Vaccine manufacturing capacity in low– and middle-income countries

In 2022 and 2023, the Future Vaccine Manufacturing Research Hub (the 'Vax-Hub') carried out interviews and a literature review on the barriers, enablers and potential policy solutions related to bringing innovative vaccine solutions to and building local manufacturing capacity in low- and middle-income countries (LMICs)[1] *.*

This policy brief summarises findings from a literature review and stakeholder interviews. It highlights the biggest challenges related to technology transfer, maps existing initiatives that help address some of these challenges, and provides policy recommendations to enable further progress.

Context

The lack of timely access to Covid-19 vaccines played a significant role in LMICs being disproportionately affected by the COVID-19 pandemic. Unequal vaccine access resulted in a higher proportional death toll and prolonged the pandemic by giving the virus the opportunity to spread and mutate [2]. To increase resilience and prepare for future disease outbreaks and pandemics, and to achieve global health security, equity and drive progress towards the Sustainable Development Goals (SDGs), it is necessary to accelerate the development, manufacture and distribution of vaccines worldwide [3,4, 29]. Immunisation plays a key role in achieving 14 of the 17 SDGs and it is closely aligned with the SDG transformative promise to 'leave no one behind' as articulated by the Immunization Agenda 2030 (IA2030) [29, 30]. An essential part of vaccine equity is sufficient local vaccine manufacturing capacity. Local productive capacity also benefits an economy in the long-term, by nurturing expertise and creating quality jobs in LMICs, which in turn contributes to structural transformation, economic growth, and pandemic preparedness [5, 6].

Key points

1. Vaccine manufacturing markets are highly concentrated in a few geographical regions, dominated by a small number of manufacturers, and focussed on specific diseases.
2. To prepare for future disease outbreaks, and ensure global health security and equity and drive progress towards the Sustainable Development Goals (SDGs), it is necessary to build vaccine manufacturing capacity in low- and middle-income countries and to facilitate technology transfer activities.
3. Challenges pertain to inadequate costs and upfront capital requirements, access to technology and technology platforms, regulatory maturity, infrastructure capabilities, knowledge systems, collaboration, and policy coherence.

[1] The World Bank Group defines LMICs for the fiscal year 2023 as those countries with a gross national income (GNI) per capita of $1,085 or less in 2021. Lower-middle income economies are those countries that have a GNI per capita between $1,086 and $4,255 per year [1].

The Vax-Hub

The Vax-Hub was a five-year research programme (2018-2023) funded by the UK's Department of Health and Social Care's Official Development Assistance programme, the UK Vaccine Network. The Vax-Hub's mission is to secure supply of essential vaccines to LMICs.

Building on the success of the 2018-2023 Vax-Hub, two new vaccine hubs were awarded research funding in 2023 - Manufacturing Research Hub for a Sustainable Future (Vax-Hub Sustainable) and the Vaccines Manufacturing Hub for LMICs (Vax-Hub) Global.

Although there is a growing number of manufacturers globally that are involved in all steps of vaccine manufacturing, from research and development (R&D), the production of drug substances, to fill and packaging before supply to the market [7], the vaccine manufacturing and distribution market is highly concentrated in a few geographical regions, as illustrated in the tables below.

As of November 2022, there are 94 manufacturers worldwide. Not counting COVID-19 vaccines, fewer than ten manufacturers provide 70% of global vaccines doses and 85% of the global value of vaccines [7]. For instance:

- Manufacturers are headquartered in a few geographic areas, mostly in China, India, the European Union, Indonesia, Japan and the United States of America [6].
- Africa produces less than one percent of the vaccines that are administered on the African continent [6, 7]. Only four countries currently have vaccine manufacturing operations: Egypt, Senegal, South Africa, and Tunisia, although many other countries are also planning the establishment of vaccine manufacturing activities [8].[2]
- Asia is responsible for 24% of global vaccine volume (including for Covid-19) [7]. This is mainly due to the presence of suppliers in China and India [7]. In Southeast Asia, there are only four vaccine producing countries: Indonesia, Myanmar, Thailand, and Vietnam [9, 10].
- In Latin America, only Cuba, Brazil, Mexico, and Colombia have some levels of self-sufficient vaccine production. Other Latin American countries tend to focus on distribution within health systems rather than technology transfer [11].

Many global suppliers are only able to produce a few vaccines and tend to only provide vaccines for local markets [7]. The top ten vaccines by volume account for 92% of the global volume of vaccines [7]. There have been developments to focus on diseases that primarily affect LMICs, although many vaccines have traditionally

Regional vaccine volume distribution versus supply – with COVID-19 (in %)

	Distributed in:					
Supplier	Africa	Americas	Eastern Mediterranean	Europe	South-East Asia	Western Pacific
Africa	0	0	0	0	0	0
Americas	17	57	26	56	61	15
Eastern Mediterranean	0	0	0	0	0	0
Europe	25	29	23	39	2	6
South-East Asia	43	6	27	2	79	1
Western Pacific	14	8	17	4	13	78
TOTAL	100	100	100	100	100	100

Regional vaccine volume distribution versus supply – without COVID-19 (in %)

	Distributed in:					
Supplier:	Africa	Americas	Eastern Mediterranean	Europe	South-East Asia	Western Pacific
Africa	1	0	0	0	0	0
Americas	7	31	9	11	1	5
Eastern Mediterranean	0	0	4	0	0	0
Europe	26	39	26	76	3	5
South-East Asia	57	21	56	6	93	5
Western Pacific	9	8	4	7	3	85
TOTAL	100	100	100	100	100	100

[2] These include Algeria, Ethiopia, Kenya, Uganda, Morocco, Ghana, Rwanda and Nigeria

targeted diseases that affect affluent countries [7]. Diseases that are associated with markets that are perceived to lack commercial value are often neglected, underinvested in, lack products in the development pipeline, and have extended timelines and availability delays [7]. For instance, hookworm, schistosomiasis and leishmaniasis, as well as other diseases prioritised by the WHO R&D Blueprint still do not have a vaccine [7].[3] As a result, the Partnership for African Vaccine Manufacturing (PAVM) prioritises manufacturing of vaccines for 22 diseases.[4]

Vaccine manufacturing capacity in LMICs relies on technology transfer, where the knowledge and ability to carry out a manufacturing process is shared from an originator to a secondary user [5, 7]. Conducting successful technology transfers is critical to enable countries to acquire the knowledge, experience, and equipment necessary for advanced and innovative industrial products and processes [12].

Addressing challenges related to technology transfer

Technology transfer is intertwined with a broader set of challenges, barriers, and solutions to building local vaccine manufacturing capacity. Below we highlight the key challenges identified in the literature review and interviews with stakeholders, and map some of the initiatives that are already in place to address some of these challenges.

Costs and upfront capital requirements

There is a need for coordinated financing and procurement mechanisms, large public and private investments, official development assistance, and to create funds and facilities for funding that can be mobilised quickly [5, 7, 13, 14]. Many LMICs lack the capital that is necessary to start a commercial vaccine manufacturing plant and to meet requirements for drug safety, quality and efficacy, and good manufacturing practices (GMP) [4, 7]. There are also operational costs linked to raw materials, skilled personnel, and running utilities for vaccine production (although these depend on facility design) [4, 15].

Interviews confirmed the cost challenges in the manufacturing of vaccines. They highlighted the challenge of making vaccine manufacturing feasible from a business perspective. The ability to create the business case for vaccine manufacturing and to predict long-term demand for vaccines are key challenges. They also highlighted the challenge of the price sensitivity of key global health actors who cost vaccines at a price that is not much higher than that of manufacturing, which makes it difficult for LMICs to enter global markets.

Interviews

Vax-Hub conducted 21 scoping meetings and interviews with stakeholders from organisations in academia (n=3), the Hub user group (n=3), UK policy (3), the United Nations (2), and international organisations (n=7)

Summary of topics

- Costs and upfront capital requirements
- Access to technologies and technology platforms
- Regulatory maturity: strong regulatory systems are required across the entire vaccine life cycle
- Infrastructure: hard and soft infrastructure challenges increase costs of manufacturing
- Skills and training: lacking manufacturing know-how and a skilled workforce
- Knowledge systems: related to R&D, real-time monitoring and data-sharing.
- Collaboration and policy coherence: lacking collaboration and coordination amongst different initiatives

[3] This includes Zika, Lassa fever, Nipah and henipaviral diseases, Rift Valley Fever, Crimean-Congo haemorrhagic fever and filoviruses [6].
[4] These include i) legacy diseases: Hepatitis B, Diphtheria, Whooping Cough, Tuberculosis, Measles, Yellow Fewer, Cholera, Typhoid, Meningococcus, ii) expanding diseases: Human Papillomavirus, Pneumococcus, Rotavirus, COVID-19, Malaria, HIV, and iii) outbreak diseases: Ebola, Influenza, Chikungunya, Rift Valley Fever, Lassa Fever, and Disease X. The following do not have a vaccine: HIV, Chikungunya, Rift Valley Fever, Lassa fever, Disease X (placeholder name adopted by the WHO to represent a hypothetical, unknown pathogen).

PAVM's Framework for Action

Outlines the ambition to quadruple the vaccine workforce to approximately 12,500 full-time employees (FTE), which will require the training of 10,500 new FTEs to meet their goal of "enabling the African vaccine manufacturing industry to develop, produce and supply over 60 percent of the total doses required on the continent by 2040."

PAVM estimates that 9,500 new jobs will be needed and that there will be approximately 10% brain drain. PAVM focuses on Capability and Capacity Centres to address talent gaps and challenges to foster partnerships between research institutions, manufacturing companies, and educational institutions.

They also highlight the importance of collaboration with international and global institutions to fill critical talent gaps and support the scaling of local programmes in the short to medium term [6].

There needs to be long-term and sustainable funding, as well as investments in excess capacity to be able to respond rapidly if a pandemic occurs. Other interviewees noted that governments should recognise the need to invest in vaccines over a long time period and the operational costs of vaccine manufacturing. One interviewee felt that as an LMIC manufacturer it was more difficult to access the established funding mechanisms that exist. They said that, by creating a global benchmark for the capabilities necessary to get funding, it would be easier for these manufacturers to access global funding streams.

Know-how and a skilled workforce

Lacking manufacturing know-how and a skilled workforce creates barriers to vaccine manufacturing across the entire value chain [5, 6, 7, 8]. Concerted efforts are necessary to train a new multi-disciplinary and permanent workforce [4, 15]. Some of the challenges in LMICs relate to the cost of expat labour and brain drain. The workforce needs to have knowledge that is scientific, technical, regulatory, and product-specific for manufacturing, GMP, and quality control systems [6].

Interviewees noted that there should be a mix of training that invites researchers and industry stakeholders to countries with already established vaccine manufacturing capabilities (such as the UK and the USA) and to run training initiatives in LMICs and regions, for example by training the trainers. They also noted the importance of involving biomanufacturers as designers and participants in these programmes.

Interviewees highlighted that training programmes should focus on collaboration in developing technologies and products, regulatory challenges and strengthening, combine practical and theoretical training, contribute to GMP and clinical trial design, focus on basic scientific expertise (for example on the basics of biologicals and biopharmaceuticals), and build capabilities across the whole downstream and upstream of vaccine manufacturing. A comprehensive training system should use a combination of online and in-person modules [4, 16]. Geographical diversity in the availability of training programmes in LMICs is needed to ensure that benefits are shared across countries and regions.

There has been an increased focus on the need to build vaccine manufacturing capacity since the COVID-19 pandemic (for example. PAVM's Framework for Action). However, many interviewees highlighted that initiatives are often not coordinated, not well-curated, and there is a lack of criteria and capacity to measure success. Information sharing, collaboration, and global and regional frameworks for skills and training across the entire vaccine supply chain can contribute to creating links and information sharing between different initiatives.

Access to technologies and technology platforms

There needs to be an increased focus on vaccine platform technologies, whereby vaccines for different diseases are delivered within a single system. Platform approaches allow extensive safety and efficacy testing to be carried out on the delivery system before the emergence of a new disease, thereby shortening delivery times. Innovative vaccine platform technologies can offer acceleration, flexibility, and pandemic readiness [17, 18]. Not counting COVID-19 vaccines, 60% of manufacturers use traditional platforms and only 4% use innovative platforms. 36% of COVID-19 vaccines used innovative technology platforms [7]. Manufacturers that use innovative technologies often have headquarters in the WHO Regions of the Americas and Europe, apart from the Serum Institute in India [7]. There are also challenges related to the skills, infrastructure, and equipment that are needed for technologies [7, 13, 14].

Interviewees agreed that there should be a broad focus on technologies and technology platforms to adequately prepare for future disease outbreaks. They noted the importance of building technology capabilities in inter-pandemic contexts that can be applied in the case of a pandemic. When prompted, interviewees noted that they prioritise mRNA and viral vectors, as vaccine technologies with high potential.

Regulatory maturity

Strong regulatory systems are required across the entire vaccine life cycle and should be streamlined to facilitate investment [4, 5, 6, 7, 8]. The WHO defines regulatory maturity in terms of reaching a certain level of assured quality, as defined by the WHO's maturity level (ML) 3 and 4. ML3 are stable, well-functioning and integrated regulatory systems and ML4 pertains to regulatory systems operating at an advanced level of performance and continuous improvement [19]. National regulatory systems that have reached these levels are concentrated in High Income Countries (HICs), as illustrated below.

WHO mRNA vaccine technology transfer hub

In June 2021, the WHO announced the mRNA vaccine technology transfer hub. The objective of the hub is to build capacity in low-and-middle income countries to produce mRNA vaccines through a centre of excellence and training (the mRNA vaccine technology hub). The hub is located in Cape Town, South Africa, and works with a network of technology recipients in LMICs. The hub shares technology and technical know-how with local producers and provides training and financial support to build human capital for production know-how, quality control and product regulation, and assists with necessary licences [25].

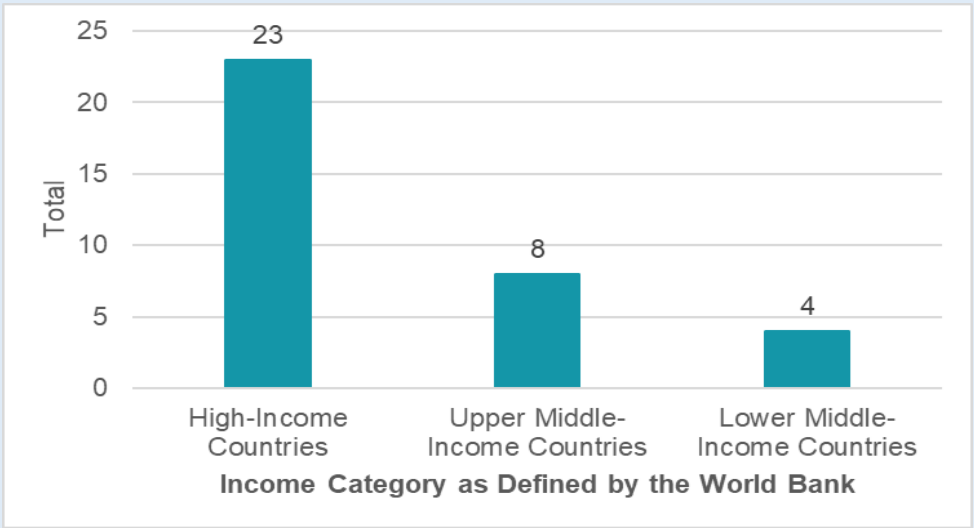
Vaccine platform technologies

Vaccine platform technologies is where a single delivery system, for example, a viral vector, is developed that can be modified to produce vaccines against a number of different pathogens [28].

Vaccine platform groups

The WHO defines the different platform groups according to i) traditional platform groups: toxoids, polysaccharide, live-viral and inactivated vaccines, ii) modern platforms group: protein-based and conjugate vaccines, and iii) innovative platforms groups: nucleic acid (such as mRNA) and viral vector vaccines [7].

Vaccine producing countries with maturity level 3 or 4 in national regulatory systems (N=35)



Source: WHO 2022

For instance, whilst there are 54 national medicines regulatory authorities (NMRAs) in Africa, only 7% of these perform all the core functions that are expected of NRMAs [8]. Interviewees highlighted that training is an important tool for building the capabilities necessary to reach regulatory maturity at a national level. However, for any measure to be successful, it is necessary with WHO pre-qualification so that LMICs are able to sell to the Gavi the Vaccine Alliance and UNICEF, as well as other countries. WHO pre-qualification is critical to manufacture and sell vaccines at lower volumes and to make vaccine manufacturing cost-effective.

Infrastructure capabilities

Hard infrastructure challenges for vaccine manufacturing include water quality, availability of services and spare parts, uninterrupted electricity supply, communication and transport networks, and access to ports [7, 8]. Poor infrastructure is especially prevalent in the last mile of vaccine production [5]. Soft infrastructure challenges relate to laws and regulations, norms, and cultures that impact trust and social capital, competition and tariff policy, regulations and regulatory frameworks, and standards (for example related to GMP) [8]. Together, these challenges increase the cost of vaccine manufacturing. Interviewees highlighted the importance of investing in and building the necessary infrastructure in LMICs.

Knowledge systems

Knowledge systems, particularly related to research and development (R&D) and real time monitoring and data sharing, create a conducive environment for building vaccine capabilities across the entire vaccine value chain and facilitates technology transfer deals between local industry and international partners [8, 14, 17, 20]. However, in some LMICs, investment in research systems accounts for less than 0.5% of GDP due to competition with other government priorities [20]. Challenges often relate to inadequate financial and human resource support, monitoring and evaluation, a lack of collaboration between research institutions, and brain drain [20]. Institutions, local partner engagement, coordination of funding, incentives and national priorities are critical in addressing these challenges [8, 20]. Interviewees highlighted as an example that much of the research in universities at the African continent tends to be blue skies and long-term, but that capabilities also need to be developed for manufacturing. They underlined the need to strengthen R&D systems in LMICs. Some interviewees expressed that they would be interested in collaborating with more academic institutions and hubs, like the Vax-Hub.

Collaboration and common goals

It is necessary to promote collaboration underpinned by a human-rights based approach among stakeholders from government, academia, industry, civil society, and philanthropic organisations [8, 14, 17, 31]. Interviewees felt that work needs to be done at the national, regional, and global level to facilitate collaboration and highlighted the importance of information-sharing across initiatives. All the different elements of the enabling environment need to be supported coherently and at the same time. There is a need for simultaneous support in market demand, skills, infrastructure, and regulation, which requires extraordinary levels of coordination between a wide array of different stakeholders. Coordination requires strong political commitment both domestically and internationally.

Regional collaboration is especially conducive to reduce costs [4]. Examples include the Partnership for African Vaccine Manufacturing, which aims to enable the African vaccine manufacturing industry to “develop, produce and supply over 60 percent of the total vaccine doses required on the continent by 2040” [6]. Other initiatives include the creation of new vaccine manufacturing plants [21], investments from development finance institutions and multilateral development banks [22], bilateral support [23], regional partnerships [6], technology transfer hubs [24], training hubs [26], and COVAX task forces [26].

Whilst COVID-19 provided an impetus for a growth of different initiatives, these initiatives are often not coordinated. Evidence has shown that a long-term vision and coherence across industrial, trade and health policies are key factors in successfully developing local manufacturing capacity [32]. Interviewees highlighted the importance of creating common goals and policy objectives through collaborations between the scientific and policy community. To achieve policy coherence, they noted that public health considerations need to be linked with vaccine manufacturing.

One interviewee highlighted the importance of having a national leader to facilitate these conversations, such as a public health authority. They also noted the misalignment between global and national health priorities, and that certain diseases (such as tropical diseases) might be less prioritised by the global health community. Greater alignment can be achieved by ensuring that LMICs are represented in global policy fora. Assessments of needs, investments, and the viability of initiatives at national and global levels are also required [14].

Wider governance issues

It is necessary to situate technical solutions within the wider policy landscape related to vaccine manufacturing [5, 7, 8, 13]. Some of the governance issues that have been addressed by other stakeholders include:

- At the industrial level: industrial expertise and resource, as well as industrial policy.
- At the international level: global trade and tariff regimes, intellectual property rights systems, global regulatory capacity, and the need to harmonise medicines procurement [6, 13, 14].
- At the national level, challenges relate to transparency, favourable economic and policy environments, institutions and practices, as well as political will and stability [5, 6, 7, 8, 13, 14, 17].

Conclusion

There are significant challenges to overcome to build vaccine manufacturing capacity in low- and middle-income countries. Vaccine manufacturing markets are highly concentrated in a few geographical regions, dominated by a small number of manufacturers, and focussed on specific diseases. To prepare for future disease outbreaks and ensure global health security and equity, it is necessary to build vaccine manufacturing capacity in low- and middle-income countries and to facilitate technology transfer activities.

Policy recommendations

- Coordinated financing and procurement mechanisms can address the capital requirements for vaccine manufacturing in LMICs. Vaccine manufacturing needs to be feasible from a business perspective and ensure sustainable financing that recognises the long-term funding requirements for vaccine manufacturing.
- Training and skills programmes are necessary across the vaccine development value chain and to build regulatory maturity. Initiatives need to be coherent, well-curated, and require common criteria for what good looks like.
- There should be a broad focus on technologies and technology platforms to adequately prepare for future disease outbreaks.
- Strong regulatory systems are required across the entire vaccine life cycle. Regulatory training can contribute to the strengthening of national regulatory systems.
- Investments are needed to solve both hard (water quality, availability of services, transport networks etc.) and soft infrastructure challenges (policy and regulatory frameworks).
- It is necessary to strengthen research and development in LMICs, including for long-term and blue skies research, as well as practical and basic scientific knowledge.
- Collaboration should be promoted among diverse stakeholders from government, academia, industry, civil society, and philanthropic organisations. Work needs to be done at the national, regional, and global level to facilitate collaboration, information-sharing, and to set common policy goals and objectives.

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Our research

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Authors

Lead author: Emily Ryen Gloinson, former Policy Adviser in the PIU.
Martina Micheletti, Professor of Bioprocess Fluid Dynamics, UCL Department of Biochemical Engineering; Jenny Bird, former head, Policy Impact Unit; Jane Doogan, project manager, Vax-Hub; and Anca Tacu, Policy Adviser in the PIU.

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