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Geographical Diversification of Vaccine Production

Challenges for Africa and Latin America

WILLIAM D. SAVEDOFF

Abstract

Africa and Latin America are the world regions most dependent on importing vaccines. Though they differ demographically, economically, politically, and historically, many of the issues they face when seeking to promote vaccine production are similar. In this regard, they have much to learn from each other in terms of options and strategies.

After characterizing the relevant differences and similarities between the two regions, this paper argues that negotiating and implementing regional agreements is the most reliable way for each region to promote vaccine production compared to alternatives. It describes some of the more prominent regional vaccine initiatives that are underway and outlines options for governing such arrangements based on regional experiences inside and outside health.

The paper argues that the most significant obstacle to promoting vaccine production is effective demand because most countries are too small on their own to support the scale required to motivate and sustain production. In addition, the prospects for regional or subregional agreements to assure producers that there will be sustained demand for their vaccines are unlikely due to the difficulties of establishing binding international pacts to pool purchasing in sufficient volumes. A second critical obstacle is an adequate number of individuals with the requisite skills for biomedical research, development, and manufacturing. Finally, without a high-quality and efficient regulatory systems, it is difficult for countries to assure vaccine quality, let alone attract private investors.

The paper concludes by reviewing some common strategies for promoting vaccine production, including actions on the demand side, supply interventions, and institutional factors. It considers the advantages of regional agreements and discusses characteristics for such agreements that are important to their success.

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Geographical Diversification of Vaccine Production: Challenges for Africa and Latin America

William D. Savedoff
Senior partner, Social Insight
savedoff@socialinsight.org

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CENTER FOR GLOBAL DEVELOPMENT
2055 L Street, NW Fifth Floor
Washington, DC 20036

1 Abbey Gardens
Great College Street
London
SW1P 3SE

www.cgdev.org

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Foreword

The COVID-19 pandemic showed how fragile global vaccine supply chains remain—and underscored the need for greater vaccine manufacturing capacity to respond to future pandemic threats. As high-income countries secured vaccine doses early, regions such as Africa and Latin America, which were almost entirely reliant on imports, were left waiting. In the aftermath, ambitious regional efforts to bolster manufacturing capacity on both continents, backed by international development partners, have been gaining momentum.

In this CGD policy paper, Bill Savedoff connects lessons across these two regions. Despite differing demographics, economies, and histories, they face strikingly similar challenges: limited market scale, shortages of skilled workers, weak regulatory capacity, and political fragmentation that undermines collective action.

As Savedoff argues, turning those aspirations into real progress will require far more than building new factories. The central constraint is that most countries are too small to guarantee the long-term demand certainty that vaccine producers require. Without binding regional agreements to pool procurement and finance vaccine purchases, even significant investments will fail to sustain production capacity. Progress will also hinge on strengthening regulatory systems, expanding biomedical training, and fostering biomedical innovation ecosystems.

Regional cooperation offers a clear path forward—but only if governments move from declarations of intent toward enforceable cooperation. Pooling demand, harmonizing regulation, and investing in workforce and infrastructure are slow—often arduous—tasks that can encounter significant political, economic, and structural roadblocks. Yet the paper argues they are the surest route to vaccine resilience before the next crisis strikes.

Janeen Madan Keller
Policy Fellow and Deputy Director Global Health
Center for Global Development

Introduction

The COVID-19 crisis exposed the degree to which most low- and middle-income countries are vulnerable to supply disruptions for critical vaccines, medicines, and medical supplies. During the crisis, countries with high incomes and/or domestic production were able to secure vaccines and medical supplies – or obtain them sooner – than countries that lacked these advantages (Glassman et al. 2022; Brown and Rosier, 2023). This degree of vulnerability generated numerous calls to geographically diversify production, particularly for vaccines,[1] which have proven to be extremely cost-effective interventions for averting premature death and disease (WHO, 2017; Ozawa et al. 2016).

Numerous regional and subregional initiatives to promote vaccine production[2] in new places have been announced in the last few years. The Partnership for Accelerating Vaccine Manufacturing (PAVM) – led by the African Union – aims for Africa to manufacture 60 percent of its vaccine needs by 2040. In Latin America, PAHO is leading a regional initiative to support the development of mRNA hubs in Brazil and Argentina. In 2021, Southeast Asian countries adopted a Vaccine Security and Self-Reliance Strategic and Action Plan (2021–25) to set priorities for regional cooperation. Gavi's African Vaccine Manufacturing Accelerator (AVMA) is already functioning, launched in June 2024 with US$1.2 billion in funding.[3]

Initiatives in regions with substantial domestic R&D and vaccine production such as Europe or Asia are going to be substantially different than efforts in regions with less capacity. This is particularly true for Africa which, as a region, imports almost all its vaccines. Quite a few countries in Latin America produce vaccines, but the region still imports more than 60 percent of its requirements. In addition, Latin America's reliance on external vaccine sources during health emergencies, such as the COVID-19 pandemic, is larger than for routine vaccines.

Africa and Latin America differ significantly regarding their demographics, economic resources, political affinities, and histories. But the questions they face when seeking to promote vaccine production are similar. They also have much to learn from each other in terms of the available options and possibilities of success.

Therefore, this paper addresses two questions:

1. What are the key differences between Africa and Latin America in terms of their capacities to become more self-sufficient in vaccine production?
2. How do these regional differences affect the kinds of policies, public programs, and regional agreements that could be successful?

1 For example, the WTO's director-general called for geographical diversification of vaccine production in a speech to European Union legislators on May 20, 2021. See https://www.latimes.com/world-nation/story/2021-05-20/wto-chief-calls-for-diversification-of-vaccine-production, accessed Feb. 5, 2025.

2 For this paper, the term "production" will refer to the entire sequence of activities from manufacture of Active Pharmaceutical Ingredients (API) to the completion of finished vials of vaccines. "Manufacturing" will refer to most of this process up through batch processing but exclude repackaging and fill and finish activities.

3 For additional examples, see the partial list provided in the appendix.

After characterizing the two regions, the paper describes some prominent regional vaccine initiatives and considers options for governing such arrangements. The paper then discusses the major obstacles to vaccine production and concludes by assessing some options to promote vaccine production through regional or subregional agreements.

The paper argues that the most significant obstacle to promoting vaccine production is effective demand because most countries are too small on their own to support the scale required to motivate and sustain production. In addition, the prospects for regional or subregional agreements to assure producers that there will be sustained demand for their vaccines are unlikely due to the difficulties of establishing binding international pacts to pool purchasing. A second critical obstacle is an adequate number of individuals with the requisite skills for bio-medical research, development, and manufacturing. Finally, without a high quality and efficient regulatory systems, it is difficult for countries to assure vaccine quality, let alone attract private investors.

Of the alternatives available to address these obstacles, strong regional agreements to combine resources, demand, creditworthiness, and regulatory capacity are the most promising. Technological advances can reduce the need for scale by, for example, routinizing manufacturing steps and diagnostic phases, but it cannot fully compensate for high-skilled workers or a strong regulatory system. Exports are another way to overcome hurdles related to demand within a country, but the scope for exporting depends greatly on the strategies of other much stronger regions, especially Asia.

Vaccine production and consumption in two regions

Vaccine production is a complex process that requires a substantial network of inputs, services, reputational devices, financial instruments, and inter-institutional arrangements to succeed. A critical aspect of vaccine production is society's very low tolerance for health risks associated with immunization (Plotkin et al. 2017). Vaccine producers must identify safety risks from the earliest stages of development and, even after approval and use, they must continuously monitor their vaccines to assure that risks to health do not materialize or are detected early and remedied at once.

A critical aspect of vaccine production is society's very low tolerance for health risks associated with immunization.

Among vaccines, some have more stable demand, such as those routinely administered to infants and young children for diseases like measles and pertussis. In other cases, vaccine production is financially and technologically problematic because of uncertain demand. With recent outbreaks like SARS1, Zika, and COVID-19, vaccine production requires an existing capacity to innovate and to rapidly analyze and develop new compounds. But lack of predictability also hampers response times when – once developed and authorized for use – the vaccines have to be manufactured at scale.

Finally, economic viability requires large-scale and efficient production. Facilities that produce less than 50 million vials per year are simply too small to be financially sustainable. The fixed costs of investment can be quite large, typically more than US$500 million for product development and another US$50 to US$700 million for facilities and equipment. Firms also face costs associated with obtaining regulatory approval and licensing in each country they wish to sell their vaccines (Ortiz-Prado et al. 2021). Estimates for producing a Measles-Rubella vaccine in Africa found that the combination of high fixed and operating costs would lead to a cumulative financial loss over 10 years of about US$100 million (GAVI, 2022). Despite this, some vaccines may be financially viable if they involve inexpensive and easy to apply technologies and/or do not face low-priced competition within existing markets (e.g., pentavalent vaccines).

For most countries, justifying the large investments and reaching the necessary scale would require exporting and, therefore, achieving internationally-recognized standards of efficacy, safety, and quality. For example, Bangladesh produces an oral cholera vaccine for domestic use but has been unable to sell it internationally because its regulatory authority is not recognized by WHO to have the required levels of competence (Shaikh et al. 2020; Greenhoe and Guzman, 2023). Finally, unless production is efficient, manufacturers will find it difficult to compete against established manufacturers already in the market (The Wellcome Trust et al. 2023).

Vaccine production involves many different tasks. For full autonomy, countries would need to ensure they have the capacity for research and development and clinical trials. They would also need manufacturers who could supply a range of inputs – from Active Pharmaceutical Ingredients[4] to glass vials. Alternatively, countries might accept some degree of reliance on producers in other countries, especially if they can negotiate binding international agreements. In such cases, a country might focus on clinical research or bulk production, while importing APIs or other critical inputs.

Comparing vaccine production and consumption between Africa and Latin America, therefore, requires more than a list of existing producers and current demand. It also requires information to assess the context within which vaccine production does (or can) occur and the supportive network of relationships between the institutions of science, engineering, manufacturing, public policy, medicine, international trade, and politics. The rest of this section summarizes these contextual and relational factors in terms of their impact on vaccine demand and supply.

Demand factors

Successfully promoting vaccine production in Africa and Latin America requires sufficient demand to justify the investment at scale. In rough terms, Africa's need for vaccines is larger than Latin America's because of its large and growing population. Africa's population is also younger, so it has

4 Active pharmaceutical ingredients are the chemicals or agents that are key to the vaccine's effectiveness. Other materials may be included in the production process, but they are less critical and tend to be available from a larger number of suppliers.

a disproportionate need for infant and childhood vaccines. By contrast, Latin America has greater need for vaccines against diseases found among older people (e.g., shingles). Latin America's higher income allows it to rely on its own financial resources to purchase vaccines rather than rely on foreign assistance.

Demographics and epidemiology

One of the largest differences between Africa and Latin America is demographic. Africa's population of 1.47 billion people is more than twice that of Latin America (about 680 million). Africa's population is also very young, with about 45 million births annually.[5] Children younger than 5 years make up 14.3 percent of the population, while the share of those over 65 years old is projected to grow slowly to just 5 percent in another 25 years (Aranco et al. 2022). By contrast, about 10 percent of Latin Americans are already over 65 years old, a population share that will double by 2050 (Aranco et al. 2022).

While both regions need a full range of vaccines, Africa's birth cohorts – roughly 4 times larger than Latin America and still growing over the next 35 years (see Table 1) – require more conventional vaccines to support childhood immunization programs. By contrast, Latin America as a region is facing declining demand for childhood vaccines and a relative increase in demand for vaccines against illnesses like shingles and seasonal flu which are more critical for older people.

Africa's birth cohorts – roughly 4 times larger than Latin America and still growing over the next 35 years – require more conventional vaccines to support childhood immunization programs

Other factors affecting vaccine requirements in the two regions are epidemiological. Africa has a higher burden of infectious diseases than Latin America.[6] Many infectious diseases that are insignificant in the world's highest income countries are widespread in Latin America and Africa. Developing new vaccines for these diseases, or improving existing ones, is important but not necessarily profitable. Some of the diseases of greater importance to these regions include malaria, dengue, chikungunya, yellow fever, and meningitis.

Economic resources

Economic resources affect whether the population's need for vaccines is translated into effective demand. Countries can enter longer-term commitments to purchase vaccines if they have higher

5 Hannah Ritchie and Edouard Mathieu (2023) – "How many people die and how many are born each year?" Published online at OurWorldinData.org. Retrieved from: 'https://ourworldindata.org/births-and-deaths' on May 1, 2025.

6 The large increase in infectious diseases in Latin America and the Caribbean in 2020 and 2021 was due to COVID-19, classified as a respiratory infection. The Haitian earthquake in 2010 accounts for the other short-term increase in disease burden visible in the chart.

national incomes, effective tax systems, higher public health spending and, for low-income countries, access to external funding.[7]

Overall, Latin America has more economic resources and higher spending on vaccines from domestic revenue than Africa. Latin America's Regional Domestic Product (RDP)[8] is about US$7.1 trillion compared to US$2.9 trillion for Africa. Given that Latin America has a smaller population, Latin America's RDP per capita is then US$10,800 compared to Africa's at US$1,960. Both regions exhibit extremely high income inequality across and within countries, allowing some countries to dedicate significant resources to immunization programs while others depend almost entirely on external assistance.

Africa relies more on external assistance to finance its vaccine purchases than Latin America. Overall, immunization programs in Sub-Saharan countries[9] cost about US$55 per surviving infant compared to US$213 in Latin America. But Sub-Saharan African governments only finance 45 percent of this expenditure, the other half is provided through development assistance. By contrast, Latin American governments cover 90 percent of their immunization expenditures, relying on development assistance for less than 1 percent of their programs (Ikilezi et al. 2021).

Because current technologies for vaccine production exhibit large economies of scale, effective demand is critical to promoting new sources for vaccines. On their own, most countries do not have large enough populations and effective demand to support vaccine production at efficient scales of production (The Wellcome Trust et al. 2023). More than half of Africa's 52 countries have populations of less than 15.4 million people (see Table 2). In Latin America, half of the 34 countries[10] have a population below 3 million. The countries that come close to having adequate populations to support vaccine manufacturing in conventional ways are Brazil (211 million) and Mexico (130 million) in Latin America, and Nigeria (228 million), Ethiopia (129 million), and Egypt (115 million) in Africa. Even so, their populations are significantly less than the world's major vaccine producers: India (1.4 billion), China (1.4 billion), the European Union (448 million), and the United States (335 million).

On their own, most countries do not have large enough populations and effective demand to support vaccine production at efficient scales of production.

7 Government budgets and development assistance are the main sources of funding for immunization programs in low- and middle-income countries. Out-of-pocket and private prepaid spending account for less than 10 percent in every region according to the data in Ikilezi et al. 2021.

8 Regional Domestic Product is calculated as the sum of the GDP of all countries in the region. A true measure of regional domestic product might be larger or smaller depending on the degree to which income to factors located in a given country derive from activities within or outside the region.

9 Data in Ikilezi, et al. 2021 provides aggregations by regions, but not for Africa as a whole.

10 Note that Latin America and the Caribbean has an additional 11 countries with populations below 1 million which have been excluded for the purposes of this analysis.

TABLE 1. Number of countries and population (in millions) by region, 2021

Region/Country	Number	Average	Total	Minimum	Maximum	Median
Africa	52	28.3	1,470.5	0.1	227.9	15.4
Canada	1	40.1	40.1	40.1	40.1	40.1
China	1	1,410.7	1,410.7	1,410.7	1,410.7	1,410.7
East Asia & Pacific	30	31.7	950.2	0.1	281.2	1.2
Europe & Central Asia	23	17.7	407.9	0.2	143.8	3.0
European Union + UK	28	18.5	517.2	0.6	83.3	9.4
India	1	1,438.1	1,438.1	1,438.1	1,438.1	1,438.1
Latin America & Caribbean	34	19.3	657.2	0.1	211.1	3.0
Middle East	16	18.6	297.1	1.2	90.6	8.5
South Asia	7	73.4	513.5	0.5	247.5	29.7
United States	1	334.9	334.9	334.9	334.9	334.9
World	217	41.4	8,037.4	0.1	1,438.1	6.5

Notes: Excludes countries with fewer than 1 million inhabitants. Regions correspond to the World Bank's regional classifications with the following modifications:

- Africa includes all of Africa, that is, Sub-Saharan Africa plus Morocco, Algeria, Tunisia, and Egypt
- Middle East includes all the World Bank's MENA countries except for the four countries in North Africa
- USA, China, India, and Canada are listed separately
- Europe and Central Asia excludes EU countries, which are classified as EUU
- European Union + UK includes 27 European Union members and the United Kingdom
- Bermuda is officially part of North America but is included in Latin America & Caribbean for this table.

Source: World Bank Development Indicators – https://databank.worldbank.org/reports.aspx

Supply factors

Vaccine supplies are highly concentrated. Ten out of twenty vaccines monitored by WHO are in markets in which the top 2 producers account for more than 70 percent of market share. These include vaccines for Measles-Mumps-Rubella, Yellow Fever, Human Papillomavirus, and BCG (for tuberculosis). Sub-Saharan Africa relies on manufacturers in India (55%) and Indonesia (10%) for 55 percent and 10 percent of their vaccines, respectively.[11]

On the supply side, reducing this reliance on relatively few foreign producers through promoting end-to-end[12] vaccine production requires human resources with a range of skills, a robust science and technology sector, engineering and manufacturing experience, the ability to perform clinical trials, and access to critical inputs and financing. Yet, Africa and Latin America are relatively weak in most of these areas.

11 Similar data is not available for the Latin America region due to the way that WHO aggregates its regions, including the United States along with all of Latin America in its Americas region.

12 "End-to-end" vaccine production refers to the entire chain of events required to develop vaccines from the earliest stages of research & development through clinical trials, manufacturing at scale, and delivery to healthcare providers.

Human resources and scientific output

Human resources are a critical factor in producing vaccines, and one which cannot be created by simply establishing a new training program. Rather, human resource development for vaccine production requires a range of skills and experience in research, specialized industrial processes, laboratory services, and manufacture of ancillary supplies. In this sense, broad-based investments in establishing an *ecosystem* for fostering skilled human resources is needed (GAVI, 2022). Technology transfer agreements can play a role in workforce development; however, countries still need people with the experience in research, development, good management practices, quality assurance, quality control, and other facets of vaccine production if they are going to be able to absorb techniques and training from such collaborations (WEF, 2024).

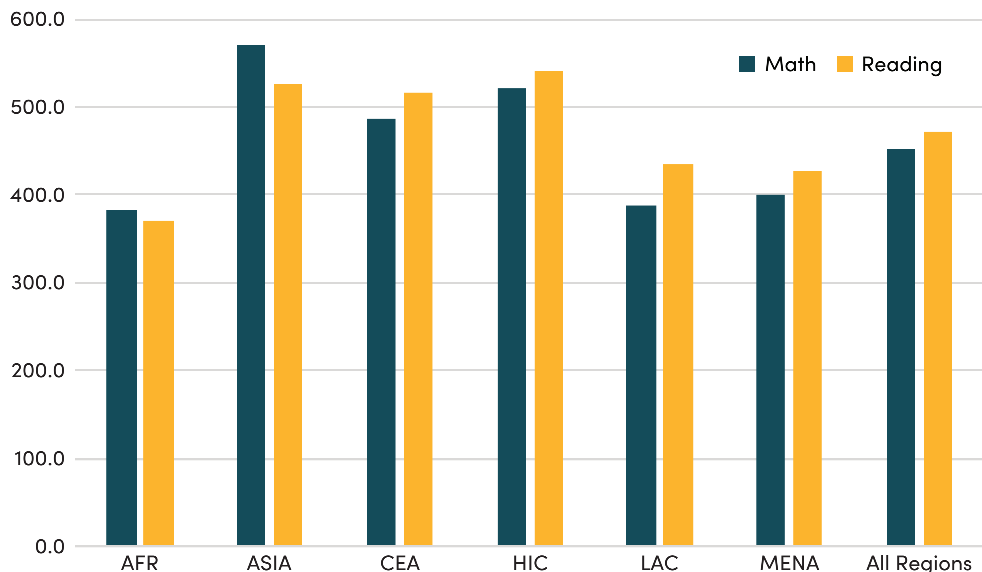
Detailed evidence is not available on the number of people with the kinds of qualifications required for vaccine production or on how many qualified people are needed for an active vaccine production center. Nevertheless, the following review of some aggregate data suggests that human resources could be the most significant constraint to expanding vaccine production in both Africa and Latin America.

Africa has the lowest rates of education enrollment, attainment, and quality among all regions. For tertiary education, which is a minimum requirement for key personnel involved in vaccine production, African enrolment was less than 10 percent of the tertiary-age population in 2021, compared to 50 percent in Latin America and 80 percent in Europe and North America. This comparison suggests that Latin America is better prepared to support vaccine production, but the tertiary enrolment rate overstates its advantage. First, average educational achievement across 16 Latin America countries, as indicated by median math and reading scores, is quite close to the average for 14 African countries (see Figure 1).[13] Second, Latin America lags Africa with respect to English language proficiency. A study of 19 countries found that Europe, Asia, and Africa all had higher English Language proficiency than Latin America (Teferra et al. 2022).

An indication of the human resource supply is the amount of scientific output. Despite having 18 percent of the world's population, Africa only produces about 3.5 percent of the world's scientific articles in biology and biomedical sciences. Latin America does somewhat better; with 8 percent of the world's population, it generates about 5.3 percent of these publications. The corresponding scientific output for Europe, the United States and China (which have world population shares of 5.6, 4.2, and 18 percent, respectively), is 21.6, 14.8, and 25.6 percent of the world's biological and biomedical literature (see Table 2).

13 For a list of countries, see Appendices.

FIGURE 1. Average of median math and reading scores at 4th grade by region



Notes: Scores based on TIMMS and PIRLS in various years, 2011 to 2014.
Source: (Patel and Sandefur, 2020).

FIGURE 2. Average of percent above benchmark by region

Notes: Scores based on TIMMS and PIRLS in various years, 2011 to 2014.
Source: (Patel and Sandefur, 2020).

As a result of these limits, Africa has only 198 researchers per million people, 20 times less than the US and the UK which have more than 4,000 researchers per million people. While figures are not available for Latin America as a whole, one of the better educated populations in the region, Chile, has 428 researchers per million – one-tenth of the US and UK rate (UNESCO UIS Statistics, 2025).

TABLE 2. Vaccine supply factors for selected countries and regions

Selected Countries/Regions	Share of 4th Graders Above Math Benchmark (%)	Doctoral Graduates 2017	Share of World Doctoral Graduates	Publications	Share of World Publications	Vaccine Manufacturers (Special Reports on AFR and LAC)	Vaccine Manufacturers (WHO Purchase Database)	mRNA Companies
Africa	–	–	–	15,127	3.5%	14	4	–
Sub-Saharan Africa (incl. ZAF)	–			3,118	0.7%	7	–	0
Algeria	–	n/a		571	0.1%	2	–	0
Egypt, Arab Rep.	–	n/a		3,749	0.9%	2	1	0
Morocco	26	n/a		772	0.2%	2	–	0
South Africa	–	2,815	0.7%	3,118	0.7%	3	1	0
Tunisia	35	n/a		696	0.2%	1	1	0
European Union		*79027*	18.1%	94,328	21.6%		20	*42*
France	–	13,583	3.2%	8,956	2.1%		2	5
Germany	97	28,404	6.7%	14,744	3.4%		1	11
Netherlands	99	4,747	1.1%	4,249	1.0%		2	5
Switzerland	–	4,150	1.0%	3,522	0.8%		2	5
United Kingdom	–	28,143	6.7%	12,494	2.9%		2	16
Latin America & Caribbean				22,951	5.3%	24	9	0
Argentina	51	2,314	0.5%	2,181	0.5%	5	1	0
Brazil	59	21,609	5.1%	12,960	3.0%	6	4	0
Chile	81	697	0.2%	1,480	0.3%	0	–	0
Colombia	49	770	0.2%	1,450	0.3%	3	–	0
Costa Rica	71	108	0.0%	222	0.1%	0	–	0
Cuba	–	n/a		168	0.0%	3	2	0
Mexico	67	9,310	2.2%	4,490	1.0%	4	1	0
Canada	–	8,003	1.9%	8,439	1.9%		1	11
China	–	56,464	13.4%	111,794	25.6%		25	34
India	–	28,778	6.8%	21,881	5.0%		11	6
Japan	99	15,674	–	14,351	3.3%		1	7
Korea, Rep.	–	n/a	–	9,875	2.3%		1	21
United States	96	71,042	16.9%	64,422	14.8%		11	123
World	–	421,000	100.0%	436,530	100.0%		116	244

Sources:

- 4th grade test scores from Patel and Sandefur 2020.
- Doctoral Graduates from World Population Data.
- Share of world publications refers to biological and biomedical articles and is provided by the National Science Foundation analysis of international scientific publications.
- Vaccine manufacturers - first column from (Global Health Consulting, 2022; The Wellcome Trust et al. 2023). Second column from WHO Vaccine purchasing database.
- mRNA companies from www.beacon-intelligence.com on a slide at a WHO presentation downloaded from https://cdn.who.int/media/docs/default-source/immunization/pdvac/pdvac-2023/04_manufacturing_strategy_in_africa_panel_1__121223-merged.pdf on 3/10/2025.

Vaccine manufacturers

Both regions have some vaccine manufacturing, many collaborations with multinational corporations to produce vaccines, and even more activity related to specific phases of vaccine production such as clinical trials or Fill and Finish (F&F). Nevertheless, data on firms, factories and agreements is not readily available due to complex corporate structures and reticence to share what companies consider proprietary information. Still, it is possible to make some assessments based on trade data and surveys. These sources tend to agree that vaccine production capacity in Africa is minimal, and that capacity in Latin America is significant. Yet neither region has substantial vaccine capacity relative to the largest producers, i.e., China, Europe, India, and the United States.

One source of information that provides a common base for international comparison is vaccine manufacturers who sell internationally and are listed in WHO's Vaccine Purchasing database. That source indicates the presence of 4 vaccine manufacturers in Africa and 9 in Latin America. This contrasts with 20 in the European Union, 25 in China, 11 in India and 11 in the United States. Of course, this excludes manufacturers who produce only for domestic markets.

African manufacturing

In Africa, a 2022 survey identified 13 vaccine manufacturers of which three were in South Africa, two each in Algeria, Egypt, and Nigeria, and one each in Ethiopia, Morocco, Senegal, and Tunisia. Ten were involved in F&F, while five had the capacity to produce drug substances (DS) and three were engaged in Research & Development (R&D). The technology platforms range from live-attenuated and inactivated viruses through mRNA. The vaccine produced by Institut Pasteur de Dakar is the only one which is prequalified by the World Health Organization (WHO) (The Wellcome Trust et al. 2023).

At the end of 2022, two of these firms were not producing vaccines and one was only importing vaccines for distribution (Institut Pasteur Morocco). Two firms were engaged in F&F for a single vaccine: COVID-19 (Aspen of South Africa and Saidal of Algeria). Another four firms produced a single vaccine, manufacturing drug substances and conducting F&F for rabies, yellow fever, and BCG vaccines. Three firms produced five or more vaccines while also demonstrating capacity for all phases of vaccine development (R&D, DS, and F&F), namely Afrigen (South Africa), Biovac (South Africa), and Innovative Biotech (Nigeria).

Latin American manufacturing

In Latin America, a 2022 survey identified 19 public and private organizations manufacturing vaccines. Five were in Brazil, four in Argentina, three in Colombia, two each in Cuba and Uruguay, and one each in Mexico and Nicaragua. Latin American manufacturers use many technology platforms including inactivated virus, subunit protein virus, attenuated virus, particles similar to the virus, and mRNA. Five manufacturers in the region were producing the BCG vaccine, 7 were producing pentavalent vaccines, four were producing influenza vaccines, three were producing

the pneumococcal vaccine, 2 were producing vaccines for HPV and for Yellow Fever, and one was producing an MMRV vaccine (see Appendix).

At least eight of these manufacturers, in Argentina, Brazil, Colombia, Cuba and Mexico, have the capacity to produce active ingredients as well as conduct F&F, including for BCG, pneumococcal, yellow fever, and influenza. Fourteen of them are engaged in bulk production (see Appendix). However, this may give a misleading impression of self-reliance when it comes to emergencies or supply disruptions. For example, Brazil produces more than half of the vaccines for its domestic immunization programs, but more than 90 percent of its domestic production relies on importing active ingredients. In addition, more than three-quarters of those ingredients come from just two countries, China and India (Tonini et al. 2023).

"Innovation Hubs" and national innovation systems

Countries with strong research, product development, and commercial application of knowledge tend to have multiple characteristics which, when combined and well-articulated, create a self-sustaining ecosystem for innovation and investment. This has been analyzed in many ways, including innovation hubs (Malik et al. 2021), regional innovation systems (Guzman et al. 2024; Asheim and Gertler, 2006), national innovation systems (Lundvall, 2016), big science organizations (Li-Ying et al. 2022), and country capabilities (Maloney, 2017; Cirera and Maloney, 2017). These approaches share a common perspective that many complementary factors are required to support successful knowledge-based sectors like vaccine production. Nevertheless, they vary regarding such things as the significance of different factors, the importance of geographical proximity, the role of the public sector, etc.

A rough overview of each region suggests that only a handful of places could be characterized as having adequate mix of factors to constitute such hubs or innovation centers for vaccine production. In Africa, South Africa has the elements of an innovation and production hub for vaccines between the manufacturing capacity and academic resources available in Pretoria and Cape Town. Cairo also has the elements of a major center for vaccine production. Both potential hubs are still at an extremely small scale relative to major centers in high-income countries, China, and India. Other possible centers in Africa are limited. For example, Nigeria has some of the technical capacity and vaccine production but lacks substantial university centers, infrastructure, and regulatory capacity.

In Latin America, Argentina, Brazil, Cuba, and Mexico have end-to-end vaccine production capacity in places that also have universities, research centers, input suppliers, and public infrastructure, with internationally recognized regulatory authorities. These hubs are in Buenos Aires (mAbxience, ANLIS, and Sinergium Biotech), the Rio de Janeiro/São Paolo/Belo Horizonte triangle (Bio-Manguinhos/Fiocruz, Fundação Ezequiel Dias (FUNED), União Química), Havana (Biocubafarma), and Mexico City (BIRMEX). Colombia has many of the required features but would require substantial investment to reach the levels of these other hubs.

Supply and demand: Balances

Vaccines are part of a global market, which is dominated by high-income country multinationals, along with Chinese and Indian manufacturers. China and India are particularly important today because, out of 3,000 firms producing active ingredients, China accounts for almost half of them and India accounts for about one-fifth. In fact, API manufacturing is increasingly concentrated in low-cost Asian nations rather than highly regulated markets in the US and EU (Tonini et al. 2023).

The results of this market concentration can be seen in global balances of supply and demand. The world market for vaccines in 2023 was 7 billion doses of which half were for polio (OPV), COVID-19, and influenza. Excluding COVID-19, about 5.5 billion doses were sold, comparable to the level in 2019. The total value of these vaccines was close to US$80 billion, just under US$60 billion without COVID-19. This value is significantly higher than the US$40 billion in sales in 2019 due to a shift in composition toward higher cost vaccines, particularly HPV, shingles, RSV and mABS (WHO, 2025).

Vaccines are part of a global market, which is dominated by high-income country multinationals, along with Chinese and Indian manufacturers.

In 2023, the 10 largest vaccine manufacturers accounted for 73 percent of doses produced and 85 percent of the financial value. Ninety other manufacturers accounted for the remaining quarter of doses produced and about 15 percent of financial value. SII was the largest manufacturer, accounting for 22 percent of the market. Along with SII, four other top 10 companies are based in India (SII, BBIL, BioE, Haffkine and Biofarma). Four of the top 10 were based in high-income countries (Pfizer, Sanofi, GSK and Moderna), with CNBG-Sinopharm based in China. By value, the story is completely different, with six HIC-based companies accounting for more than 80 percent of all sales (Pfizer, Merck, GSK, Sanofi, Moderna, and CSL) (WHO, 2025).

Among the top 20 vaccines, nineteen had more than five manufacturers (Yellow Fever Vaccine only has four manufacturers). However, only two of these vaccines (for hepatitis B and seasonal influenza) had a diversified production base when defined as the top two firms producing less than half of the volume. Furthermore, only five vaccines have more than five prequalified manufacturers (for tetanus, polio diphtheria, pertussis, and seasonal influenza), a precondition for export.

WHO's vaccine purchase database anonymizes countries, making it impossible to relate the purchase information presented for 2023 with regional locations.[14] However, a GAVI report using data from 2022 provides some disaggregation that can serve the purpose (GAVI, 2022). Using population as a proxy for demand, WHO's vaccine purchase database shows that Asia produced more than 16 billion vaccines in 2022, relative to a population of 4.75 billion, while Europe produced

14 WHO's 2024 Global Vaccine Market Report provides a breakdown of regional sources and purchasers of vaccines in terms of shares, but not in absolute numbers of doses or value.

5.4 billion doses relative to a population of less than 1 billion. The Americas produced 5.6 billion doses for a population of about 1 billion; while Africa produced only 30 million doses relative to a population of 1.4 billion. If it were possible to disaggregate the "Americas" between the US and other countries, it would show that most of the vaccine production is in the United States with Latin America being a net importer.

Africa used US$1.4 billion of vaccines in 2022, of which it produced less than 1 percent. UNICEF purchases about half the vaccines used in Africa, with funds from GAVI (US$726 million in 2020) and other institutions (US$137 million). The remaining one-third is procured directly by African governments or through channels other than UNICEF, amounting to US$519 million, and is predominantly procured by North African countries and South Africa (GAVI, 2022).

African demand will increase because of population growth, rising survival rates, and the presence of many endemic infectious diseases. By 2040, the value of African vaccine procurement is projected to reach somewhere between US$2.8 billion and US$5.6 billion depending on demographic and economic trends. This corresponds to an increase from the current level of 1.3 billion doses per year to an estimate of between 1.6 billion and 2 billion doses in 2040 (GAVI, 2022).

In Latin America, Cuba and Brazil produce more than half of their domestic vaccine consumption while other countries rely mostly or entirely on imports. The degree of import-dependence in Latin America varies by vaccine. In 2022, Latin America had agreements to produce 683 million doses of COVID-19 vaccines which exceeded the demand by about 167 million doses. By contrast, almost all other vaccines with Latin American production were in deficit: Measles, BCG, Pentavalent, Pneumococcal, and HPV2 (see Table 3). Of the vaccines surveyed, Yellow Fever was the only one with excess regional production of 26 million doses relative to demand of 19 million doses.

TABLE 3. Vaccine supply and demand in Latin America, 2022 (millions of doses/year)

Vaccine/Disease	Supply	Demand	Surplus/Deficit[1]
COVID-19[2]	683	556	167
Measles (MMR/MMRV)	12	19	-7
Yellow Fever	26	19	6
BCG	7	16	-9
Pentavalent	4	31	-27
Pneumococcal Vaccine	16	33	-16
HPV[2]	8	18	-10

Notes:
[1]Does not necessarily equal the difference between supply and demand due to rounding.
[2]Depends on licensing and evolution of the disease in terms of how many boosters are required.
Source: Reproduced from Yellow House. "PROSUR STUDY". Mimeo.

Implications of expanding vaccine production for global markets

Efforts to promote vaccine production have implications for global markets which, in turn, will affect the sustainability of new locations for vaccine production. The world has excess production of some vaccines and deficits in others. Expanding supplies for vaccines that are in surplus could increase regional self-reliance but at the expense of putting other manufacturers out of business.[15] Alternatively, focusing on vaccines which are globally undersupplied may be easier due to less competition, while simultaneously increasing global resilience by increasing the number and geographical locations of vaccine producers.

According to a GAVI report, five vaccine antigens (pentavalent, IPV (for polio), Typhoid, Japanese encephalitis and measles) are well-supplied and increasing production could generate market problems (i.e., destructive competition) (GAVI, 2022). Global production of another five vaccines (cholera, measles-rubella, yellow fever, Ebola, and malaria) is relatively low or concentrated such that additional manufacturing capacity would be welcome. Finally, it concluded that production of improved vaccine products for four antigens (rotavirus, pneumococcal, HPV, and meningitis) would be helpful to global supplies (GAVI, 2022). Thus, decisions about which vaccines to produce will affect global markets, with implications for long-term success and costs.

Institutional factors

Institutional factors that affect vaccine production include regulatory capacity, transparent and efficient procurement systems, provisions for intellectual property, reliable legal frameworks for domestic and international contracting, information, and stable transparent governance. This section will focus on two particularly important factors: regulatory capacity and procurement. Without regulatory capacity, vaccine safety cannot be assured, and exports are constrained. Procurement systems may encourage or discourage sustained vaccine production, depending how they are structured and implemented.

Vaccine regulation

Most high-income countries have established high regulatory standards for vaccines to assure effectiveness and guarantee extremely low risks of adverse reactions. Avoiding adverse effects is important for social decision-making, i.e., deciding when benefits are worth the risks. However, driving the risk of adverse effects extremely low is also important to assure public cooperation and reduce vaccine hesitancy. Consequently, vaccine developers need to pass numerous hurdles, including initial demonstrations of effectiveness and safety in animals, controlled tests among human subjects, and then broad clinical trials, before the products are approved for widespread use. Alongside this testing process, producers need to demonstrate that they are using Good

15 This could lead to inefficiencies if the new vaccine production capacity is subsidized and higher cost than the vaccine production capacity that was pushed out of the market.

Manufacturing Practices (GMP) to ensure that product quality is reliable and consistent across batches. Finally, a rigorous regulatory system requires manufacturers to continue monitoring for changes in safety or efficacy that may arise.

WHO coordinates a system for reviewing and classifying the capacities of national regulatory authorities (NRAs). Initially, organizations were recognized as “Stringent Regulatory Authorities” if they met the highest standards. This category included most high-income country regulators. Among LMICs, there were four WHO-recognized SRAs: ANVISA (Brazil), COFEPRIS (Mexico), NMPA (China), and TITCK (Turkey). The SRA designation has been replaced by a different system which classifies NRAs (or regional regulatory authorities, RRAs) as “WHO Listed Authorities” if they meet standards “to support WHO recommended regulatory functions.” WHO Listed Authorities (WLAs) are classified using a Global Benchmarking Tool which has four degrees of maturity (see Box 1). An NRA is assessed relative to different functions and products. Thus, an NRA might reach the third level of maturity for vaccine production but not for medicines (WHO, 2021).

BOX 1. WHO definitions of maturity levels for medical regulatory authorities

The maturity of regulatory systems is divided into four levels, characterized as follows:

- **ML1:** some elements of regulatory systems exist;
- **ML2:** evolving national regulatory systems that partially perform essential regulatory functions;
- **ML3:** stable, well-functioning and integrated regulatory systems; and
- **ML4:** regulatory systems operating at advanced level of performance and continuous improvement.

Source: WHO, 2021, Glossary, p. 9.

Overall, Latin America has had a much stronger regulatory environment than Africa, though Africa has made rapid strides in the last five years. Prior to 2020, Latin America had three SRAs (Argentina, Brazil, Mexico) and Africa had none. As of December 2024, Latin America had globally recognized “Functional NRAs for vaccines” in Brazil, Cuba, and Mexico. Regionally recognized NRAs included Argentina, Chile, and Colombia. By contrast, at the end of 2024, Africa still lacked any regionally or globally recognized NRAs, though 8 of them (Egypt, Ghana, Nigeria, Rwanda, Senegal, South Africa, and Zimbabwe) had reached maturity level 3 and were in the process of improving their capacity.[16]

Latin America has a much longer history of producing vaccines (beginning in the early 19th century) and of establishing regulatory standards, especially after the creation of the Pan-American Health Organization in the early 20th century. Brazil, Cuba, and Mexico continued to develop strong regulatory systems throughout recent decades. Since 2010, PAHO has been formally guiding a

16 Definitions, lists, and explanations can be found online at https://www.who.int/initiatives/who-listed-authority-reg-authorities, last accessed May 4, 2025.

process to strengthen the region's NRAs. It identified eight NRAs that were judged to be among the region's best performers. PAHO has coordinated a process of benchmarking, information sharing, and technical exchanges using the regional reference NRAs to demonstrate best practices for guaranteeing quality, safety and efficacy of medicines (PAHO, 2021).

The African Medicines Agency (AMA), African Vaccine Regulatory Forum (AVAREF), and African Medicines Regulatory Harmonization (AMRH) have initiatives underway to strengthen the continents' regulatory authorities. The AMA is focused on improving and harmonizing regulation of medical products across African Union members. The AVAREF is focused on increasing the efficiency of clinical trials, while the AMRH is aiming to improve the environment for pharmaceutical producers, designating 11 regulatory authorities to lead a process of improving regulatory capacity (The Wellcome Trust et al. 2023).

African NRAs have been supported by many organizations over the years, including the EU, Gavi, UNICEF, and WHO. African countries are now taking a more proactive role in this process. As of February 2025, seven African NRAs that have reached Level 3 Maturity signed an agreement to support stronger regulatory systems throughout Africa, streamline approval processes, encourage mutual reliance on regulatory decisions, and create an enabling environment for local production of vaccines.[17]

Government and regional procurement

Procurement is critical to vaccine production because of tradeoffs among its many goals. In the short-run, procurement is about obtaining good quality vaccines for a low price. However, in the long-run, procurement decisions affect such things as the reliability of supply, the degree of competition, the price level, and quality. Buyers have few options when procuring vaccines if they represent a small share of the market and if they are not creditworthy. On the other hand, they can strongly influence the market if they are procuring large volumes or high value products and can guarantee timely payment. Aggregating demand to have more purchasing power and better credit are reasons that regional procurement can be an effective public policy tool.

Buyers have few options when procuring vaccines if they represent a small share of the market and if they are not creditworthy.

One of the most successful programs for pooling procurement of vaccines is UNICEF. It is active in almost all aspects of vaccine production by forecasting and aggregating demand, raising funds, and handling procurement and logistics. UNICEF has played a significant role, in combination with the

17 "Landmark Agreement Among Africa's Leading National Medicines Regulatory Authorities to Foster Collaboration," Africa CDC Press Release. https://africacdc.org/news-item/landmark-agreement-among-africas-leading-national-medicines-regulatory-authorities-to-foster-collaboration/ accessed on May 5, 2025.

Gavi Alliance, other international partners, and national authorities, in averting at least 37 million deaths in the first two decades of this century (Lindstrand et al. 2021; Shattock et al. 2024).

A more recent story of international cooperation, though with mixed results, was COVAX and the response to COVID-19. COVAX aggregated demand for COVID-19 vaccines before they existed. It coordinated donations from richer countries to finance vaccines for poorer ones and participated in an Advanced Market Commitment to accelerate vaccine development. It failed relative to its ambitions when high-income countries and major vaccine-producing countries (China and India) prioritized their own populations, and when donors failed to fulfill their comments for donations (Glassman et al. 2022; Brown and Rosier, 2023).

Latin America has a relatively long and solidly institutionalized experience with both utilizing and governing regional procurement. PAHO's 35 members authorized it to create a "Revolving Fund" in 1979 to help countries purchase vaccines, syringes and cold-chain equipment (Cornejo et al. 2023). The PAHO Revolving Fund works with countries to project demand, aggregates demand in bulk procurement processes in which it negotiates, contracts, and plans for deliveries. It assures that vaccines meet the necessary quality standards. PAHO then pays suppliers under an agreement requiring countries to reimburse the institution within 60 days. Based on the positive experience of the Revolving Fund, PAHO also established a "Strategic Fund" in 2000, using a similar model to purchase medicines and health supplies on behalf of member countries.

The Revolving Fund and Strategic Fund help countries by assuring good credit, achieving better prices, providing highly specialized procurement services, and arranging delivery. These are functions that countries could do for themselves, but probably not as effectively or at similarly attractive prices. Latin American countries sit on PAHO's Board, so that they have input into supervision of the funds and can influence policies. They also ultimately pay for the vaccines, giving them a strong stake in the success of the program (DeRoeck et al. 2006).

In Africa, GAVI and UNICEF are the main institutions engaged in regional procurement. UNICEF procures and distributes about two-thirds of the vaccines used in Africa, most of which are paid for by the Gavi Vaccine Alliance. Unlike PAHO's revolving fund, however, African countries that receive UNICEF-procured vaccines have more limited voice in governance and rely mostly on donations to finance the purchases.

However, this is changing, with more active country engagement. In 2021, the African Union (AU) established a stand-alone entity called the African Vaccine Acquisition Trust (AVAT) which purchased COVID-19 vaccines for AU members with US$2billion from the African Export-Import Bank (Afreximbank). Afreximbank acted as the main agent, receiving demand projections from countries, negotiating contracts with vaccine manufacturers, and handling financial and contractual elements of the process, while UNICEF provided delivery and logistics services. Using this experience, the AU assembly called for creating a "Pooled Procurement Mechanism" that will be

implemented through the Afreximbank with support from the UN Economic Commission for Africa. Depending on how it is structured and implemented, this regional procurement mechanism could achieve for Africa what the PAHO Revolving Fund has achieved for Latin America. Nevertheless, as long as funds used to procure vaccines come from donations, the mechanism may not follow priorities of African governments, undermining commitment to this regional approach.

While pooled procurement empowers buyers, leveraging this power can have unintended consequences if it drives prices below costs or otherwise jeopardizes the viability of vaccine manufacturers. To maintain economies of scale for any specific vaccine, the market cannot include too many producers. On the other hand, without more producers, it is hard to rely on competitive pressures to keep prices down. Government policies can shape the vaccine market through policies like information sharing, demand forecasting, and indicative priorities. More directive policies can also be used, including production target plans, setting conditions for initiating investments, privileging local production in procurement, or reserving procurement opportunities for winning bidders or prequalified firms. Interviews with firms currently producing vaccines for Africa or considering production in Africa valued the supportive policies like information sharing but were not in favor of more directive policies (The Wellcome Trust et al. 2023).

Regional policies and possibilities

The preceding discussion characterized the two regions in terms of their consumption and production of vaccines, along with the regulatory and procurement strategies. This section turns to the task of asking how regional or subregional agreements could diversify vaccine production, starting with a look at how well each region is already engaged and integrated internally. It then considers the relationships with extra-regional actors that are important to each region's capacity for obtaining vaccines. After considering some cross-national agreements, and the lessons they provide, the section concludes by assessing options for promoting vaccine production in each region.

Regional integration

Despite political aspirations and sporadic initiatives, both Africa and Latin America have historically had stronger economic and political ties with high-income countries outside their regions than within. Africa has had stronger links to Europe in terms of private sector engagement, foreign aid, technology transfer and political agreements. Latin America has exhibited greater engagement the United States, its multinational corporations as well as academic and research centers. In the case of regional organizations like PAHO, the

> Africa and Latin America have historically had stronger economic and political ties with high-income countries outside their regions than within.

Organization of American States and the Inter-American Development Bank, the United States has played a significant role in negotiating policies and setting agendas. When it comes to economic supplies, however, Asia has become the main source for both regions. This is notable in almost all regions for APIs which are largely produced in China and India. For Latin America and Africa, India is the most significant source of low-cost generic vaccines.

By many measures, Africa and Latin America are weakly integrated. Both regions are tied to the world economy largely as suppliers of agricultural and mineral exports, relying on manufactured imports from both high-income regions like the United States and Europe as well as middle-income countries like China. Economic ties within each region are quite low: the sum of exports and imports as a share of regional GDP is less than 6 percent in both regions, compared to shares as high as 19 percent within Europe and Asia (see Table A1 in Appendix 2).

In some regards, Latin America has stronger regional ties than Africa. Despite linguistic diversity among its indigenous populations, the majority – and particularly those living in urban areas – tend to speak Spanish or Portuguese and have common cultural referents from the colonial mixing of African, Hispanic, and Indigenous roots. As a facet of this intraregional "glue," Latin America is the only region in the Global South that has more intraregional mobility among university students than inter-regional mobility. About 42 percent of Latin American university students studying outside the country of their birth were studying in other Latin American countries. For Africa, the figure is substantially less than one-third (Teferra et al. 2022).

Latin America has also been a pioneer in the creation of regional institutions, although often led and assisted by the United States. The first official international health organization, the Pan-American Health Organization, was established in 1902. It was only in 1920 that the League of Nations was established with its Health Bureau and not until after World War II that WHO and its regional offices for Africa, the Middle East, Europe, Asia, and the Western Pacific were created. (PAHO became the WHO regional office for the Americas). The first of the regional development banks for low- and middle-income countries was the Inter-American Development Bank, established in 1961 (followed by the creation of the African Development Bank in 1964 and the Asian Development Bank in 1966). Latin America was also the first region to eradicate smallpox and polio, an indication of its practical capacity to engage in regional cooperation.

Despite these strong regional ties, Latin America has been regularly torn by political polarization. The ideological and practical policy differences between factions are hard to characterize in simple ways. But the result is that collaboration at a high level among political leaders is severely constrained (Ordóñez, 2023). Were it not for the existence of institutions like PAHO and the IADB, it is unclear whether countries in the region would have cooperated much during the COVID-19 crisis.[18]

18 Observations by the author in 2020–2022 as a participant in negotiations to create advance market commitment agreements, negotiate vaccine purchases, and begin efforts to build regional manufacturing capacity.

Africa is more diverse than Latin America in many ways. Linguistically, more than 1,000 languages are spoken but, furthermore, the colonial era left the continent divided between countries where English, French, German, and Portuguese are used as national languages. Africa has more countries than Latin America (52 compared to 34) and divisive politics. Still, it appears that African leaders may recognize the imperative of collaborating as a region more than Latin America (Ordóñez, 2023). The AU assumed a prominent role during the COVID-19 pandemic and has obtained member status of the G20. The AU is also promoting a continent-wide free trade agreement which, unlike the efforts in Latin America, is envisioning more complete integration with free movement of people and goods within a system of harmonized trade and intellectual property laws (Ordóñez, 2023).

The AU, AfDB, and UNECA, are monitoring progress toward greater regional integration with an index that has five dimensions related to infrastructure, free movement of people, trade, production, and macroeconomic policy (African Union, 2020). The most recent report began with optimistic pronouncements about the future, citing the endorsement by 50 countries to establish the African Continental Free Trade Area (AfCFTA). If successful, the AfCFTA would create a free trade zone with more than a billion people. However, the report (prepared prior to COVID-19) acknowledged that regional integration in Africa is low overall, especially in terms of production and infrastructure. It noted that South Africa leads all the other countries in terms of integration, with Kenya taking a distant second place. Among the least integrated countries are South Sudan and Eritrea.

Current policies and initiatives

Current initiatives for promoting vaccine production are taking place at the national, regional, and international levels. They can be divided into categories based on the role of the public sector, whether a country intends to manufacture vaccines on its own, partner with private firms, or focus on creating conditions favorable to private vaccine producers. The purely public sector approach was common in the 20th century but has become rare in recent years because of rapid technological advances in bio-medicine and a shift in political policies favoring a limited government role in economic activities.

Brazil exemplifies this shift. It initially built research and vaccine production capabilities within the public sector but has transitioned toward partnering with international vaccine producers. Brazil's Bio-Manguinhos is a division of the Fundação Oswaldo Cruz (Fiocruz) and is linked to the Ministry of Health. It was founded in 1976 to assure vaccines for Brazil and has also exported vaccines through PAHO and UNICEF. It has collaborated with Glaxosmithkline (GSK) on several initiatives since entering an agreement to supply Oral Polio Vaccine in 1985. This collaboration has continued with technology transfer agreements for Hib, MMR, and rotavirus. Bio-Manguinhos also partnered with Oxford University and AstraZeneca in developing a vaccine for COVID-19. It is one of two Latin American centers being supported by WHO/PAHO for mRNA technologies.

The Egyptian Vaccine Manufacturers Alliance (EVMA) is an example of governments supporting private sector expansion. The Alliance's public goals are self-sufficiency, capacity to respond to health emergencies, and contributing to Africa's overall vaccine production goals. It aims to create conditions that encourage vaccine production domestically by providing information, facilitating coordination, and promoting partnerships. It is engaged with at least 10 multinational vaccine producers, such as SII and Pfizer, five local manufactures (BGP, VACERA, VBC< GYPTO Pharma, EVA Pharma and Gennvax), and numerous international organizations including Africa CDC and the Gavi Alliance. The Alliance is also taking an active role in training and in financing fellowships in fields related to biomanufacturing.

Since the COVID-19 crisis, numerous initiatives have sought to promote vaccine production by creating more centers with genetic platform capacities, such as mRNA. In addition to the technology transfer agreements that started during the crisis, WHO is promoting mRNA vaccine technology transfer hubs throughout the world. In Latin America, Argentina and Brazil have been selected to participate and PAHO (WHO's regional office) is implementing it as the Innovation and Regional Production Platform. In Africa, WHO is supporting South Africa, Egypt, Kenya, Nigeria, Senegal, and Tunisia. The South African Hub, led by Afrigen, is already operational.

Currently, the most significant international efforts for Africa include the African Vaccine Manufacturing Accelerator (AVMA) and the Regionalized Vaccine Manufacturing Collaborative (RVMC). The AVMA is a Gavi program, financed with up to US$1 billion. It is a demand-side instrument that will pay firms upon WHO prequalification and "top-up" prices for doses. It is giving priority to vaccines with drug substances manufactured in Africa. RVMC's activities mainly involve information sharing, coordination, and strategy. The RVMC has its secretariat at the Coalition of Epidemic Preparedness Innovations (CEPI) and other founders included the Word Economic Forum and the United States National Academies of Medicine.

Implications and strategies

Strategies to promote vaccine production can take many paths because the processes are complex, the range of potential vaccines is large, and markets are already supplying a wide spectrum of vaccines and inputs. Depending on national priorities, countries may be more concerned with medical countermeasures (MCM) to outbreaks of epidemics and other health emergencies or focused on building capacity to produce routine vaccines. They might focus on substituting domestic production for imports or seek to develop capacity in producing entirely new vaccines. Even after selecting a particular vaccine, countries have options regarding how to start: beginning with F&F capacity and working backward toward production of APIs or beginning with R&D and working forward toward API manufacturing, batch production, and F&F.

Choosing goals and strategies must consider such things as existing market conditions, the innovation ecosystem, and market projections. In this regard, all options are not necessarily on

the table. Choosing a strategy requires an iterative process between investment strategies, vaccine market conditions, and political goals. Furthermore, choosing to pursue national strategies or regional collaboration entails many of the same issues and tradeoffs. For example, it may be preferable for national strategies to focus on building capacity for routine vaccines with predictable demand, while focusing regional initiatives on building the collective capacity to respond to medical emergencies. The uncertain demand for outbreaks of old and new infectious diseases can be more efficiently shared across countries.

Along with setting goals and selecting strategies, implementation and financial sustainability are critical to expanding vaccine production. WHO's GAP Program sought to expand global capacity to produce pandemic flu vaccines, beginning in 2006 with nine countries. However, by 2016, only three countries had any significant production (Brazil, India, and Korea). In 2022, Moderna announced plans to invest US$500 million in a vaccine manufacturing plant in Kenya, only to scale back the project and ultimately abandon it two years later (Mercurio, 2024). On the other hand, the Gavi Alliance successfully expanded the number of vaccine suppliers for its programs from five in 2001 to 18 in 2021; and half of the current manufacturers are based in Africa, Asia or Latin America (GAVI, 2022).

These factors – tradeoffs among goal and strategic options, along with the challenges of financial sustainability and implementation – are significant for both Africa and Latin America. However, differences between the two regions have implications regarding which goals are more relevant, what strategies are available, how likely financial sustainability can be reached, and the likelihood of successful implementation. Political commitments and support also play a significant role in both regions, for domestic vaccine production policies and even more for the ability to craft regional subregional vaccine production agreements.

Differences between the regions have implications

Vaccine production is a global industry and, therefore, many of the opportunities and policies available to Africa and Latin America will be similar. Nevertheless, the regional differences also lead their goals and opportunities to diverge.

The *demographic and epidemiological profiles* in Africa are more favorable for routine childhood vaccines, given that its population is very young and aging slowly. Latin America, by contrast, is going to be experiencing much greater demand for vaccines that protect older cohorts, both because its population is older and because it is aging quickly.

Supply capacity in Africa is much more limited than in Latin America. Existing *vaccine producing capacity* is significant for only a few sites and relatively few vaccines. Educational attainment levels, which are a prerequisite for training a skilled workforce, are also quite low in Africa. These factors are going to require much larger up-front investments by African nations than in Latin America.

Latin America has substantial production capacity in four countries, and it may be able to address human resource constraints through investments focused on biomedical training and improving schooling quality.

Strong regulatory systems are also a prerequisite for expanding regional vaccine production. In this regard Latin America is reasonably prepared because WHO's Listed Authorities include several Latin American countries and dozens of prequalified vaccines are already being produced. Africa's most advanced NRAs are at the ML3 maturity level and have programs in place to improve their capacity. But as of today, only one vaccine produced on the continent has met standards for WHO prequalification. Proposals to expand the pathways for regulatory approval would also benefit regional initiatives like those within Africa and Latin America. These proposals note that the current system is slow and poorly resourced and alternatives are needed to address the growing volume of new vaccines, new production facilities, and cross-country variation in willingness to accept risks. (Halabi and O'Hara, 2024).

These characteristics of demand, human resources, and regulatory capacity affect domestic vaccine production strategies as well as regional ones. For regional or subregional collaboration, however, countries need to create institutions which command broad support and legitimacy. Otherwise, agreements will not provide the credible sustained financial commitment required to create and sustain vaccine production. Latin America seems more advanced on this score, with more than a century of cooperation through PAHO and a half century of pooling vaccine procurement through the PAHO Revolving Fund. Nevertheless, current political divisions are an obstacle to designing new agreements or greatly expanding them.

Despite Africa's shorter experience with regional collaboration, current conditions seem more favorable to regional engagement as demonstrated by the proactive stance of the AU during the COVID-19 pandemic and current momentum toward a continent-wide free trade agreement. Substantial funding is also being made available to Africa from Europe and the Gavi Alliance. However, this funding is double-edged. External funds may accelerate efforts to promote vaccine production in Africa but without greater financial commitment from member countries, such an expansion may not be sustainable.

Effective demand may be the largest obstacle.

Thus, Africa and Latin America face four significant obstacles to expanding vaccine production in their regions. Effective and sustained demand may be the largest obstacle. Most countries are too small to reach the market scale required for support vaccine production, both in terms of volume and of credible commitments – backed by funding – to purchase vaccines. The second most significant obstacle to diversification is on the supply side, related to human resources. Few countries have enough individuals with the requisite skills, from college-level biomedical sciences through active post-doctoral research, capable of engaging with

the international scientific community in numbers sufficient for a vibrant and growing vaccine production hub. This second obstacle is affected by total population and quality of basic education that are needed to foster the critical mass of skilled workers required for vaccine production. The third most significant obstacle is regulatory nature. High quality and efficient regulatory authorities are a critical factor in assuring the quality, efficacy, and safety of vaccines, as well as attracting private investment and technology transfers. Finally, political animosities, national chauvinism, and shortsightedness need to be overcome if countries are going to sign on to binding agreements that would allow them to reap the benefits of regional collaboration.

Demand strategies

A common feature of most countries in Africa and Latin America is their small populations. Yet options exist for countries to overcome the constraints of their limited populations. First, putting **more financial resources** behind vaccine purchases increases effective demand. Ethiopia has 129 million people, about the same as the population of France and Britain combined. However, Ethiopia's GDP of US$164 billion makes it difficult to pay the premiums that would be required to assure domestic vaccine production. (By contrast, the GDPs of France and Britain, when combined, are US$6.4 *trillion*). This is the kind of stark international inequity that conditions the geographical distribution of effective demand for vaccines and vaccine development.

A second strategy for assuring adequate demand at scale is to promote domestic vaccine production with the expectation of **exporting to other countries and regions**. An internationally-recognized regulatory authority is a prerequisite for exporting, in order to reassure buyers that vaccines are safe, consistent and reliable. Small countries – like the Netherlands and Cuba – have succeeded in developing strong local vaccine production capacity. However, the Netherlands benefited from building its industry in the mid-20th century when resource requirements were far more limited and later by gaining access to the market and regulatory agreements of the European Union. Cuba also started in the mid-20th century and, initially, benefited from linkages to Soviet allies and financial support. Later, it leveraged its scientific, clinical, and engineering capacities to develop partnerships with countries that have access to large markets and large manufacturing facilities. Today, countries seeking to build vaccine production on an export strategy must contend with the presence of low-cost producers in the global market unless they are developing new technologies or new vaccines. For newer vaccines, they still must compete with other centers of scientific investigation linked with existing vaccine production centers.

A third strategy is to **develop strong regional or subregional procurement agreements** that can offer producers a large stable market. Africa has an advantage over Latin America in its overall size (1.47 billion people and growing at a rate of 2.3 percent, compared to Latin America which has 658 million and is growing by 0.7 percent annually). Meanwhile, Latin America has an advantage over Africa in terms of its purchasing power, with regional per capita income of about US$10,800 compared to Africa's US$1,960. Regional agreements are an effective way to realize

these advantages of scale; however, they can only be effective if countries accept terms that bind them to the agreement. Without such commitment devices it is difficult to convince investors and manufacturers that the creation of a regional market is real.

Though Latin American countries individually may have problems assuring sellers that purchasing agreements will be honored in a timely fashion, the region still has an advantage over African countries because the countries themselves are financing their purchases. African purchases gain credibility today from regional procurement by UNICEF but, in the medium-term, that channel is less certain to persist due to its reliance on external contributions.

Beyond addressing scale, regional agreements are attractive for several reasons. They can give priority to diseases that are more common or only experienced within the region, they can diversify demand risks across the region, and they can economize on fixed costs related to regulation, information, and infrastructure. A multiplicity of regulatory systems can be a particularly problematic hurdle for commercial manufacturers, even when they are interested in partnering with different countries. Regional agreements that allow procurement to recognize qualifications by NRAs in other regional member countries, therefore, can be an effective way to attract new production.

Supply strategies

On the supply side, three general approaches have been used to promote vaccine production: subsidies and incentives that engage the private sector, direct investments by governments, and international – especially regional – agreements.

Subsidy and incentive instruments can encourage the expansion of vaccine production on the supply side mainly by reducing costs. For example, government investments in education and infrastructure can expand the supply of skilled workers, lower the costs of transportation networks, and increase the reliability and availability of energy, water, and waste disposal. Governments can also promote the agglomeration of industries in geographically proximate locations through a combination of zoning, regulation, and infrastructure provision. Assisting domestic firms in negotiating partnerships with multinational companies that provide access to technology, training, and expansion of domestic capacities is another way that governments can encourage private expansion of vaccine production.

Direct investments are another category of supply strategies. Many countries have established state-owned firms to conduct R&D, produce DS, and complete vaccine production with F&F as a way of assuring supplies of basic vaccines for their populations. They also invest directly in schools, universities and research centers. Direct investment can be costly for countries that have difficulty mobilizing domestic revenue. It also entails risks of low efficiency when public management is weak.

Nevertheless, many success stories involve state-owned firms which either produce vaccines themselves or complement the private sector in important ways. The race to develop COVID-19 vaccines provided several cases where public seed money or parastatals made rapid progress possible. For example, the United States government established a Biomedical Advance Research and Development Authority (BARDA) in 2009 to address the emergence of new diseases and pandemics. In May 2020, BARDA collaborated with different parts of the US government in "Operation Warp Speed" to accelerate the development of vaccines, medications and diagnostic tools (Bonvillian, 2024). China also adopted a state-driven model that involved collaboration with businesses. The government's large public investments mitigated the risks facing companies, concentrated resources in the most promising candidates, and ensured wide sharing of information to improve collaboration across all actors (Hu and Chen, 2021).

Regional agreements are a third way to expand supply but, unlike agglomerating demand, subsidizing supply investments is often more difficult to achieve. Countries have experience with regional infrastructure agreements – such as the Itaipú Dam that provides electricity and other services to Paraguay, Brazil and Argentina or CERN which is a European collaboration in high-energy physics research. When these agreements are developed, the common interests in achieving the benefits are counterbalanced by national interests in being the host for facilities. Some agreements overcome this difficulty by signing binding agreements prior to choosing the locations of facilities, which are then chosen through a bidding process. Whatever method is used to overcome this problem, it is essential to have clear ways to equitably distribute benefits so that participation is more beneficial than default (The Yellow House, 2022).

Ingredients for successful regional approaches

While countries have options for promoting vaccine production, negotiating and entering regional agreements can substantially improve their chances of success. However, regional agreements are not without their costs or difficulties. Some ingredients that can improve the probability of reaching effective agreements are clarity regarding goals, specialization across countries, and governance that assures political buy-in through voice and representation.[19]

Promoting vaccine production is a high-level goal that countries seeking to develop a regional agreement need to elaborate at lower levels. For example, is the goal aiming for

- self-sufficiency in routine vaccines or readiness to produce vaccines in a pandemic?
- vaccines for children, the entire population, or the elderly?
- conventional vaccine platforms like attenuated virus or frontier technologies like mRNA?

19 A different set of ingredients for success was presented in a background paper prepared for an initiative to promote vaccine production in South America. It listed 6 lessons for successful regional agreements to promote vaccine production: political solidarity, appropriate procurement legislation, harmonized regulations or mutual recognition of regulatory authorities, adequate predictable funding, shared objectives, and fees or budget to cover administrative costs (The Yellow House, 2022).

A well-focused regional agreement – with a single goal – may be easier to develop because it would limit the range of commitments required of member countries. On the other hand, by including several goals, benefits can be spread across members and more opportunities for negotiation appear. This in turn can facilitate adherence to agreements. For example, a region could plan to invest in multiple platforms which are then bid out to member countries. In this way, a country has a chance of benefitting directly from investments in its own hub but also becomes dependent upon other countries for vaccines based on other platforms. This kind of specialization within the region can also increase resilience in the event of a new pandemic by assuring that several platforms and hubs are available to tackle the challenges associated with a new bacteria or virus. Unfortunately, it also runs counter to the benefits of physical agglomeration discussed earlier.

Governance is perhaps the most difficult part of establishing successful regional agreements. More than anything else, they require trust: trust that countries will abide by the agreement, trust that benefits will be shared equitably, trust that countries will not overly prioritize their own interests over others (especially during emergencies), trust that any future adjustments will be negotiated openly and even-handedly. While trust makes agreement easier, governance mechanisms always benefit from provisions to ensure that all members have input into decision-making processes, that agreements are managed transparently, and that provisions are enforced fairly. Agreements that are largely indicative or rely upon documents like Memoranda of Understanding are easier to achieve but tend to be less effective at assuring cooperation than those that are binding, like treaties.

As Africa and Latin America explore greater regional cooperation on vaccine production, they may want to consider some of the following recommendations that are derived from a variety of academic, official, and consulting reports (The Wellcome Trust et al. 2023; GAVI, 2022; CEPI, 2024a; 2024b; The Yellow House, 2022; Global Health Consulting, 2022; WHO, 2025).

- *Vaccines:* Focus on undersupplied and region-specific vaccines.

Some vaccines that are considered oversupplied include BCG, IPV, OPV, and even COVID-19 mRNA. Unsurprisingly, these are vaccines whose manufacturing is considered of low or medium complexity and for which demand is either stable (the first three) or has drastically declined (COVID-19 mRNA). Other vaccines with low or medium complexity for which there is room in the market include vaccines against cholera, Rotavirus, HPV, measles, Meningitis, and Yellow Fever. In the longer term, malaria, hexavalent vaccines, Ebola vaccines, and pneumococcal vaccines appear to be good candidates for expanding production without encountering problems in the global market. Vaccines for diseases like meningitis, malaria, Ebola, and Zika which are important to Africa and Latin America are also good candidates. Some vaccines, like those against shingles, are of greater importance to Latin America and its aging population while hexavalent vaccines are a priority in Africa given its large birth cohorts. Any decisions about promoting vaccines or platforms need to be monitored and regularly updated. In addition, analysis aimed at assessing future trends in demand

and supply are essential because investments in a particular vaccine can often take a decade to reach maturity.

- *Selectivity for locations:* Bid out hub investments with attention to diversification of platforms, vaccines, and country size.

Concentrating vaccine production in Brazil or South Africa could be detrimental to vaccine security for a variety of reasons. Giving other countries a role in phases of production (e.g., clinical trials) or establishing hubs for platforms that are not yet represented in the region are ways to encourage collaboration and foster positive dynamics of interdependence.

- *Strong procurement agreements:* Establish binding regional procurement agreements, including Advance Market Commitments.

While procurement agents like PAHO and UNICEF can often count on cooperation by offering attractive prices and inexpensive procurement and logistic services, their ability to negotiate good terms is stronger when the countries are legally bound to purchase through the agent. Without a binding commitment, defections are always possible, especially by large vaccine-producing members. Advance Market Commitments (AMCs) are powerful procurement tool to promote innovation and expansion of vaccine supply, but this instrument will fail without credible long-term sustained commitments for countries to abide by the AMCs terms.

- *Regulatory systems:* Strengthen NRAs with mutual recognition and specialization.

Activities required to satisfy regulatory authorities generate significant costs for vaccine production. These costs are justified when they ensure the quality, safety and efficacy of vaccines and maintain public confidence in vaccines. However, lowering these costs without jeopardizing vaccine quality, safety, and efficacy, can accelerate the availability of new vaccines and attract investors and firms into new vaccine markets. Improving the quality of NRAs is essential to improving regulatory efficiency. If, in addition, regional agreements can be negotiated for NRAs to have a process for recognizing vaccine qualification by their peers, or even to specialize in different kinds of vaccine regulation, countries will have a powerful instrument to encourage vaccine production within their region.

African and Latin American countries could also advocate for international action on expanding pathways for regulatory approvals. The current system based on requiring WHO prequalification and monitoring of NRAs is underfunded and slow. Either substantially new resources are needed to make this system more responsive and agile or alternative pathways, including mutual recognition accords and alternative evaluators need to be explored and implemented.

- *Human resources:* Increase training, establish conditions for retaining skilled workers, and encourage scientific exchange.

Investments in human resources tend to be undertaken at the national or subnational level. For example, South Africa explicitly adopted a strategy in 2001 to develop its biotechnology capacities and committed US$70 million to the effort. The government promoted regional innovation centers, funded post-doctoral work, and financed career opportunities for experienced and well-trained workers to encourage retention (The Wellcome Trust et al. 2023; Al-Bader et al. 2009).

Nevertheless, in specialized fields like biomedicine and immunology, countries would benefit if they could agree to share the fixed costs of establishing training centers. WHO has designated (and endorsed) Korea as the single global training hub for biomanufacturing skills. This hub was launched in 2024 in collaboration with the Asian Development Bank, the Inter-American Development Bank and the International Vaccine Institute with the goal of training people from low- and middle-income countries In vaccine and biopharmaceutical manufacturing skills (*Asia Education Review*, 2024). However, this global hub only has the capacity to train about 500 people each year. Thus, if Africa and Latin America want to accelerate their progress in building human resource capacity, they could consider investing in regional training hubs. Furthermore, by promoting exchanges among, and facilitating intra-regional mobility of skilled personnel, they can encourage more people to enter these fields, generating a larger skilled pool for the region as a whole. This appears to be particularly true in Latin America, where intra-regional training and mobility is quite high.

- *Partnering:* Negotiate with international firms for technology transfer on a regional market basis.

Current agreements for technology transfer are often negotiated bilaterally. Thus, for example, GSK agreed to transfer measles vaccine technology to Brazil on condition that Brazil will supply the Latin American market and not sign comparable agreements with other Latin American countries. Having been negotiated bilaterally, this can be seen negatively as an attempt by Brazil to control the Latin American market. However, if this had been negotiated openly as a regional deal, it might be viewed as one of many opportunities to bring vaccine production to the region. It is the latter dynamic that regional agreements can pursue as a way of improving production and trust in the regional market.

Conclusions

Countries in Africa and Latin America are almost entirely dependent on vaccine imports apart from a few countries in each region. Even those that produce vaccines rely heavily on importing drug substances, importing supplies, and negotiating agreements to transfer technology. Furthermore, relative to the countries that lead vaccine production globally, Africa and Latin America have small research and biomedical manufacturing communities and few innovation hubs. The possibilities of promoting vaccine production on a country-by-country basis are limited by the scale of national markets, limited numbers of skilled personnel, and weak regulatory authorities. Thus, regional or

subregional agreements are a promising way to promote vaccine production if countries can solve the political issues required to implement strong forms of cooperation.

Though Africa and Latin America are already engaged in many regional initiatives – and not just for vaccine production – regional cooperation and solidarity have not been strong. Latin America has more experience with regional collaborations, facilitated by longer periods of independence, common language, and common cultural referents. Nevertheless, much of the regional achievements were possible because of the engagement of the United States; and the current wave of political polarization has undermined the development of new regional solidarity initiatives. For the most part, African countries gained independence only in the last half of the 20th century, and they have substantial linguistic and cultural diversity. Nevertheless, compared to Latin America, they may have a greater sense of urgency in building a common continental approach to their development challenges.

To promote vaccine diversification, these regions would need to address a large range of issues to achieve:

- More reliable, long-term commitments to purchasing vaccines
- A larger pool of skilled human resources
- Strong regulatory systems
- Long term investment and incentives to promote innovation hub creation and growth
- Innovative partnerships within and beyond regional boundaries to gain access to technologies, best manufacturing practices, clinical trial networks, regulatory improvements, inputs, supplies, key medical ingredients, and distribution networks.

The most critical factor is probably the first one mentioned above, i.e., reliable long-term commitments to purchasing vaccines. Without a long-term sustained commitment to purchase vaccines, it is extremely difficult to justify investment – either public or private – in building the costly infrastructure and institutions for vaccine production. In this regard, Latin America is better positioned than African in terms of sustaining its own procurement. Most African countries depend on external funding from high-income countries for procuring vaccines, making demand dependent on external decisions more than domestic revenue mobilization and budgeting.

In both cases, regional agreements could make long-term commitments to vaccine purchasing more credible by diversifying risk, especially if the agreements include provisions to enforce payment by member countries. Regional agreements could also be more effective at improving human resources, increasing the efficiency of regulatory systems, promoting the growth of innovation hubs, and negotiating technology transfer agreements with leading multinational firms and vaccine-producing countries. Regional agreements may be difficult to negotiate and implement, but the only real impediments are national chauvinism and shortsightedness. The antidotes to these impediments are well-known: solidarity, appeals to a common cause, and enlightened self-interest.

Appendices

Appendix 1: Countries included in education quality comparison

Africa	Latin America and Caribbean
Burundi	Brazil
Benin	Chile
Burkina Faso	Colombia
Botswana	Costa Rica
Cote d'Ivoire	Dominican Republic
Cameroon	Ecuador
Congo	Guatemala
Morocco	Honduras
Niger	Mexico
Senegal	Nicaragua
Chad	Panama
Togo	Peru
Tunisia	Paraguay
South Africa	Trinidad and Tobago
	Uruguay
	Brazil

Source: (Patel and Sandefur, 2020).

Appendix 2: Additional figures and tables

TABLE A1. Population and income, selected countries and regions, 2023

Selected Countries/Regions	Population (millions)	World Share	GDP (US$ billions)	World Share	Pop'n 0–4 (%)	Pop'n 0–4 (millions)	Pop'n (0–14) (millions)	Population (>65) (millions)
Africa	1,471	18.2%	2,881	2.7%	14.7	216	581	52
Sub-Saharan Africa (incl. ZAF)	1,260	15.6%	2,045	1.9%	15.1	190	517	40
Algeria	46	0.6%	248	0.2%	10.3	5	14	3
Egypt, Arab Rep.	115	1.4%	396	0.4%	10.3	12	37	6
Morocco	38	0.5%	144	0.1%	8.4	3	10	3
South Africa	63	0.8%	381	0.4%	9.3	6	16	4
Tunisia	12	0.2%	49	0.0%	7.4	1	3	1
European Union	449	5.6%	18,591	17.5%	4.5	20	66	97
France	68	0.8%	3,052	2.9%	5.1	3	11	15
Germany	83	1.0%	4,526	4.3%	4.6	4	12	19
Netherlands	18	0.2%	1,154	1.1%	4.9	1	3	4
Switzerland	9	0.1%	885	0.8%	4.9	0	1	2
United Kingdom	68	0.8%	3,381	3.2%	5.2	4	12	13

TABLE A1. (Continued)

Selected Countries/Regions	Population (millions)	World Share	GDP (US$ billions)	World Share	Pop'n 0–4 (%)	Pop'n 0–4 (millions)	Pop'n (0–14) (millions)	Population (>65) (millions)
Latin America & Caribbean	658	8.2%	7,100	6.7%	7.2	47	150	63
Argentina	46	0.6%	646	0.6%	6.0	3	10	6
Brazil	211	2.6%	2,174	2.0%	6.3	13	42	22
Chile	20	0.2%	336	0.3%	5.0	1	3	3
Colombia	52	0.6%	363	0.3%	6.8	4	11	5
Costa Rica	5	0.1%	86	0.1%	5.6	0	1	1
Cuba	130	1.6%	107	0.1%	4.6	6	2	2
Mexico	130	1.6%	1,789	1.7%	8.0	10	32	10
Canada	40	0.5%	2,142	2.0%	4.8	2	6	8
China	1,411	17.5%	17,795	16.8%	4.1	58	234	202
India	1,438	17.8%	3,568	3.4%	8.0	115	360	100
Japan	125	1.5%	4,204	4.0%	3.3	4	15	37
Korea, Rep.	52	0.6%	1,713	1.6%	2.6	1	6	9
United States	335	4.2%	27,721	26.1%	5.4	18	59	58
World	8,062	100.0%	106,172	100.0%	8.1	652	2,019	804

Source: World Bank Development Indicators, accessed March 18, 2025.

TABLE A2. Approximation of intraregional trade as a share of regional GDP (%), 2021

Region/Countries	Intraregional Trade (US$ billions)	GDP (US$ billions)	Exports + Imports within Region as Share of Regional GDP (%)
Africa	139.9	2,593	5.4
Latin America	268.7	5,151	5.2
US + Canada	666.9	24,641	2.7
Middle East	197.4	9,461	2.1
Europe	6,090.7	32,463	18.8
Asia	7,469.7	39,122	19.1

Notes: All monetary figures in 2021 US dollars. Regions don't match exactly from one database to the next. This table was created by adjusting the regional categories in detail for Africa and Latin America, but with less detail on Europe and Asia.
Sources: World Bank WITS database for trade data. WHO's GHED for GDP. US and Canadian data from US Census Bureau.

Appendix 3: Figures and tables reproduced from other reports

Figure 4: Capacity mapping – Existing capabilities per manufacturer in Africa

Manufacturer	Country	Vaccines	R&D	DS	F&F	Import for distribution
Afrigen	South Africa	Covid-19	●	●	●	
		Hepatitis B	●			
		Rift Valley Fever	●			
		TB	●			
Aspen	South Africa	Covid-19			●	
Biovac	South Africa	BCG				●
		Covid-19			●	
		GBS	●			
		Hepatitis B				●
		Hexavalent			●	
		OCV	●			
		OPV				●
		Pneumococcus			●	
		Measles				●
EPHI	Ethiopia	Rabies		●	●	
Innovative Biotech	Nigeria	Covid-19	●			
		Ebola	●			
		HIV	●			
		HPV	●			
		Yellow Fever	●			
Institut Pasteur d'Algérie	Algeria	Rabies		●	●	
Institut Pasteur de Dakar	Senegal	Yellow fever		●	●	
Institut Pasteur Morocco	Morocco	BCG				●
		Influenza				●
		Rabies				●
		Tetanus				●
		Typhoid				●
		Yellow Fever				●
Institut Pasteur Tunis	Tunisia	BCG		●	●	
Saidal	Algeria	Covid-19			●	
Vacsera	Egypt	BCG				●
		Cholera			●	
		Covid-19			●	
		DT			●	
		DTP			●	
		Hib				●
		Hepatitis A/B/A+B				●
		HPV				●
		Influenza				●
		IPV				●
		Meningitis				●
		MMR				●
		OPV				●
		Pentavalent				●
		Pneumococcal				●
		Rabies				●
		Rotavirus				●
		Tetanus			●	
		Typhoid			●	
		Varicella				●
		Yellow Fever				●

Note: Information based on Q4 2022 operations; Two existing manufacturers with operational facilities are not manufacturing vaccine as of the time that this report is being prepared (Biovaccines, Minapharm)

Source: (The Wellcome Trust et al. 2023).

Latin American vaccine manufacturers by country, disease, capacities, regulation, and exports, 2024

Company	Country	Vaccine or Disease	Bulk	Formulation, Fill & Finish	WHO PQ	Other Regulatory Approvals	Export Within Latin America	Export Outside Latin America
Bio-Manguinhos (Immunobiological Technology Institute)/ Fundação Oswaldo Cruz (Fiocruz)	Brazil	Chickenpox; Covid-19; Diphtheria; Hib; Measles; Meningococcal disease; Mumps; Pertussis; Pneumococcal disease; Polio; Rotavirus; Rubella; Tetanus.	Y	Y	Y	ANVISA (BR); GMP	Y	Y
BIRMEX (General Biologic and Reactives from Mexico)	Mexico	Covid-19; Diphtheria; Hib; Hepatitis A; Hepatitis B; HPV; Influenza; Measles; Mumps; Pertussis; Pneumococcal disease; Polio; Rotavirus; Rubella.	Y	Y		COFEPRIS (MX); GMP	Y	N
BogotáBio	Colombia	?		Y			N	N
Centro de Ingeniería Genética y Biotecnología/ The Center for Genetic Engineering and Biotechnology (CIGB)	Cuba	Covid-19; Diphtheria; Hib; Hepatitis B; Pertussis; Tetanus.	Y	Y	Y	CECMED (Cuba); GMP; ISO 9001	Y	Y
Centro Nacional de Biopreparados/National Bio-preparations Centre (BIOCEN)	Cuba	Covid-19	Y	Y		CECMED (Cuba); GMP	?	N
Drugmex	Mexico	Covid-19				COFEPRIS (MX); GMP	?	?
Eurofarma Laboratórios S.A.	Brazil	Covid-19		Y		ANMAT (AR); ANVISA (BR); DIGEMED (Peru); GMP; INVIMA (Colombia); US FDA.	Y	N
Ezequiel Dias Foundation (FUNED)	Brazil	Meningococcal disease	Y			ANVISA (BR); GMP	N	N
Fundação Ataulpho de Paiva (FAP)	Brazil	Tuberculosis	Y	Y		ANVISA (BR); GMP	N	N

Latin American vaccine manufacturers by country, disease, capacities, regulation, and exports, 2024 (Continued)

Company	Country	Vaccine or Disease	Bulk	Formulation, Fill & Finish	WHO PQ	Other Regulatory Approvals	Export Within Latin America	Export Outside Latin America
Instituto Nacional de Salud/ National Institute of Health (Colombia)	Colombia	Tuberculosis	Y	Y		INVIMA (CO)	N	N
Instituto Biológico Argentino S.A.I.C.	Argentina	Diphtheria; Hib; Influenza; Tetanus; Tuberculosis	Y	Y		ANMAT (AR); GMP	N	N
Instituto Butantan	Brazil	Covid-19; Diphtheria; Hepatitis A; HPV; Influenza; Rabies; Tetanus.	Y	Y	Y	ANVISA (BR); GMP	Y	?
Instituto Finlay/The Finlay Institute (IFV)	Cuba	Diphtheria; Leptospirosis; Meningococcal Disease; Tetanus; Typhoid.	Y	Y		CECMED (Cuba); GMP	Y	Y
Laboratorio Avi-Mex, S.A de C.V/Avimex	Mexico	?	Y	Y		COFEPRIS (MX); GMP	N	N
Laboratorios Richmond SACIF	Argentina	Covid-19		Y		ANMAT (AR); GMP	N	N
Liomont	Colombia	Covid-19; HPV; Influenza	Y			DIGIMED (Peru); EMA; GMP; Infima; US FDA	Y	N
mAbxience	Argentina	Covid-19	Y			ANMAT (AR); COFEPRIS (MX); EMA; GMP; US FDA	Y	Y
Méchnikov Latin American Institute of Biotechnology	Cuba	Covid-19; Influenza	Y	Y		CECMED (Cuba); GMP	?	N
National Institute of Human Viral Disease "Julio Maiztegui" (INEVH)/ANLIS (The National Administration of Institutes and Health Laboratories) Malbran Institute	Argentina	Argentine hemorrhagic fever; Diphtheria; Tetanus; Tuberculosis	Y	Y		ANMAT (AR); GMP	?	?

Latin American vaccine manufacturers by country, disease, capacities, regulation, and exports, 2024 (Continued)

Company	Country	Vaccine or Disease	Bulk	Formulation, Fill & Finish	WHO PQ	Other Regulatory Approvals	Export Within Latin America	Export Outside Latin America
National Institute of Human Viral Disease "Julio Maiztegui" (INEVH)/ANLIS (The National Administration of Institutes and Health Laboratories) Malbran Institute	Argentina	Diphtheria; Hib; Pertussis; Rabies; Tetanus	Y	Y		ANMAT (AR); GMP	N	N
SGS Vaccines and Biological Products Colombia	Colombia	?				GMP	N	N
Sinergium Biotech	Argentina	Hepatitis A; HPV; Influenza; Pneumococcal Disease	Y			ANMAT (AR); GMP; INVIMA (Colombia)	?	?
União Química	Brazil	Covid-19	Y			ANMAT (AR); ANVISA (BR); DIGEMED (Peru); EMA; GMP; INVIMA (Colombia); US FDA.	N	Y
VaxThera S.A.S.	Colombia	?		Y			N	N

Source: Path Survey of Vaccine Manufacturers in Latin America. https://tableau.path.org/t/Diagnostics/views/LatAmVaccinesDashboardV2/BLiSSDashboardFinal accessed 7/15/2025.

Examples of pooled procurement

- AVAT, **African Vaccine Acquisition Trust** (AU and Afreximbank).
- AMSP, **Africa Medical Supplies Platform**: online centralized digital platform for all medical supplies with preference for African suppliers. Task force is broad. Afriexem and AU make decisions.
- EAC, **East Africa Countries Pooled Procurement**, 2008, HIV/AIDS medicines negotiated centrally then countries buy based on contract. Governed by EAC Council of Ministers.
- EU, **EU Covid 19 Vaccines Strategy**, from 2020, for join vaccine procurement. Governed by EU Council and implemented by an EU Commission.
- GCC, **Gulf Cooperation Council Group Purchasing**, est. 1978, 6 countries, has achieved cost savings of 30% in purchases. GCC Charter authority. Saudi Arabia provides regulatory standards but need no objection from other countries. Delivery and payment made by countries.
- OECS, **Organization of Eastern Caribbean States**, est. 1986, 9 countries, centralized tending and procurement system based on a drug revolving fund, 37% savings for 25 items over 5 years. Commission established under ECS Treaty. Revolving drug fund.
- **PAHO Revolving Fund**, pooling demand, centralizing negotiations, contracting, demand forecasting. Governed by WHO/PAHO Directing Council, pooling demand. PAHO issues tenders/contracts and plans deliveries. WHO PQ or SRA for regulatory standards. PAHO pays suppliers and countries must reimburse within 60 days.
- **UNICEF Procurement Services**, negotiating, procurement, logistics, delivery services for vaccines and other health products. ~100 countries get some or all vaccines via UNICEF. Governed by UNICEF. UNICEF pools demand, issues tenders/contracts and plans deliveries with suppliers. WHO PQ regulatory approval required. There is no revolving fund, so UNICEF must be paid in advance.

Note: All of these pooled mechanisms insist on a single price for all members, except for UNICEF which has tiered pricing.

Partial listing of regional initiatives

- The Partnership for Accelerating Vaccine Manufacturing (PAVM) – led by the African Union – aims for Africa to manufacture 60 percent of its vaccine needs by 2040.
- In Latin America, PAHO is leading a regional initiative to support the development of mRNA hubs in Brazil and Argentina.
- In 2021, Southeast Asian countries adopted a Vaccine Security and Self-Reliance Strategic and Action Plan (2021–25) to set priorities for regional cooperation.
- African countries are considering an initiative to establish a US$50 billion market for vaccines and medicines as well as invest in regional capacity to develop and manufacture vaccines which would be housed in the Africa Centres for Disease Control and Prevention (Africa CDC).

- The Regionalized Vaccines Manufacturing Collaborative (RVMC), incubated by the World Economic Forum is now hosted by CEPI.
- Gavi's African Vaccine Manufacturing Accelerator (AVMA) is already functioning, launched in June 2024 with US$1.2 billion in funding available over a 10-year period. It is promoting vaccine production in Africa with investments in supply and "top-up" incentives for African-based manufacturers.
- At the G-20 meeting in Rio de Janeiro in 2024, countries launched the "Coalition for Local and Regional Production, Innovation and Equitable Access" to promote voluntary cooperation for expanding access to vaccines.
- In 2022, members of ASEAN announced principles for eventually developing a legal instrument that would create an ASEAN Pharmaceutical Regulatory Framework (APRF).

Range of vaccine technologies/platforms

- Toxoid vaccines (tetanus) which use a toxin produced by the infection.
- Inactivated vaccines (dengue), dead version of pathogen.
- Attenuated live vaccine (measles, yellow fever).
- Similar particle vaccines (HPV) non-infectious molecules.
- Subunit vaccines which use part of the pathogen (subunit proteins or conjugate vaccines or polysaccharide vaccines).
- Replicative and non-replicative viral vector vaccines (modified version of a different virus with a protein inserted).
- Nucleic acid vaccines – including mRNA and DNA, which use cellular mechanism to produce proteins which trigger immune response.

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