

ROTAVIRUS VACCINE INTRODUCTION AND COVERAGE

THE STATUS

Just over half of all countries in the world have introduced rotavirus vaccines into their immunization programs (as of March 2022). Introductions of rotavirus vaccines have especially climbed since 2013—from 53 to 114. With recent introductions, an estimated 77 million infants—or 57% of the world’s infants—now live in countries or subnational regions that have introduced rotavirus vaccines (see Figures 1–3).

Many of the countries with the highest burden of rotavirus disease have recently introduced rotavirus vaccination into their national immunization program—such as India, Pakistan, Afghanistan, and the Democratic Republic of Congo. Of other high-burden countries, Nigeria has been approved by Gavi, the Vaccine Alliance, to introduce the vaccine with its support.

FIG.1 PERCENT OF INFANTS WORLDWIDE WHO LIVE IN COUNTRIES THAT HAVE INTRODUCED ROTAVIRUS VACCINES⁽¹⁾

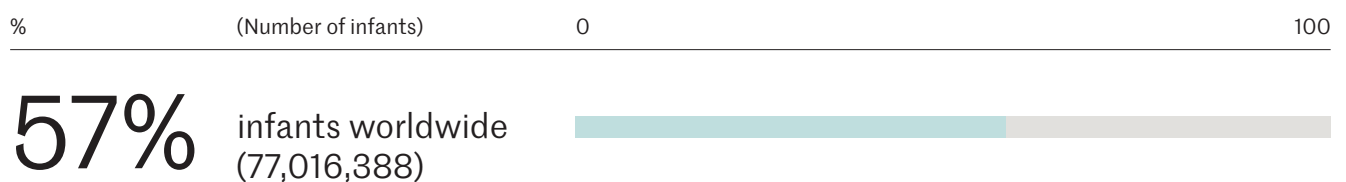


FIG.2 NUMBER OF COUNTRIES THAT HAVE INTRODUCED ROTAVIRUS VACCINE (BY MARCH 2022)⁽¹⁾

By level of introduction

114 countries
have introduced
rotavirus vaccines

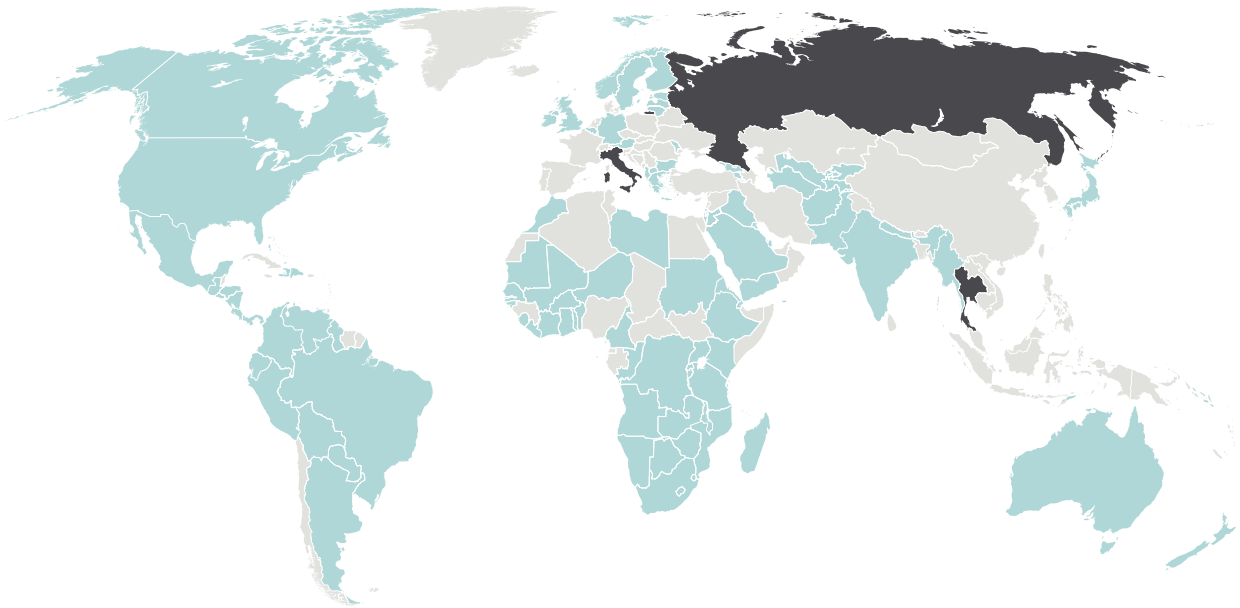
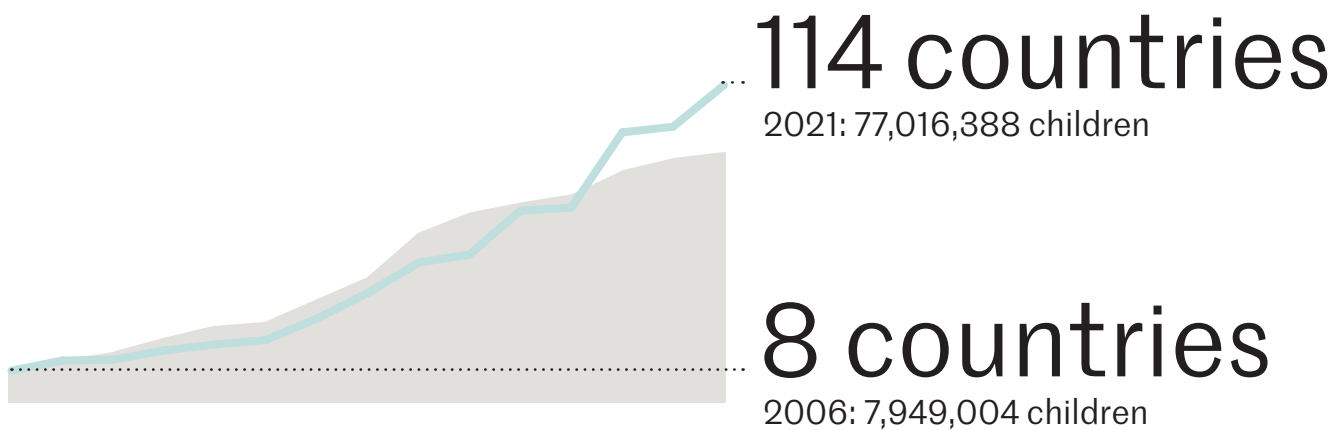


FIG.3 PROGRESS IN INTRODUCING ROTAVIRUS VACCINES SINCE 2006⁽¹⁾

— Countries that have introduced — Children with access

2006 2011 2016 2021 Number of countries and children with access



COUNTRY SUCCESS STORIES

Successful rotavirus vaccine introduction in key high-burden countries significantly expands global access to rotavirus vaccines.

India: Indigenous vaccines

With a birth cohort of more than 25 million, India's decision to introduce rotavirus vaccine represents a major step forward in increasing global access to these vaccines. The Government of India began phasing the introduction of rotavirus vaccines in 2016, with partial support from Gavi over several years, ultimately achieving universal roll out in 2019.

A major factor was the development, clinical testing, and licensure of two locally-produced vaccines, ROTAVAC® and ROTASIIL®. Another key step was the establishment of a rotavirus surveillance network in the early 2000s, which greatly increased evidence of the prevalence and severity of rotavirus in Indian children.

Pakistan: Provincial leadership

While the national immunization advisory committee recommended that the country include rotavirus vaccine in its national immunization program in 2011, the actual introduction of rotavirus vaccine in Pakistan began as an initiative by the Punjab provincial government. With strong political leadership, Punjab began a pilot introduction in six districts in 2016 using its own funds. After Pakistan secured Gavi support for nationwide introduction, the vaccine was rolled out in the rest of Punjab province in 2017.

This phased approach allowed time for each province to expand its cold chain capacity and make other preparations to ensure a successful introduction. The last province, Baluchistan, launched the vaccine in early 2018.

Afghanistan: Goal-driven

Afghanistan had a high estimated rotavirus mortality rate (98 per 100,000) and among the world's highest number of annual rotavirus-related deaths, totaling about 4,800.⁽²⁾ Given the substantial burden of disease and the Ministry of Public Health's priority to reduce child mortality by one-third by 2020 (from the 2003 level), the country successfully applied for Gavi support in 2017 and introduced the vaccine in 2018.

The Democratic Republic of Congo: Adaptations

In 2019, the Democratic Republic of Congo (DRC) took action to reduce its high rotavirus mortality rate (103 per 100,000) by introducing rotavirus vaccine into its routine immunization schedule. The DRC became the first Gavi-supported country to introduce ROTASIIL® in Africa. While the introduction required vast adaptations to inform local decision-makers on the products, cold chain implications, benefits, challenges, and administration, it also paved the way for other countries to benefit from this new heat-stable vaccine.



Onid Ali, aged four months, receiving ROTAVAC® in Assam, India

REMAINING GAPS

Despite significant progress in the past several years, just under half of the world’s countries have yet to introduce rotavirus vaccines. This leaves an estimated 58.6 million children—43% of the world’s infant population—without access to rotavirus vaccines (See Figure 5).

low- and lower-middle-income countries is the availability of external financial support for the vaccine. Of the countries in these income brackets that have adopted the vaccine, 89% received support from Gavi for the vaccine introduction (see Figure 4)⁽³⁾.

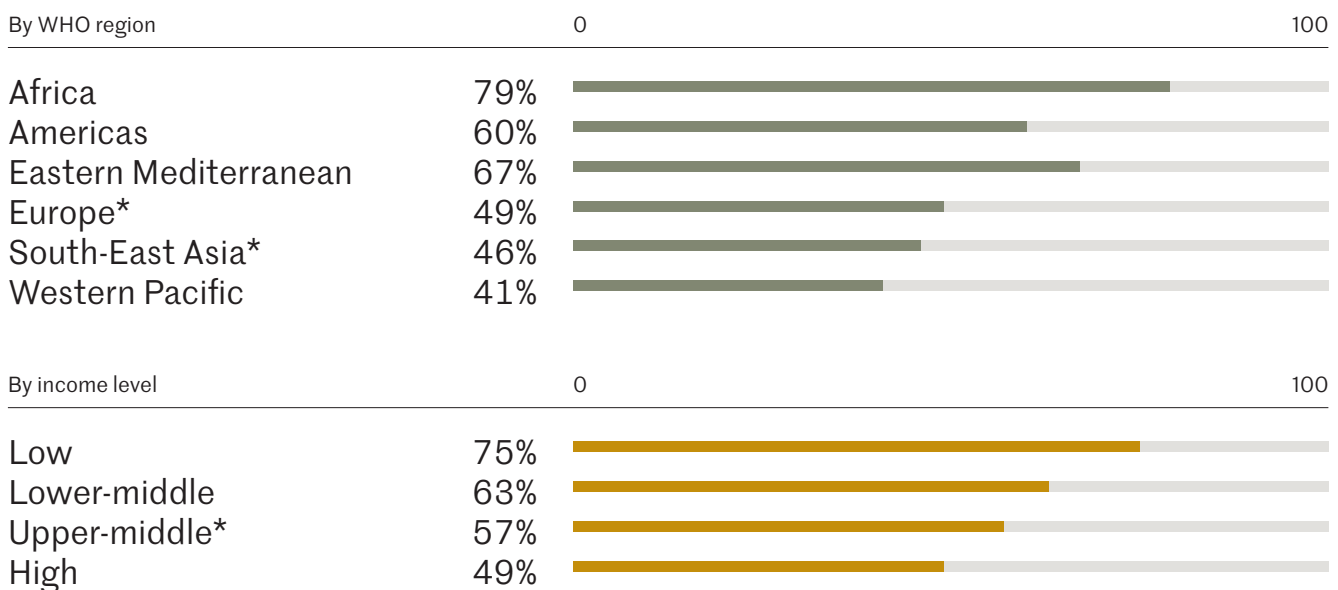
Pace of vaccine introduction

Rates of vaccine introduction vary greatly by region and income level. Unlike with most new vaccine introductions in the past 20 years, the leaders in introducing rotavirus vaccine have been low-income and lower-middle-income countries in Africa, the Eastern Mediterranean region, and Latin America, while upper-middle- and high-income countries have fallen behind. For example, just under half of European countries, normally leaders in adopting new vaccines, have introduced rotavirus vaccines into their national immunization programs (see Figure 4). A key reason for the higher rates of rotavirus vaccine introduction in

Barriers

Middle-income countries that have never received Gavi support must finance the vaccine on their own and often pay higher prices than those offered to Gavi due to a policy called “tiered pricing” (see page 6). Only 52% of middle-income countries that were never eligible for Gavi support have introduced the vaccine. In addition, the COVID-19 pandemic significantly impacted routine immunization programs globally—halting new rotavirus vaccine introductions and disrupting access. Other barriers to countries introducing rotavirus vaccines include a lack of public awareness of the disease (see page 6).

FIG.4 PERCENT OF COUNTRIES THAT HAVE INTRODUCED ROTAVIRUS VACCINES (2022)⁽³⁾

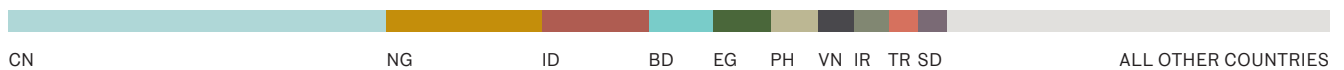


*Include regional introductions.

FIG.5 WHERE CHILDREN WITHOUT ACCESS TO ROTAVIRUS VACCINES LIVE

Worldwide, 58.6 million children lack access to rotavirus vaccine. Most of them live in just 10 countries.

71% of all children without access live in 10 countries⁽¹⁾
(41,727,596 children)



% of children without access	Country (Number of children without access)		% of children without access	Country (Number of children without access)
29%	China (16,810,000)		4%	Philippines (2,135,056)
12%	Nigeria (6,918,846)		3%	Vietnam (1,583,012)
8%	Indonesia (4,750,192)		3%	Iran (1,531,607)
5%	Bangladesh (2,867,382)		2%	Turkey (1,305,825)
4%	Egypt (2,544,165)		2%	Sudan (1,281,573)

BARRIERS TO THE INTRODUCTION OF ROTAVIRUS VACCINES

Some barriers to countries introducing rotavirus vaccines are common to new vaccines, while others are specific to rotavirus.

Cost and financing

Prices on the global market range considerably, from under \$5 per course for Gavi countries to over \$180 per course in the U.S.⁽⁴⁾ The vaccine would increase some countries' entire vaccine budgets by up to 45%—a key reason that some middle-income countries have not yet introduced it, despite national advisory committee recommendations.⁽⁵⁾ Countries transitioning from Gavi support are concerned about having to eventually cover the entire cost, even at current Gavi prices. The arrival of lower-cost vaccines, including those produced in developing countries, on the global market may help reduce this barrier.

Perceived low burden

Public health authorities and the medical community are often unaware of the burden or potential severity of rotavirus gastroenteritis and thus may not consider the disease a priority. This is especially true in high- and middle-income countries with low diarrhea mortality.⁽⁶⁾ Perceptions that rotavirus disease is not severe and the lack of caregiver awareness about the disease accounted for more than half of all responses to a 49-country survey concerning barriers to rotavirus vaccine use.⁽⁷⁾ This perception, along with cost, has led policymakers in some countries to question the need for and value of rotavirus vaccination.

On the other hand, local studies of rotavirus burden and the potential epidemiological and economic impact of vaccination have been a major factor in introduction decisions in countries ranging from high-income Western European countries to low- and middle-income countries in Africa and Asia.

Vaccine safety concerns

Intussusception is a rare obstructed bowel syndrome that occurs naturally in infants regardless of rotavirus vaccination status. The very slight increase of this occurrence following rotavirus vaccination has been a factor in some countries deciding not to introduce the vaccine, particularly in some high-income countries where rotavirus diarrhea results in few deaths. A review of several studies found an excess risk of intussusception of 1–5 per 100,000 infants vaccinated in some settings, while it found no increased risk in others.^(7,8) This estimated increase in risk, compared to the increased risk of delaying or withholding vaccination, led WHO in 2013 to continue to recommend universal rotavirus vaccination and to lift the originally recommended age restrictions. (For more about this topic, see brief on Rotavirus Vaccine Safety.)

Programmatic challenges

The need to expand cold chain capacity to accommodate rotavirus vaccines has delayed introduction in some countries.⁽⁹⁾ Malawi's existing cold chain capacity was only 50% of what was needed for rotavirus vaccine introduction.⁽¹⁰⁾ Gavi-eligible countries can receive support to expand their cold chain systems. In addition, new vaccines are available in multi-doses vials, reducing their storage volume but presenting other programmatic challenges (for product details, see brief on Current and Upcoming Rotavirus Vaccines).

ROTAVIRUS VACCINATION COVERAGE

Rotavirus vaccination coverage varies widely (see Figure 6). The COVID-19 pandemic has greatly impacted routine immunization and data collection. Across the world, vaccination coverage for all routine immunizations has decreased in 2020, including for rotavirus vaccine. Attention and research is needed to regain lost ground and continue the work to increase coverage.

Countries that were phasing in use, such as Pakistan and India, were shown to have low coverage, although this rate is now higher as the vaccine is programmatically established. Countries with recent introductions may also have low coverage since it often takes a few years to fully integrate a new vaccine into a routine immunization program.

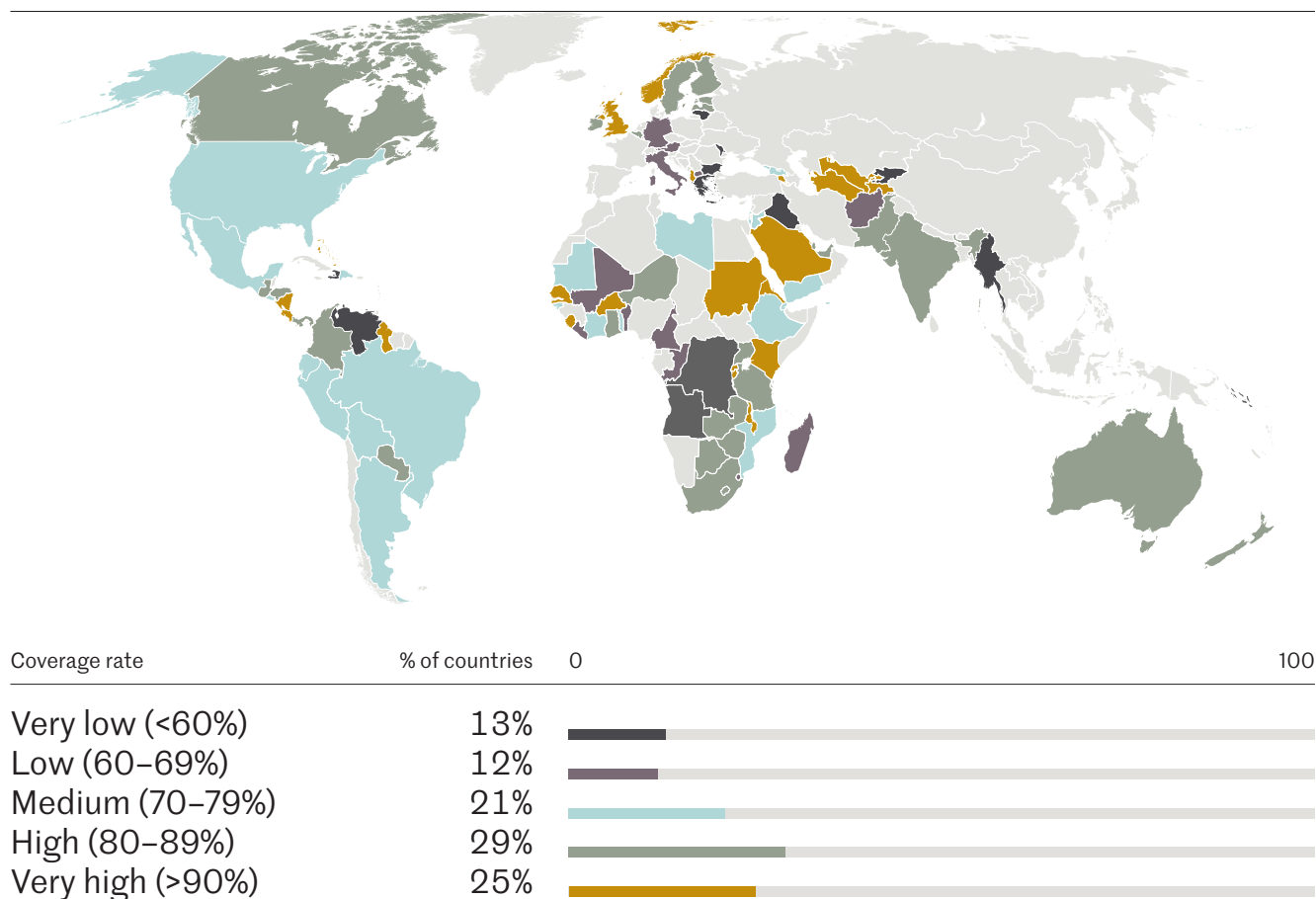
Taking into account countries that haven't

introduced the vaccine, plus current coverage, an estimated 60% of all infants are currently unvaccinated.

While low coverage rates may reflect overall weaker immunization programs, most countries with unsatisfactory rates perform better with other vaccines, such as DTP-containing vaccines.⁽¹¹⁾ Some African countries have large gaps in coverage between rotavirus and DTP3 vaccines, while others have achieved equally high coverage with rotavirus vaccine.

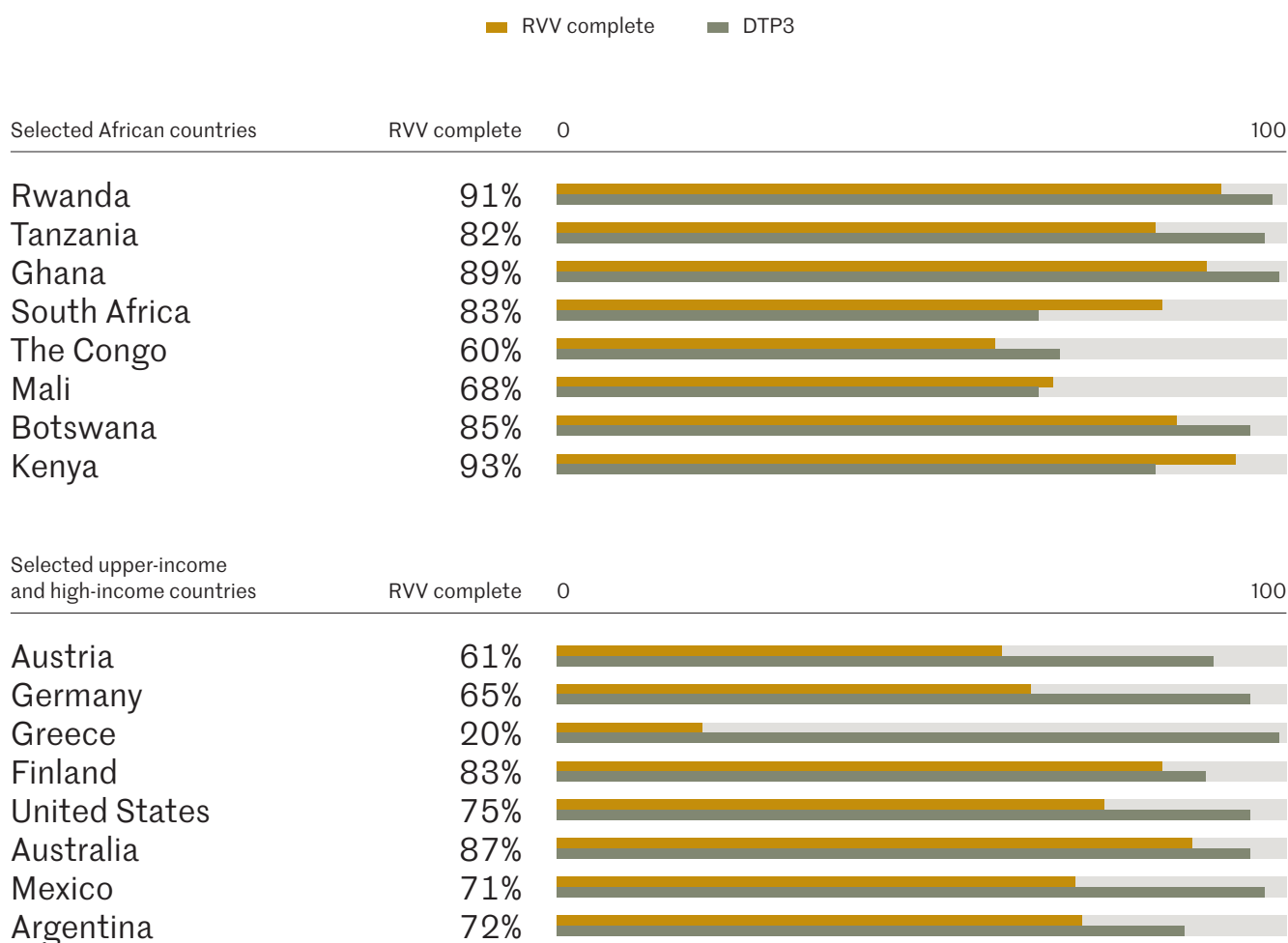
Some of the greatest gaps in coverage between rotavirus vaccine and other routine vaccines are in Europe and the Americas, including some countries that introduced the vaccine more than 10 years ago (see Figure 7)⁽⁶⁾.

FIG.6 ROTAVIRUS VACCINE COVERAGE RATES IN COUNTRIES THAT HAVE INTRODUCED THE VACCINE (2020 WHO-UNICEF ESTIMATES)^{(12)*}



*Map shows some countries that have recently introduced and have not fully scaled up coverage.

FIG.7 COVERAGE RATES OF ROTAVIRUS VACCINE (RVV) VS. DTP3 IN SELECTED COUNTRIES (2020 WHO-UNICEF ESTIMATES)⁽¹²⁾



REASONS WHY ROTAVIRUS VACCINATION COVERAGE IS OFTEN LOWER THAN OTHER ROUTINE VACCINATIONS

Continuation of age restrictions

WHO initially recommended age restrictions for rotavirus vaccination, limiting the first dose to before 15 weeks and the last to before 32 weeks to minimize the risk of intussusception, but these restrictions were lifted by WHO in 2013 to increase coverage. These age restrictions are still recommended by some vaccine manufacturers and many countries in Europe and the Americas with lower mortality rates have kept age restrictions for rotavirus vaccination, especially for the first dose, to minimize the slight increased risk of intussusception following rotavirus vaccination. This narrower window was found in a U.S. study to account for around one-third of the difference in coverage between rotavirus and DTaP vaccines.⁽¹³⁻¹⁶⁾

Perceptions of doctors and parents

Lingering safety concerns among healthcare providers and parents, and hesitancy about using a new live attenuated vaccine may help explain the many missed opportunities for rotavirus vaccination found in a U.S. study, which showed that many children received another vaccine but not the rotavirus vaccine during the recommended timeframe.⁽¹⁶⁾ In a 2010 survey of U.S. physicians, key barriers to use of the vaccines that they reported were their concerns about the vaccines' safety, safety concerns of parents—reported by 39% of family doctors and 15% of pediatricians—and parents' belief that the vaccine isn't necessary, reported by one-quarter of pediatricians.⁽¹⁶⁾ This may be similar in many European countries as well.

WHY HIGH ROTAVIRUS VACCINATION COVERAGE MATTERS

Outbreaks in countries where rotavirus vaccines have been used for over a decade show the importance of improving coverage, especially where access to care is limited.

Unvaccinated Children

In a study in Texas in the U.S., children with acute gastroenteritis whose regular health care provider had low (<40%) coverage rates for rotavirus vaccines, were more than three times as likely to be rotavirus positive as patients whose providers had $\geq 80\%$ vaccination coverage.⁽¹⁷⁾ These unvaccinated children were likely serving as a reservoir for the persistent, though lower level, transmission of rotavirus following introduction of the vaccines.

Vulnerable Populations

Rotavirus outbreaks continue to occur in the U.S., where the overall rotavirus vaccination coverage rate is 75%—18 percentage points behind DTP3 coverage, and likely lower in certain areas. Unvaccinated people with other health conditions are especially vulnerable. One outbreak in a subacute care facility for children in California had an attack rate of 96% (24 out of 25) among patients, 70% of whom hadn't received a single dose of rotavirus vaccine.⁽¹⁹⁾

Halving Hospitalizations

A study done by McGill University in Montreal, Canada of the impact of a free rotavirus vaccination program estimated that every 10% increase in coverage with two or more doses of rotavirus vaccine would result in a reduction of >8% in all hospitalizations of children due to gastroenteritis.⁽¹⁸⁾ If all areas in the study had reached the maximum coverage obtained of 72.5% with two vaccine doses, acute gastroenteritis hospitalizations would have declined by nearly half (47%).



Scientists at McGill University estimate how better coverage of rotavirus vaccine would improve impact.

WHO RECOMMENDATIONS FOR UNIVERSAL CHILDHOOD ROTAVIRUS VACCINATION⁽²⁰⁾

“Rotavirus vaccines should be included in all national immunization programmes and considered a priority, particularly in countries with high rotavirus gastroenteritis-associated fatality rates, such as in South and South-eastern Asia and sub-Saharan Africa.

“The use of rotavirus vaccines should be part of a comprehensive strategy to control diarrhoeal diseases with the scaling up of both prevention (promotion of early and exclusive breastfeeding, handwashing, improved water supply and sanitation) and treatment packages packages (low osmolarity ORS and zinc).”

From WHO's Position Paper on Rotavirus Vaccines, published in July 2021.

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ROTA Council thanks the following organizations for their support: Bharat Biotech, Bill & Melinda Gates Foundation, CDC, GSK, PATH, and Sabin Vaccine Institute. Suggested Citation: ROTA Council at International Vaccine Access Center (IVAC), Johns Hopkins Bloomberg School of Public Health. (2022). Rotavirus Disease and Immunization: Rotavirus Vaccine Introduction and Coverage.

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INTRODUCTION AND COVERAGE OF ROTAVIRUS VACCINE

KEY FACTS

Introduction

The number of countries that have introduced rotavirus vaccines into their national immunization program has nearly doubled in the past seven years, including countries with large birth cohorts, such as India and Pakistan. (See page 1)

Successes

The greatest uptake of rotavirus vaccines is in lower-income countries that receive support from Gavi, the Vaccine Alliance, especially across Africa, while many high- and middle-income countries have yet to introduce the vaccines. (See page 3)

Gaps

Despite recent progress, the majority of infants worldwide still live in countries or states that have yet to introduce the vaccine. (See page 4)

Barriers

Barriers to rotavirus vaccine introduction include cost and financial constraints, particularly in middle-income countries, a lack of data on or questions among policymakers about the burden and severity of the disease, and safety concerns. (See page 6)

Coverage

Rotavirus vaccination coverage lags behind coverage of DTP and other routine vaccines in countries at all levels of development, due largely to the continued adherence to age restrictions in some regions, and questions about the importance of the vaccine among health providers and parents. (See page 7)