

COVID GAP Accountability Report

Key Changes and Insights Since Previous Report:

- On April 17th, India <u>reported</u> over 9,000 new COVID-19 cases prompting some parts of the country to reintroduce mask mandates.
- The XBB.1.16 variant now <u>accounts</u> for roughly 7.2% of sequenced COVID-19 cases in the United States.
- The World Health Organization's technical advisory group on COVID vaccine composition met in March to review the performance of updated COVID-19 vaccines. The group released a <u>statement</u> saying that the updated vaccines that contain either BA.1 or BA.4/5 provide better protection than vaccines that contain only the original virus.
- The FDA <u>authorized</u> a second bivalent COVID-19 vaccine for seniors ages 65+ and those with compromised immune systems.

COVID Global Accountability Platform's (COVID GAP's) Accountability Reports highlight and analyze recent developments, track progress toward national, regional, and global targets, and identify high-priority recommendations for a more effective, efficient, and equitable pandemic response and preparedness. Drawing on data across many sources, our team tracks important measures of progress on commitments and remaining gaps, helping to hold leaders and organizations to account on these actions.

Interactive versions of the charts and graphs below are available at https://covid19gap.org/view-the-data. The data visualizations will be updated every two weeks and new metrics will be added over time, as data allow. We welcome feedback and direct engagement to identify and incorporate additional data sources and/or relevant metrics to

track Holding Leaders to Account

In the accountability reports, we present real-time analysis and track updates in the dynamic landscape of the global response to COVID-19 across five areas:

- 1. Funding the Global Response
- 2. Pandemic preparedness and health system resilience
- 3. Vaccines and Vaccinations
- 4. Test and treat
- 5. Oxygen

Tracking the COVID-19 Pandemic

Trends and changes in the pandemic overall are effectively tracked through several regularly updated dashboards. We recommend:

Johns Hopkins COVID-19 Dashboard

Our World in Data

Pandem-ic

WHO COVID-19 Dashboard









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Recent Changes in the COVID-19 Pandemic

On April 17th, India reported over 9,000 new COVID-19 cases. Parts of the country have reintroduced mask mandates in response to rising case numbers. XBB.1.16 is a "variant under monitoring" according to the World Health Organization. In the United States, the XBB.1.16 accounted for 7.2% of sequenced COVID-19 cases in the week of April 15th. In the wake of COVID-19 surges globally, it is alarming to see the long-lasting gaps in high-risk population vaccination coverage in low and middle-income countries.

1. Funding the Global Response

The ACT-Accelerator, the major global multi-lateral initiative coordinating pandemic response, has requested \$16.8 billion in grant funding to support activities from October 2021 to September 2022. In contrast, during ACT-A's first budget year (2020-2021) the funding request was \$25.4 billion (Figure 1.1). At the end of its budget year, ACT-A has raised \$5.90 billion, just over one third of the funding needed to implement its strategy. At 71.5% funded, the vaccines pillar fares best (\$4.274 billion), while the diagnostics pillar has been allocated \$72 million, just 1.5% of the target funding (Figure 1.2). The lack of funding may be indicative of waning support among wealthier countries for the "no one is safe until everyone is safe" approach.

The ACT-A transition period will run from October 2022 to March 2023, and does not include a new budget. The transition plan focuses on the funding required to meet country-level demands not global-level targets. Currently, the ACT-A transition plan acknowledges a <u>funding</u> gap of \$269.1 million across three of the four pillars (therapeutics, diagnostics, and health

Target: Vaccines \$11,902,000,000 \$11,100,000,000 Target: Diagnostics \$1,370,000,000 \$6,000,000,000 Target: \$6,600,000,000 Therapeutics \$1,571,000,000 ACT-A Pillar Vaccines Health Target: Diagnostics Systems and \$1,700, \$1,872,000,000 Therapeutics 000,000 Response Health Systems and Response

Figure 1.1. Donor country funding committed versus requested for ACT-A (2020-2021)

COVID

Source: WHO, updated March 17, 2023

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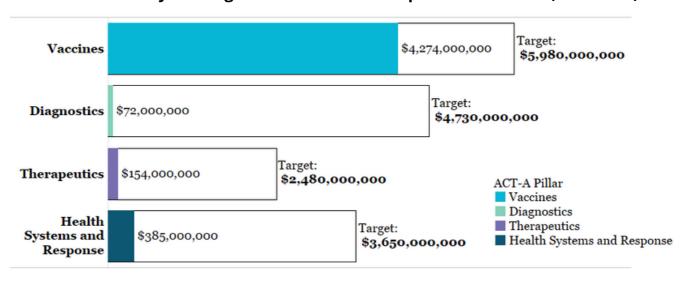
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systems and response) (Figure 1.3). Between February 6th 2022 and March 17th, the health systems and response pillar received an additional \$10 million in funding. The additional \$10 million in funding came from Japan (\$9.2 million) and Wellcome Trust (\$800,000). This leaves the health systems and response pillar 35.9% funded during the ACT-A transition period.

In February 2022, the ACT-Accelerator Facilitation Council's Finance and Resource Mobilization Working Group, chaired by Norway, set out a <u>"fair share" framework</u> to set contribution benchmarks by country. The calculation of the fair share benchmarks is based on the size of national economies and likely gains from a faster recovery of the global economy and trade.

Figure 1.2 Donor country funding committed versus requested for ACT-A (2021-2022)

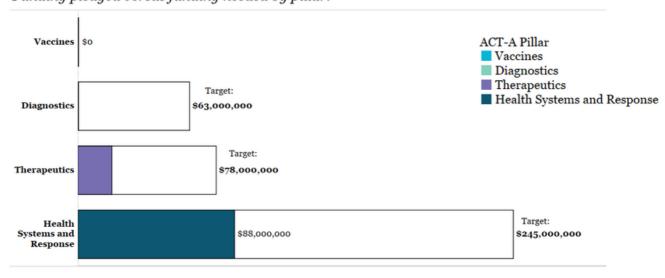


Source: WHO, updated March 17, 2023

NOTE: Figure 1 does not include ACT-A pending allocations. These funding targets (tracked at the source listed above) are set for donor countries and differ from those in the ACT-A Strategic Plan, which include expected contributions from development banks and self-funding middle-income countries.

Figure 1.3 Donor country funding committed versus requested for the ACT-A transition period (Oct. 2022 to March 2023)

Funding pledged versus funding needed by pillar.



Source: WHO, updated March 17, 2023



Several countries made new financial pledges to ACT-A during the Second Global COVID-19 Summit, which are not yet reflected in the ACT-A funding data. Canada was the first country to pledge their "fair share ask" for the 2021-2022 budget year (not yet reflected in the ACT-A data). As of September 2022, Germany and Sweden were the only countries to contribute the full fair share ask. For additional visuals for the ACT-A fair share asks, please refer to the COVID GAP website: https://covid19gap.org/funding-the-global-response

While ACT-A provides a coordination and facilitation mechanism, each organization within the ACT-A structure still fund-raises separately. Recent fundraising and replenishment events directly and indirectly related to the global COVID response have also fallen short of funding targets. The table below shows results from three recent fund-raising events as well as pending fund-raising targets in the near future.

At the Second Global COVID-19 Summit in May 2022, more than \$3 billion in new financial commitments were pledged, including about \$2.7 billion from governments and about \$700 million from the private sector. Of this new funding, \$2.5 billion is dedicated toward COVID-19 response activities and \$712 million toward a new pandemic preparedness and global health security financial intermediary fund (FIF) at the World Bank. Many of the pledges from governments were dedicated to particular areas of the response or specific ACT-A pillars, while other pledges were left unspecified. To view the visual for financial commitments from the Second Global COVID-19 summit, please refer to the COVID GAP website: https://covid19gap.org/view-the-data

CEPI	The UK hosted the Global Pandemic Preparedness Summit in March 2022 to raise funds for CEPI's 100 Days Mission, which resulted in a total of \$1.5 billion toward a total ask of \$3.5 billion (more on these contributions in Section II: Pandemic Preparedness and Health System Resilience, below).	
Gavi	In April 2022, Germany, Indonesia, Senegal, and Ghana co-hosted the Break COVID Now Summit to raise funds for Gavi COVAX Advance Market Commitment (AMC). Of the \$5.2 billion ask to support purchase and delivery of vaccines and in-country capacity support for vaccinations, up to \$4.8 billion has so far been committed, of which \$1.7 billion is from donor countries, up to \$2.1 billion is committed by financing facilities, which will "front-load" financing, and \$1 billion will be provided by multilateral development banks.	
Global Fund		

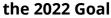


2. Pandemic Preparedness and Health System Resilience

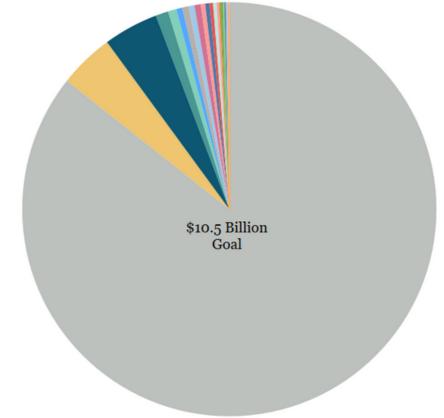
As we noted in the Path Forward report, the pandemic response over the past two years has forced countries to redistribute resources away from other pressing health needs. Health systems around the world now need increased support to improve primary care provision and resilience, which will help address the backlog of urgent non-COVID needs and better prepare for additional COVID outbreaks as well as future epidemics. Specific capabilities, such as surveillance and robust supply chains, will enable improvements in future pandemic preparedness as well as other health system needs.

Some steps are being taken to prepare the world for the next pandemic. The World Bank approved a financial intermediary fund (FIF) for pandemic prevention, preparedness, and response – now formally called <u>The Pandemic Fund</u>. The fund was formally established at the FIF Governing Board meeting on September 8-9, and the first call for proposals opened in early February 2023. The first round of funding <u>will focus</u> on comprehensive disease surveillance, early warning laboratory systems, and health workforce capacity. Between government, philanthropic, and non-profit donors, the Pandemic Fund has achieved \$1.6 billion in funding, with \$1.52 billion (95%) of that announced publicly (Figure 2.1). This is a promising start, but the projected need for the fund is \$10.5 billion per year over the next five years for investments to strengthen the capacity of low- and middle-income countries (Figure 2.2).

Figure 2.1. Government and Private Sector Contributions to the Pandemic Fund Toward



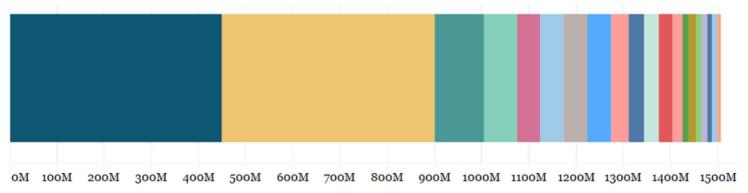




Source: COVID GAP Analysis, updated April 17, 2023



Figure 2.2. Government and Private Sector Contributions to the Pandemic Fund Toward the 2022 Goal

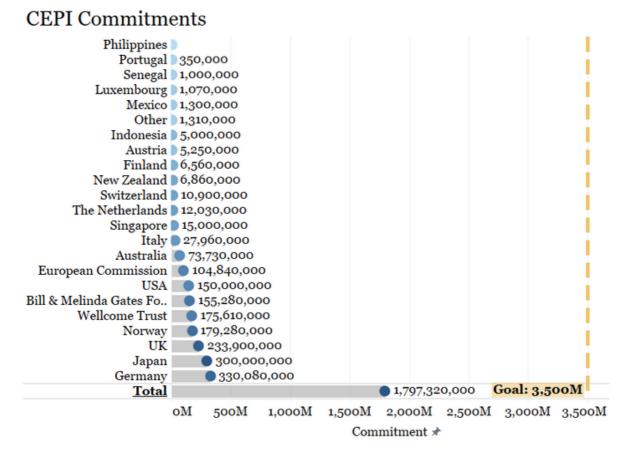


Source: COVID GAP Analysis, updated April 17, 2023

CEPI has launched the 100 Days Mission, an effort to ensure that safe, effective, and affordable vaccines can be developed and deployed within 100 days of the discovery of a new pathogen threat. This strategy includes global surveillance systems, point-of-care testing capacity worldwide, and expanded global manufacturing capacity at the ready to ensure that new vaccines can be equitably distributed.

However, fundraising for this effort is off to a slow start, with nearly \$1.8 billion raised, less than half of the \$3.5 billion target (Figure 3).

Figure 3. Funding commitments made to CEPI's 100 Days Mission



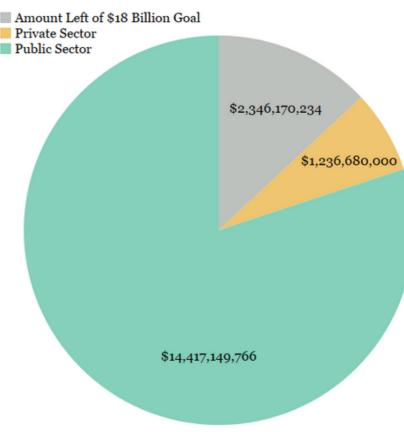
Sources: CEPI 100 Days Pledges and CEPI Investment Report, updated January 20, 2023





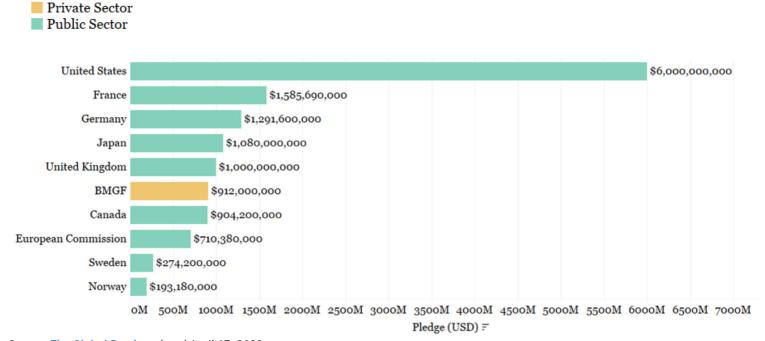
Figure 4.1 Public and Private Sector Pledges to the Global Fund at the Seventh Replenishment Conference

At the Global Fund's Seventh Replenishment Conference, over US \$15.70 billion has been raised for the next three years (Figure 4.1). Commitments come from public and private sector partners, and nongovernmental organizations (Figure 4.2). With a goal of US \$18 billion, the Global Fund aims to build back progress toward ending HIV, tuberculosis, and malaria, build resilient and sustainable health systems, and strengthen pandemic preparedness. Many partners have increased their commitments by over 30% from the sixth replenishment with several countries pledging for the first time. Recently, Luxembourg has announced an additional pledge of 3 million Euros.



Source: The Global Fund, updated April 17, 2023

Figure 4.2. Top 10 Donors to the Global Fund at the Seventh Replenishment Conference



Source: <u>The Global Fund</u>, updated April 17, 2023



Continued investments in LMIC-based manufacturing are encouraging, though many challenges remain. As detailed in our recent blog post, developments with expected longer-term benefit include:

- As part of WHO's technology transfer hub, Afrigen Biologics in South Africa developed its own version of Moderna's mRNA vaccine, using the publicly available sequence. Afrigen plans to share this with other LMIC manufacturers but production at scale is not likely before the end of 2023.
- The Partnership for African Vaccine Manufacturing released a <u>framework</u>, detailing a plan to build sustainable vaccine development and manufacturing capacity across Africa to prioritize 22 diseases. This effort is expected to cost \$30 billion over 20 years.
- Moderna and BioNTech have committed to establishing manufacturing capacity in Africa.
 Moderna will develop an mRNA facility in Kenya with assistance from the US government.
 This facility is expected to produce drug substance for up to 500 million doses of vaccine each year for use across Africa. BioNTech plans to launch modular factories called "Biontainers" to manufacture mRNA vaccines in Rwanda, Senegal, and possibly South Africa.

These and future investments in LMIC manufacturing will need to also focus on developing the supportive ecosystem that can support sustainable capacity. This includes ensuring demand (as demonstrated by the <u>lack of orders</u> for vaccines made in South Africa's Aspen Pharmaceuticals), a trained workforce, robust regulatory pathways, and financial models that address the challenge of keeping extra capacity at the ready for future health crises.

3. Vaccines and Vaccinations

Vaccination Targets: Prioritize Sub-Populations

The rapid development of safe and effective vaccines for COVID-19 was an immense scientific accomplishment. The scale and speed of the roll out of vaccines is also unmatched, though flawed and inequitable.

Global entities, such as the WHO, set ambitious targets for vaccinating the world. Unfortunately, many countries missed the global 10% coverage target (September 2021) and the 40% coverage target (December 2021) and it is widely acknowledged that more than 100 countries have missed the 70% coverage target (June 2022). The first Global COVID-19 Summit set ambitious targets for vaccination coverage with a deadline of the 2022 UN General Assembly (UNGA). Based on the latest WHO CRD data, our analysis indicates 80 countries have met the 70% vaccination coverage target and 133 countries have missed the target (Figure 5.1). Only 3.8% of low-income countries have reached this target compared to 63.4% of high-income countries.

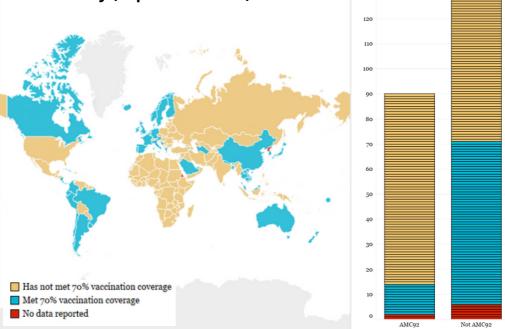
According to <u>Our World In Data</u>, only 24.8% of people living in low-income countries have received a full course of COVID-19 vaccination, compared with 74.8% in high-income countries (as of April 17, 2023) (Figure 8.2.).





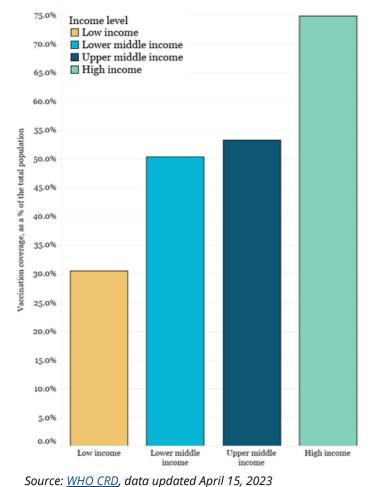
Figure 5.1 Countries on track to meet the 70% target for primary vaccination coverage by





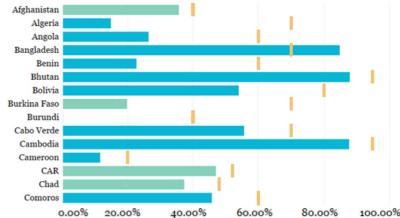
Source: WHO CRD, data updated April 15, 2023

Figure 5.2. Primary vaccination coverage by income category

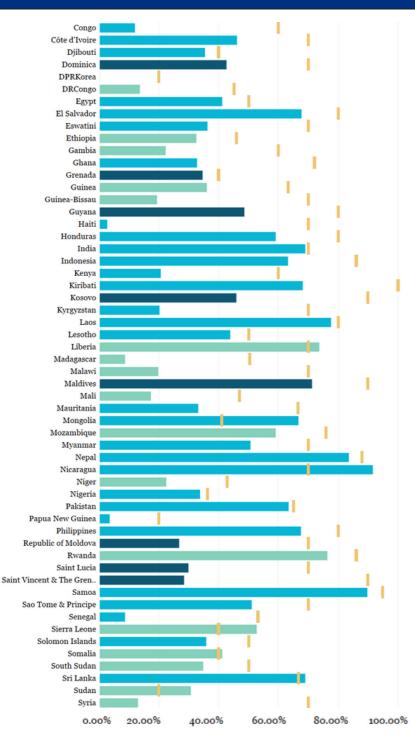


Many countries have set their own national targets for population coverage, which range from 20% to 95% with varying deadlines, but few have met the targets yet (Figure 6). Despite falling short of the targets, progress is being made and vaccinations are steadily increasing in many of these countries (see Figure 11 for vaccine rates in the 34 COVAX priority countries; data on all countries is available on the COVID GAP website).

Figure 6. Country-set vaccination coverage targets versus current coverage (for COVAX Advance Market Commitment countries only)







Income Group

Low Income Countries

Lower Middle Income Countries

Upper Middle Income Countries

In the face of Omicron and its sub-variants, COVID-19 vaccines have <u>successfully reduced</u> hospitalizations and deaths, even while infection rates remain high among vaccinated populations. Given this context, as we note in The Path Forward report, prioritization for full vaccination, including boosters, should be given to the highest-risk populations, including people over the age of 60, those with comorbidities and suppressed immune systems, and health care workers.

We are able to track vaccination coverage for ages 60+ and for health care workers in many COVAX Advance Market Commitment (AMC) countries (Figure 7) but have not yet found public data on coverage among populations with comorbidities or suppressed immune systems. Such information will be important to track over time to follow progress toward high-priority goals.

In the previous two weeks, there have not been any substantive increases in subpopulation vaccination coverage in COVAX concerted support countries.

Source: WHO CRD, data updated April 15, 2023 Note: Gold bars denote country-set coverage targets. Some countries are shown at >100% because of the administration of booster doses.

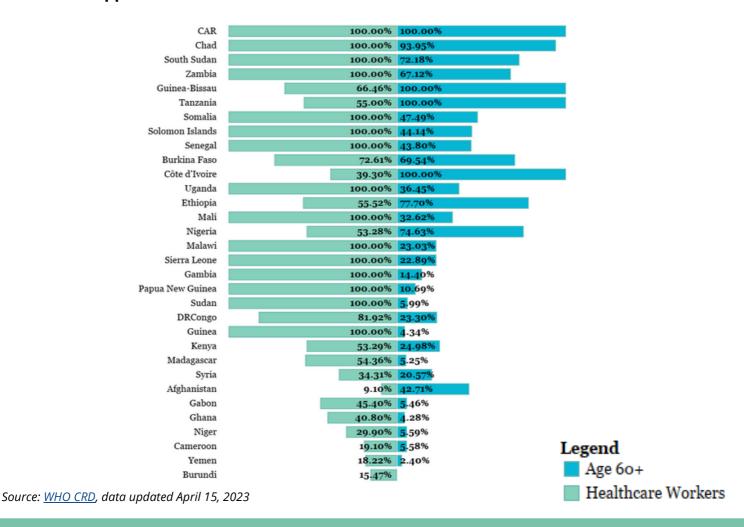
As more of the global population completes primary vaccination, and as protection wanes with time, it is also important to track progress in administering booster doses. Policies on boosters and which populations are eligible for them vary by country and are not easily tracked, but WHO does provide data on the number of boosters administered per 100 people (Figure 8.1). This metric is more appropriate for boosters than percent of population since some countries are already offering 2nd or 3rd boosters to eligible individuals, depending on national policy. However, similar trends are emerging with boosters as with primary vaccination coverage. More boosters have been administered in high-income countries with coverage decreasing with each income level (Figure 8.2). Since the last update, the number of booster doses administered per



100 persons has increased across all income levels. High income countries are reporting 48.48 booster doses administered per 100 persons which is an increase from 48.36. Upper-middle income countries are reporting 25.06 booster doses administered per 100 persons, an increase from 24.99. Lower-middle income countries are reporting 19.41 booster doses administered per 100 persons, an increase from 19.30. Low-income countries are reporting 4.96 booster doses administered per 100 persons, an increase from 4.62. [WMP1] Continued roll out of primary doses in many lower-income countries may explain some of the difference in booster coverage, however inconsistent booster policies across countries creates an additional challenge to drawing insights from this metric.

WHO also provides data on the number of booster doses administered per 100 people and total number of booster doses administered in vulnerable populations, such as healthcare workers and those aged 60+ (Figure 8.3 and 8.4). There is data missing for several countries, but similar trends emerge with booster doses administered in vulnerable populations as with boosters amongst the general population. High-income countries administer more booster doses in healthcare workers and those aged 60+ than low-income countries. This metric will be important for ensuring priority groups are reached following the WHO <u>recommendations</u> prioritizing second COVID-19 booster doses in vulnerable populations.

Figure 7. Vaccination coverage by sub-population (60+ and health care workers) for COVAX concerted support countries



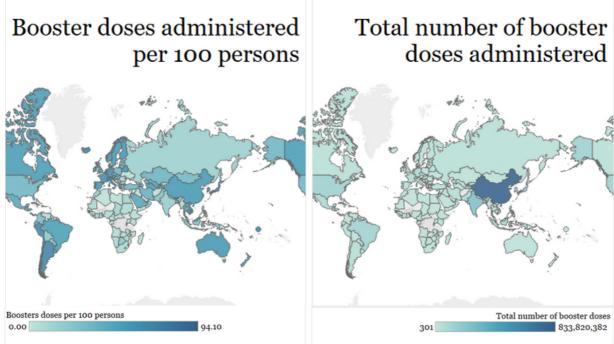
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Figure 8.1. COVID-19 booster doses administered per 100 persons and total COVID-19 booster doses administered



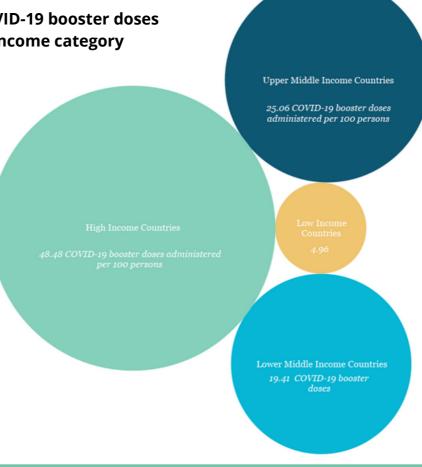
Source: WHO CRD and OWID, data updated April 15, 2023

Note: There are no data for countries in gray.

Note: WHO data was unavailable and supplemented with data from OWID for the following countries/regions: Hong Kong, Macao,

Montenegro, Russia, Serbia, Turkey, and the United Kingdom

Figure 8.2. Average number of COVID-19 booster doses administered per 100 persons by income category



COVID

Income Group

High Income Countries
Low Income Countries

Lower Middle Income Countries
Upper Middle Income Countries

Source: WHO CRD, data updated April 15, 2023

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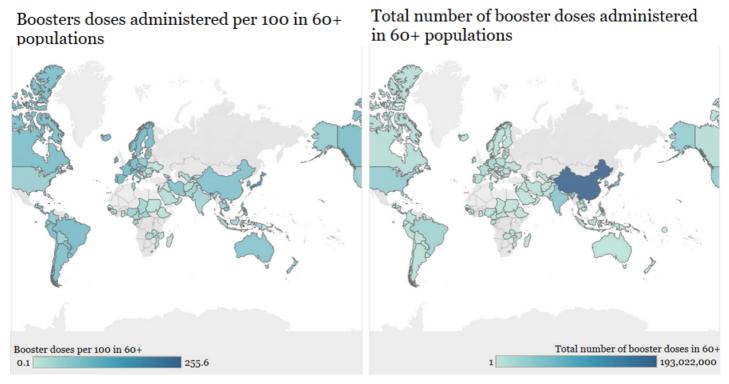
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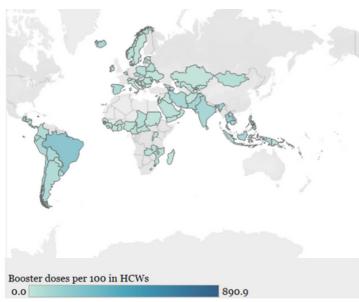
Figure 8.3. Total number of COVID-19 booster doses administered and number of COVID-19 booster doses administered per 100 in populations aged 60+.



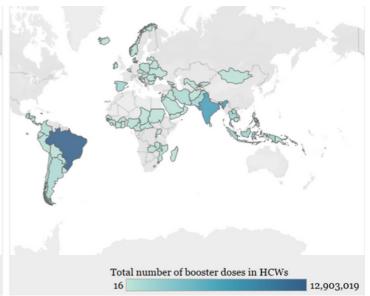
Source: <u>WHO CRD</u>, data updated April 15, 2023 Note: There are no data for countries in gray.

Figure 8.4. Total number of COVID-19 booster doses administered and number of COVID-19 booster doses administered per 100 in healthcare workers.

Booster doses per 100 in healthcare workers



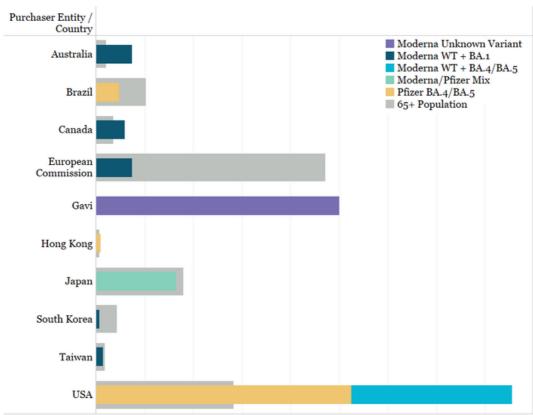
Total number of booster doses in healthcare workers



Source: <u>WHO CRD</u>, data updated April 15, 2023 Note: There are no data for countries in gray.

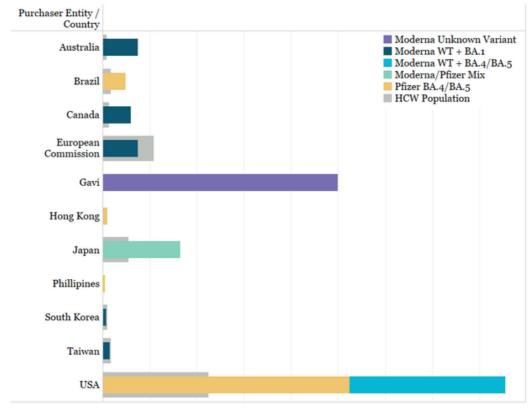


Figure 9.1. Purchases of bivalent COVID-19 vaccines compared to the population of those aged 65+



Source: Duke Global Health Innovation Center, updated April 17, 2023

Figure 9.2. Purchases of bivalent COVID-19 vaccines compared to the population of healthcare workers.



Source: Duke Global Health Innovation Center, updated April 17, 2023

Note: There is no data for healthcare workers in Hong Kong



In response to Omicron and its sub-variants Pfizer and Moderna have adapted existing COVID-19 vaccines to be bivalent, meaning they contain a portion of both the wild-type strain and omicron. These bivalent vaccines are approved for use as booster doses, with the hope that they will provide better protection against the currently circulating strains. Prioritization for these bivalent booster doses should be given to vulnerable populations. Several high-income countries have already made purchases that would allow them to vaccinate their 65+ and healthcare worker populations many times over (Figures 9.1 and 9.2). In an effort to provide equitable access to these new vaccines, Gavi and Moderna have signed an <u>agreement</u> that would allow lower-income countries to access up to 100 million doses of variant-containing vaccines.

Challenges to Reaching Coverage Goals

Vaccine supply on a global level has greatly improved over the past year and is no longer the critical limiting factor. However, supply remains an issue at the local level, particularly for low-and lower-middle income countries in Africa, Eastern Mediterranean, and South-East Asia regions (see interactive visuals on the COVID GAP website to filter country vaccination data by region and income).

For many countries, the primary challenge has shifted to having the capacity to utilize available supply before product expiration. Daily vaccination rates in many countries remain low. Lowand lower-middle-income countries report significant challenges to vaccination, including lack of sufficient cold storage and transport, shortage of health care workers, vaccine misinformation, and competing health priorities.

Countries with concerted support from the Global COVID-19 Vaccine Delivery Partnership continue to make modest progress with increasing vaccination coverage. Since our last update, South Sudan is reporting a 0.25% daily vaccination rate which is an increase from 0.01%. Sudan is reporting a 0.23% daily vaccination rate which is an increase from 0.07%. Supply is no longer flagged as a concern for Burkina Faso. Supply has recently been flagged as a concern for Sudan and Chad. Supply remains flagged as a concern for Afghanistan, the Central African Republic, Côte d'Ivoire, Guinea, Malawi, Niger, Nigeria, Sierra Leone, and Tanzania.

Vaccine Donations

Vaccine donations were a significant aspect of the supply landscape in 2021 but unfortunately deliveries were concentrated at the end of the year, overwhelming recipient countries. In addition, many of the doses donated bilaterally and through COVAX were delivered too close to their expiration dates for recipient countries to use, leading to wastage. In December 2021, recipient countries refused more than 100 million donated doses, primarily because of the short time-frame before expiry and also in some cases because storage facilities were full. Recently, the United States has decreased the pledged number of Pfizer vaccine donations from 1 billion to 600 million, citing decreased demand and service delivery bottlenecks in low and middle-income countries. This comes at a time when countries are beginning to donate new bivalent vaccines and minimizing wastage remains important.



Figure 10. Average daily vaccination rate, product utilization, and supply challenges for COVAX concerted support countries

	Change in % Pop Fully Vaccinated (Past 28 Days)	Daily Vaccination Rates (28 Day Avg)	Product Utilization Rate	Potential Supply Needed
Afghanistan	0.01	0.03%	8 4.94%	*
Burkina Faso		0.11%	72.95%	
Burundi	0.00	0.00%	14.52%	
Cameroon	0.01	0.02%	0 74.28%	
	0.00	0.01%	8 5.05%	*
Chad	0.00	0.00%	80.33%	*
Côte d'Ivoire	0.00	0.02%	98.22%	*
Djibouti	0.00	0.01%	28.24%	
DRCongo		0.05%	52.71%	
Ethiopia		0.00%	78.20%	
Gabon		0.00%	36.55%	
Gambia	0.01	0.12%	0 74.24%	
Ghana	0.00	0.02%	76.99%	
Guinea		0.00%	100.00%	*
Guinea-Bissau	0.01	0.04%	45.85%	
Haiti	0.00	0.02%	0 52.62%	
Kenya	0.00	0.01%	78.96%	
Madagascar		0.02%	48.00%	
Malawi		0.02%	83.17%	*
Mali	0.02	0.06%	78.88%	Ī
Niger		0.01%	94.00%	*
Nigeria		0.04%	93.87%	*
Papua New Guinea		0.00%	43.07%	Ī
Senegal		0.00%	53.62%	
Sierra Leone		0.15%	89.81%	*
Solomon Islands		0.02%	89.08%	Ī
Somalia		0.09%	75.50%	
South Sudan	0.07	0.25%	73.88%	
Sudan	0.05	0.23%	82.60%	*
	0.00	0.01%	46.73%	
Tanzania		0.04%	92.50%	*
Uganda		0.00%	\$55.48%	
Yemen		0.00%	59.12%	
Zambia		0.06%	73.07%	

Source: WHO CRD, data updated April 15, 2023

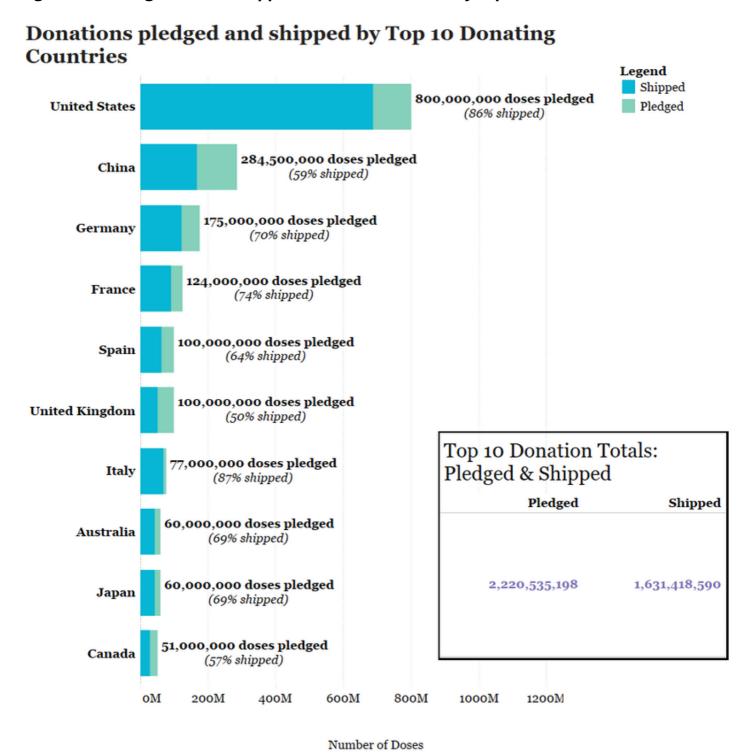






Many countries, including the United Kingdom, Spain, and Canada still have a long way to go to fulfill their donation pledges in 2022 (Figure 11.1). This needs to be done in concert with recipient countries and multilateral organizations like the African Union's African Vaccines Acquisition Trust (AVAT), so that deliveries can be planned, anticipated, and matched to capacity.

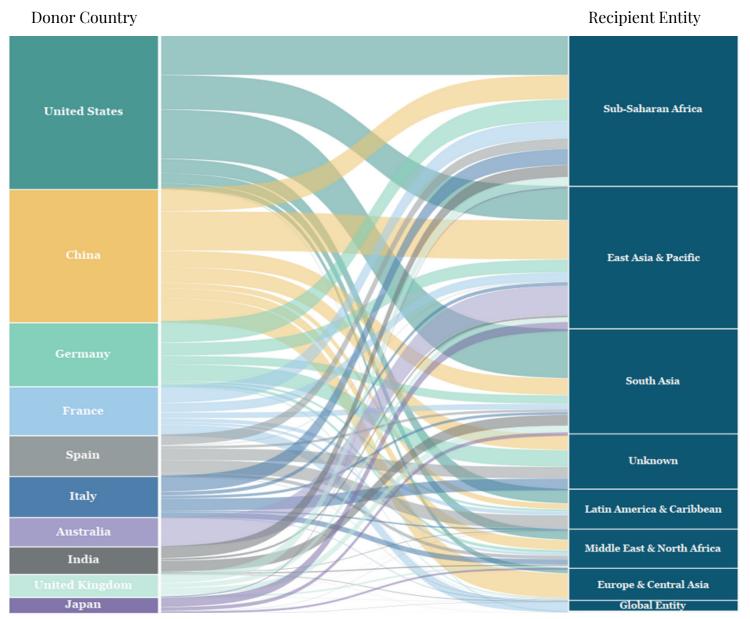
Figure 11.1 Pledged versus shipped vaccine donations, by top ten donor countries



Source: Duke Global Health Innovation Center, updated April 17, 2023



Figure 11.2 Flow of vaccine donations by top ten donor countries and recipient



Source: Duke Global Health Innovation Center, updated April 17, 2023

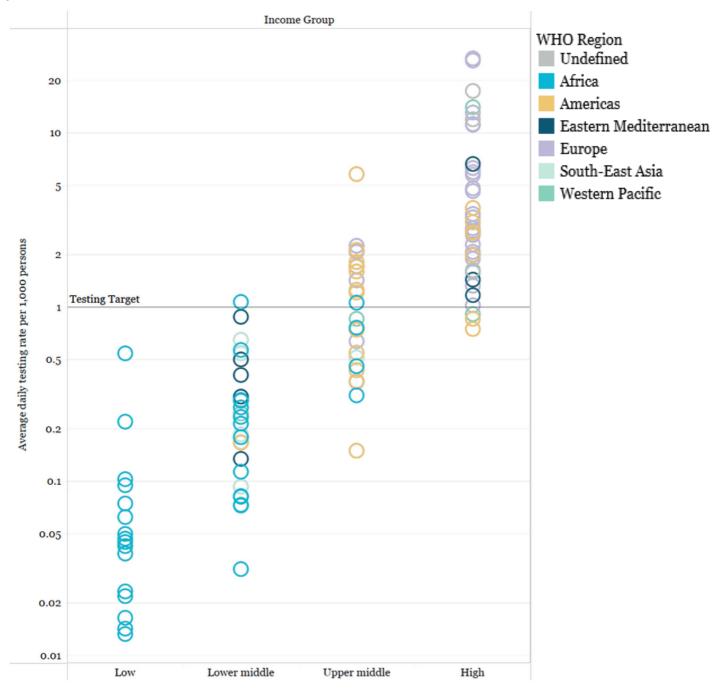
Note: To avoid dwarfing the visualization, the visual proportion of vaccines donated by the US are divided by 2.

4. Test and Treat

Test-and-treat strategies will be essential for the roll out of oral therapeutics to treat COVID-19. This will depend in part on global access to reliable diagnostics, particularly rapid tests. However, availability of diagnostics remains very low in low- and middle-income countries. Nearly all low- and lower-middle-income countries remain far below the ACT-A target of 1 test per 1,000 people per day (Figure 12.1).



Figure 12.1. Average number of daily tests per 1,000 people from January 1, 2021 to April 15, 2023



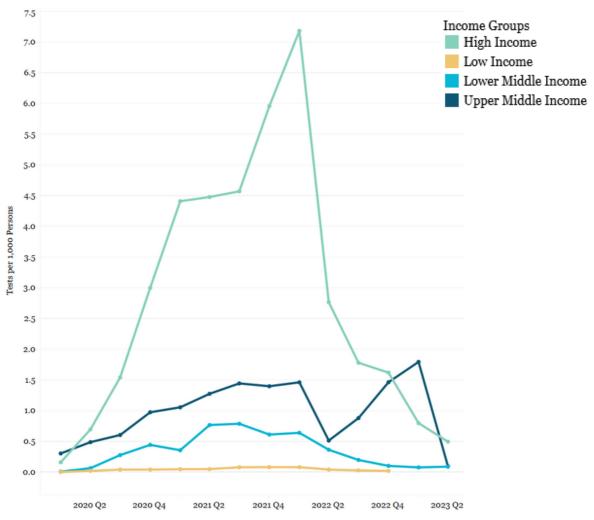
Source: FIND, updated April 15, 2023

Note: Data shown by country, WHO region, and income category. The ACT-A target of 1 test per 1,000 people per day is shown with dotted line. Average number of daily tests includes antigen and PCR tests.

The average daily testing rate rose steeply for high-income countries in 2021, rising above the 1 test per 1,000 people target in July 2020 and peaking at more than 11 per 1,000 in January 2022. Testing rates for middle-income countries remained far lower, seldom reaching the 1 per 1,000 target. For low-income countries, the line from 2020 to present is essentially flat, with testing rates that have rarely risen to even 0.1 in 1,000 (Figure 12.2).



Figure 12.2. Average number of daily tests per 1,000 people by quarter Data shown by country income category from Q1 2020 through Q2 2023.



Source: <u>FIND</u>, updated April 15, 2023

Note: Data shown by country income category from January 2020 through April 2023. Average number of daily tests includes antigen and PCR tests.

Despite broad licensing to generic manufacturers through the Medicines Patent Pool, generic production is unlikely to make a meaningful contribution to supply this year and manufacturing capacity will be largely limited to that of the originator companies, Merck and Pfizer. Merck expects to produce 30 million courses by the end of 2022 and Pfizer expects to produce 120 million courses.

Purchases for both drugs began even before the first regulatory authorizations were received. Pfizer's drug Paxlovid (nirmatrelvir/ritonavir) demonstrated strong efficacy data in Phase 3 clinical trials and therefore has been in greater demand. Pfizer has increased manufacturing of Paxlovid, but coupled with weak demand this could lead to a surplus of up to 70 million courses at the end of 2022. Xocova (ensitrelvir) is the newest oral antiviral on the market after receiving emergency regulatory approval in Japan in late November 2022. Distribution has already begun in Japan with the hopes of expanding access to LMICs through the Medicines Patent Pool.



Molnupiravir 12,509,640

Paxlovid 44,186,517

Mid-Year Production: 30,000,000

Xocova 1,000,000

OM 10M 20M 30M 40M 50M 60M 70M 80M 90M 100M 110M 120M

Figure 13. Oral therapeutic manufacturing projections for 2022 and confirmed purchases

Source: COVID GAP analysis, updated April 17, 2023

Similar to what we saw with vaccines, the majority of the purchases for oral therapeutics to date have been placed by high-income countries, with no purchases by low-income countries (Figure 14).

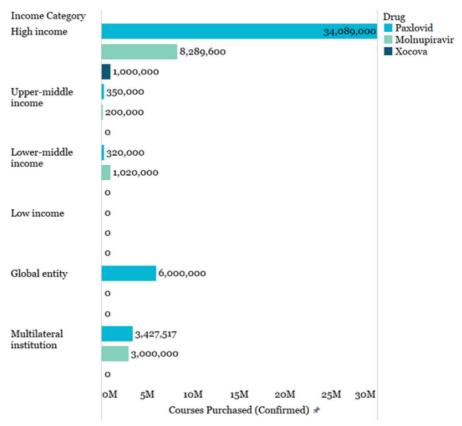
Global Fund has signed an <u>agreement</u> with Pfizer for the procurement of up to 6 million treatment courses of Paxlovid (nirmatrelvir/ritonavir). This will make the treatment available to all 132 countries eligible for Global Fund grants, subject to local regulatory approval and authorization. Pfizer expects supplies of Paxlovid to become available in 2022 dependent upon regulatory approval and country demand. This builds on Global Fund and other partners' announcement at the Second Global Summit to support test-and-treat programs in over 20 LMICs.

UNICEF has <u>announced</u> a supply agreement with Pfizer for 4 million courses of Paxlovid, dependent on "country demand, clinical recommendations, and necessary approvals." Pricing information is not publicly available. Merck has also allocated 3 million courses of molnupiravir to UNICEF throughout the first half of 2022 "for distribution in more than 100 low- and middle-income countries following regulatory authorizations." At the Summit, Merck committed to make another 2 million courses available to USAID at the company's "best access price."

Africa CDC has <u>signed</u> a memorandum of understanding (MOU) with Pfizer to make Paxlovid available to countries on the continent at cost. After the announcement of the MOU, Zambia has <u>announced</u> plans to begin procuring Paxlovid.



Figure 14. Oral therapeutics purchases by country income category



Source: COVID GAP analysis, updated April 17, 2023

Both Merck and Pfizer have licensed their oral therapeutics to 35 manufacturers each. All licenses from Pfizer are through the <u>Medicines Patent Pool</u> (MPP), while Merck has issued eight direct voluntary licenses to generic manufacturers in India in addition to 27 sublicenses via the MPP (Figure 15 and 16).

Figure 15. Licensed generic manufacturers for COVID-19 oral therapeutics *MPP sublicensees and voluntary licenses*

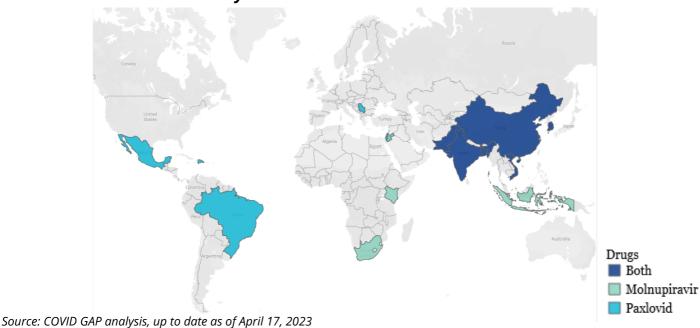
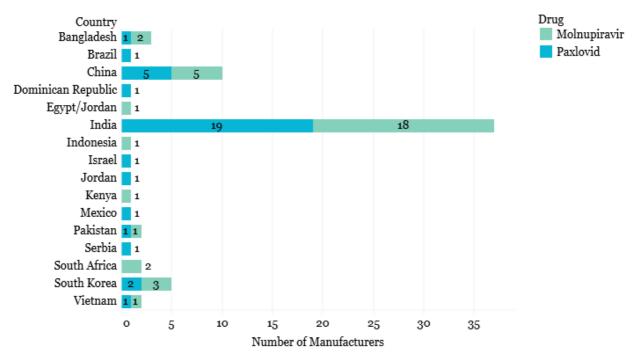




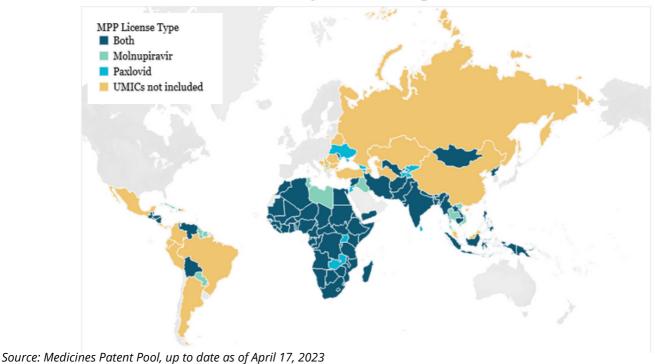
Figure 16. Number of licensed manufacturers by country and drug



Source: COVID GAP analysis, up to date as of April 17, 2023

The licenses through the MPP cover only a subset of countries for distribution. Merck recently amended its license agreement to include Thailand. Merck's deal covers 106 low- and middle-income countries and Pfizer's deal covers 95 low- and middle-income countries (Figure 17). Both licensing deals left out some notable upper-middle income countries, shown in yellow in the map below.

Figure 17. Country inclusion in the MPP sublicenses for distribution Which countries are covered by MPP licensing deals?



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While both the treatment and diagnostic pillars of ACT-A remain underfunded, scaling up access to test-and-treat capabilities is a challenge. A joint <u>initiative</u> between USAID, UNITAID, and other multilateral organizations will support LMICs in building robust test-and-treat capabilities within their health systems. Pfizer and Merck's supply forecasts for 2022 remain the same, and the demand for generic therapeutic options is weak given the current prices of oral therapeutics. The Clinton Health Access Initiative (CHAI) has put <u>ceiling price</u> commitments in place to provide generic Paxlovid for under \$25 USD per treatment course. Further regulatory support is needed from the US FDA and WHO to speed up the availability of affordable, quality assured generics. Existing test-and-treat strategies built by the Global Fund, PEPFAR, and the US President's Malaria Initiative (PMI) to address malaria, HIV/AIDS and other infectious diseases provide instructive examples and could be leveraged to increase access to COVID treatments. For more analysis and recommendations on how to improve access to oral therapeutics for COVID, see our recent report <u>Pills to People</u>.

5. Oxygen

Oxygen, currently the most frequently used treatment for COVID-19, is included in the ACT-A therapeutics pillar. ACT-A 2022 targets for oxygen include the supply of essential medical oxygen to 6 to 8 million severe and critical patients by September 2022. However, <u>reports</u> of oxygen shortages continue.

PATH provides <u>estimates of COVID-19 oxygen needs</u> for LMICs (which can be viewed by country and income group) based on the number of confirmed COVID cases and assumptions about how many of those cases will require oxygen. The tracker does not include data on available supply or shortages within LMICs.

As the February 2022 <u>African Union Statement on Access to Medical Oxygen</u> notes, supply of oxygen cylinders and ventilators is not the only issue. Barriers to oxygen access in many LMICs include lack of spare parts to repair equipment, insufficient piping and storage infrastructure, and a lack of financing to implement national oxygen plans and create oxygen systems so countries can meet their own oxygen supply needs.

Recent funding updates:

- Of the \$3.5 billion requested by ACT-A for the therapeutics pillar (which includes \$2.5 billion expected to come from donor countries, as tracked in this report), \$1.4 billion is requested to support oxygen supplies in 2022.
- Unitaid, which chairs the ACT-A Oxygen Emergency Taskforce, <u>recently announced</u> a \$56 million contribution to increase access to medical oxygen but the pillar has been largely unfunded by donor countries.
- The US Government <u>committed \$75 million</u> in December 2021 to USAID's Rapid Response Surge Support effort, which included oxygen production and delivery.
- The Clinton Health Access Initiative (CHAI) has <u>received</u> \$25 million to assist 9 countries in developing long-term oxygen solutions.

Overall, there is very little public data available on real-time oxygen needs (including actual supply, demand, and shortages). This remains an important gap in the data.



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Acknowledgments:

The authors are grateful to the entire COVID GAP team for their input, and particularly thank Katharine Olson for her support in data collection and management, Rianna Cooke for her support in developing and updating the data visualizations, and Melissa Estrada for her design support.

This report and related COVID Global Accountability Platform (COVID GAP) activities are supported by funding from the Bill & Melinda Gates Foundation and The Rockefeller Foundation. The content and recommendations in this report is an independent effort by COVID GAP, without approval by any external parties. It does not necessarily reflect the viewpoints of funders or any person who contributed to discussions with the COVID GAP team that helped inform this report.



