's internal coordination and communication about the Agency's COVID-19 response and ventilator donation program.

We assessed whether any controls were significant in the context of our audit objectives. Specifically, we designed and conducted procedures related to 4 of the 17 internal control principles—2, 3, 8, and 9—under the 5 components of internal control, as defined by GAO. We did not rely on computer-processed data to determine audit findings, results, or conclusions; therefore, an in-depth data reliability assessment was not necessary. Instead, we relied on documentary evidence, such as policies, procedures, meeting notes, the ventilator tracker; and testimonial evidence with knowledgeable USAID officials and staff to support our findings, results, and conclusions.

APPENDIX B. VENTILATOR DONATION RECIPIENT COUNTRIES



The boundaries and names used on this map and in the following tables do not imply official endorsement or acceptance by the U.S. Government.

Ventilator Donations by Region

USAID Regional Bureau	Quantity	Percentage
Africa	1,920	22%
Asia	2,515	29%
Europe and Eurasia	350	4%
Latin America and the Caribbean	3,487	40%
Middle East	250	3%
Other (NATO)	200	2%
Total	**8,722**	**100%**

Ventilator Donations by Country

Country	Ventilators Donated
Afghanistan	100
Bangladesh	100
Bhutan	15
Bolivia	200
Brazil	1000
Colombia	200
Dominican Republic	50
DRC	50
Ecuador	250
Egypt	250
El Salvador	600
Ethiopia	250
Fiji	30
Ghana	50
Guatemala	50
Haiti	37
Honduras	210
India	200
Indonesia	1000
Italy	100
Kenya	200
Kiribati	10

Country	Ventilators Donated
Kosovo	50
Maldives	60
Mongolia	50
Mozambique	50
NATO	200
Nauru	10
Nepal	100
Nigeria	200
Pakistan	200
Panama	100
Papua New Guinea	40
Paraguay	280
Peru	500
Philippines	100
Russia	200
Rwanda	100
South Africa	1000
Sri Lanka	200
St. Kitts & Nevis	10
Uzbekistan	200
Vietnam	100
Zimbabwe	20

Source for map and tables: USAID's final list of ventilator donations.

APPENDIX C. INTERVENTIONS CITED IN CONGRESSIONAL NOTIFICATIONS

Before the start of the ventilator donation program, USAID submitted eight congressional notifications between February 2020 and April 2020 citing the interventions it planned to implement in response to COVID-19.

No.	Interventions Cited in Congressional Notifications
1	Screening at points of entry and exit
2	Purchase of key commodities (diagnostics, PPE, & disinfectants)
3	Prevention and control of infections in health facilities
4	Readiness to rapidly identify, diagnose, and treat cases
5	Identification and followup of contacts
6	Awareness-raising in the population through risk-communication and community engagement
7	Implementation of health measures for travelers
8	Logistics and supply-chain management
9	Global and regional coordination
10	Country-level readiness and response
11	Developing and distributing training materials on COVID-19 for healthcare workers
12	Harmonizing COVID-19 technical guidance on disease surveillance and other operations for preparedness and response operations
13	Deploying technical experts to countries that require assistance for activities in both response and preparedness, especially where USAID does not have missions
14	Communicating what scientists know about the disease and what actions people need to take to keep themselves healthy
15	Preparing messages in local languages that target at-risk groups, including health workers, border officials, etc.
16	Using two-way channels for public information, hotlines, social media, radio talk shows, and other mediums to counter misinformation
17	Adding or improving water and sanitation (WASH) in health facilities
18	Protection of women, children, and vulnerable populations
19	Strengthening underdeveloped, deficient, and absent components of health institutions and networks
20	Nutrition
21	Laboratory strengthening and case management
22	Mitigating the social, economic, and community impacts of the pandemic
23	Supporting businesses that are engaged in the research, development, or manufacture of therapeutics, vaccines, and medical equipment and supplies for COVID-19

APPENDIX D. AGENCY COMMENTS

MEMORANDUM

TO: **Africa Regional Office, Director, Robert Mason**

FROM: **Bureau for Global Health, Deputy Assistant Administrator, Carol Chan**

DATE: **February 5, 2021**

SUBJECT: Management Comment(s) to Respond to the Draft Audit Report Produced by the Office of Inspector General (OIG) titled, *USAID Had Limited Control Over COVID-19 Ventilator Donations, Differing From Its Customary Response to Public Health Emergencies* (4-936-21-002-P)

The U.S. Agency for International Development (USAID) would like to thank the Office of Inspector General (OIG) for the opportunity to respond to this draft report which contains no recommendations for the Agency. We appreciate the extensive work of the OIG's engagement team, and the specific findings that will help USAID achieve greater effectiveness in the current Public Health Emergency of International Concern (PHEIC) and future ones.

For more than half a century, the United States has been the largest contributor to global health security and humanitarian assistance. Investments by USAID and other U.S. Government Departments and Agencies in global health substantially advance U.S. foreign-policy and national-security interests by protecting Americans at home and abroad, promoting social and economic progress, and supporting the rise of capable partners better able to solve regional and global problems. The ventilator donation program is an example of supporting a U.S. Government policy that was coordinated by the interagency, and implemented by USAID, which advanced U.S. foreign policy and national security interests.

The *Strategy for Supplemental Funding to Prevent, Prepare for, and Respond to Coronavirus Abroad*, jointly developed by the U.S. Department of State and USAID during April 2020, guided the allocation of resources from the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. A crucial principle for allocating funding has been to bolster health institutions in partner nations to address the pandemic of COVID-19 and the possible re-emergence of the disease. As such, we are financing interventions within the three main components of Pillar II of the *Strategy*: Emergency

Health Response; Strengthening Global Health Security in Affected Countries; and Supporting Health Institutions in more than 100 countries.

We appreciate the acknowledgement of the Agency's deliberate referral to reviews and after-action reports from prior PHEIC, such as Ebola and Zika, audits conducted by OIG and the U.S. Government Accountability Office (GAO), and others.

The National Security Council (NSC) pandemic playbook, developed after the 2014 West Africa Ebola outbreak, as your report notes, was referenced early in the COVID response. However, the former Administration as a policy matter did not utilize the playbook to guide the COVID-19 response. As highlighted in the report, the NSC served as a coordinating body and, in that role, provided direction to USAID regarding interagency decisions made to support the whole-of-Government effort. The whole-of-Government approach included the Department of Health and Human Services (HHS), Development Finance Corporation (DFC), Federal Emergency Management Agency (FEMA), Department of State (DoS), the Department of Defense (DoD), and the National Security Advisor (NSA).

As your report notes, the invocation of the Defense Production Act (DPA) to meet the demand for ventilators resulted in the U.S. Government ordering approximately 200,000 ventilators from 10 different suppliers for the Strategic National Stockpile (SNS) under contracts administered by the Department of Health and Human Services (HHS). As the OIG report articulates, "Ventilators are highly technical machines that support patients who are experiencing extreme respiratory distress." Further, your report highlights that three suppliers—Vyaire, Medtronic, and Zoll—were operating under existing contracts with HHS to support the SNS.

As the interagency limited the number of manufacturers available to support the manufacturing of ventilators for the USAID donation program, USAID's contractor for the Global Health Supply Chain - Procurement and Supply Management (GHSC-PSM) project, limited procurement of ventilators to those sources as directed by the NSC. While USAID acknowledges this was an atypical procurement practice, the pandemic required tighter controls on these, and other, low-density-high-demand pieces of life-saving equipment and commodities. Each donated ventilator was custom built to operate in each country context and was not supplied by previously existing inventory.

USAID applauds Chemonics, Medtronic, Vyaire and Zoll for their remarkable support of the ventilator donation program. Any critique of USAID performance should not in any way impeach or diminish the Herculean efforts made by each company to energize, protect and, in many cases, expand and diversify their respective supply chains to ensure necessary inputs were available to assemble this life-saving equipment. Private sector partners collaborated and pooled resources to facilitate the rapid scaling of operations. During this unprecedented pandemic, the entrepreneurial spirit, quality control, and mission-oriented teamwork displayed by each company should be celebrated and appreciated with unyielding pride, as a visible example of American ingenuity. Each company's employees, and their respective families, demonstrated unwavering

commitment and focus, in the face of significant personal sacrifice, to ensure high quality equipment could be provided on behalf of the American People.

Keen foresight and proactive adaptive management ensured that "wraparound" support was provided along with most of the ventilator donations. Going above and beyond the original design of the ventilator donation program, USAID enhanced the value and impact of the donation by procuring tailored packages of support, including warranties and service plans, initial supplies of accompanying equipment, and operational training for medical providers.

In addition, USAID provided in-country clinical technical assistance in 38 of the 43 countries where ventilators were donated. Clinical technical assistance is strengthening the capacity of practitioners and health systems through trainings and ongoing mentorship to provide evidence-based clinical care for COVID patients, including the use of the donated ventilator equipment.

USAID continues to collaborate, with the manufacturers of the ventilators and clinical technical assistance partners, to share best practices and relevant materials, including curated content on opencriticalcare.org. This online learning hub connects medical professionals in resource-variable settings with essential information on respiratory care and patient management. USAID's support informs, but does not direct, recipient country decisions in the deployment and distribution of the donated ventilators. In facilities where ventilators are distributed, USAID's investments in training and clinical mentorship are boosting the capacity of frontline workers to deliver quality care to patients in need, while informing improvements in facility standards on infection control, evidence-based use of therapeutics, and general management of COVID-19 patients.

We respectfully question the repeated reference by the OIG report to oxygen and the implied comparative advantage of oxygen therapies over ventilator use. Ventilators and oxygen, as complementary investments, both have utility and value in treating patients. Ventilators, and the clinical technical assistance that accompanied them, have the benefit of being almost immediately implementable and help to improve the appropriate use and impact of the available oxygen supply. Further, the investments made as part of the ventilator donation and technical assistance have laid the groundwork for appropriate training and use of the oxygen supply that will be expanded through USAID's separate investments in the oxygen ecosystem in several countries.

We appreciate the concerns raised by the OIG, regarding certain reports published in the midst of the ventilator donation program that focused on patient outcomes and long-term risks of mechanical ventilation for patients designated as critically ill. USAID anticipated up to 20 percent of all COVID-19 patients would require at least supplemental oxygen; the most critically ill patients would require intensive care and assisted ventilation. The U.S. Government was responding to requests from national governments to support them in providing the highest level of care for these patients because they were underprepared to save the lives of the most critical patients. The ventilator donation program, and associated clinical technical assistance, is intended to increase the capacities of countries' health systems to treat COVID-19 patients who are

experiencing a range of respiratory support needs. A detailed evaluation of the USAID response to the global pandemic will show a concerted effort to provide the latest evidence-based guidance on appropriate and comprehensive treatment for COVID-19 patients, including training on the use of ventilators and other forms of respiratory support. The ventilator donation program was integrated into the broader USAID response.

As the OIG report notes, growing medical evidence supports alternatives to invasive ventilation. Information on these approaches was included in trainings given by clinical technical advisors at the global and in-country level, along with trainings on other aspects of appropriate care for COVID patients. We recommend referencing the opencriticalcare.org portal which provides a more thorough overview of the various treatment options presented through the clinical trainings and mentorship. This portal further highlights how other programming, including oxygen, was effectively sequenced and layered on top of the ventilator donations. The portal's curated guidance and information on many other clinical topics helps strengthen the capacity of health practitioners in the field, to treat and care for the full range of COVID patients.[27]

In some cases, countries contributed to the decisions regarding which supplier was chosen, the ventilator model offered, and the number of ventilators received. Negotiations and accommodations often occurred in advance of any NSC direction to USAID. As a result, USAID cannot provide a comprehensive account for the content or context of background discussions that influenced country assignments. The contradictory comments made by USAID staff interviewed on this topic may be due to their understandable lack of visibility into how decisions were made at higher levels of the U.S. Government.

It is accurate to state that each country formally accepted their donations, as recorded in the signed donation acceptance letters. Once signed, the donation procurement process began in earnest and changes were not generally entertained. This programmatic rigidity, post commitment, was due in large part to the mechanics of the procurement process and the terms within each purchase order.

We question the premise of the draft report that implies the most-appropriate metric for country selection should have been more closely linked to the number of cases of COVID-19 as of the date each country was selected. The OIG must appreciate that the pandemic was not static: COVID-19 caseloads have changed markedly and in unpredictable ways since the PHEIC was declared on January 30, 2020. In fact, rates of COVID have increased dramatically in many parts of the world in just the last few weeks. While the OIG report correctly states the current infection rates in specific countries remain low, it cannot predict the future impacts of this ever-evolving pandemic. The donated ventilators and the supporting clinical technical assistance that accompanied them, is positively contributing to health system strengthening within these

[27] https://opencriticalcare.org/wp-content/uploads/2021/01/English-7-by-17--bs14v5.pdf

countries, making them more resilient and capable of responding to COVID cases than they would otherwise be.

The continued fluidity of the pandemic should not be overlooked. Subsequent findings of increased risk for severe complications from COVID-19 in countries whose citizens have a high prevalence of underlying chronic health conditions (for example, in Latin America and the Pacific Islands) should be considered. Singling out donations to countries, like the Republics of Nauru and Kiribati, as being possibly wasteful, because of no or low cases of COVID-19 patients overlooks the need for proactive measures to anticipate future outbreaks in countries with limited capacity to respond. As new strains of the COVID-19 virus emerge and multiple waves of outbreak are anticipated ahead, the OIG report overlooks the stark reality that the COVID-19 pandemic is an ongoing and evolving challenge. These islands have high rates of underlying medical conditions such as diabetes, hypertension and other metabolic disorders which increase the risk of severe mortality and morbidity. With this background and institutional experience in mind, USAID sought to maximize the value of the Administration's ventilator-donation program and, where possible, integrate the donations into the Agency's more comprehensive support of the joint *Strategy*.

APPENDIX E. MAJOR CONTRIBUTORS TO THIS REPORT

The following people were major contributors to this report: Robert Mason, audit director; Louis Duncan Jr., assistant director; Deanna Scott, lead auditor; Susannah Holmes, auditor; Lady Rammutla, auditor; Eli Wood, analyst; Laura Pirocanac, writer-editor; and Saifuddin Kalolwala, legal counsel.