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mRNA technology transfer programme

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An mRNA technology transfer programme and economic sustainability in health care

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Abstract

The World Health Organization (WHO) set up the messenger ribonucleic acid (mRNA) technology transfer programme in June 2021 with a development hub in South Africa and 15 partner vaccine producers in middle-income countries. The goal was to support the sustainable development of and access to life-saving vaccines for people in these countries as a means to enhance epidemic preparedness and global public health. This initiative aims to build resilience and strengthen local vaccine research and development and manufacturing capacity in different regions of the world, especially those areas that could not access coronavirus disease 2019 (COVID-19) vaccines in a timely way. This paper outlines the current global vaccine market and summarizes the findings of a case study on the mRNA technology transfer programme conducted from November 2022 to May 2023. The study was guided by the vision of the WHO Council on the Economics of Health for All to build an economy for health using its four work streams of value, finance, innovation and capacity. Based on the findings of the study, we offer a mission-oriented policy framework to support the mRNA technology transfer programme as a pilot for transformative change towards an ecosystem for health innovation for the common good. Parts of this vision have already been incorporated into the governance of the mRNA technology transfer programme, while other aspects, especially the common good approach, still need to be applied to achieve the goals of the programme.

Introduction

The coronavirus disease 2019 (COVID-19) pandemic exposed the global imbalance in vaccine production, supply and access. Through financial, political and technical support of domestic biopharmaceutical companies, governments in high-income countries gained control and autonomy of technological innovation and production capabilities for important health technologies, including vaccines, diagnostics and treatments. As a result, these countries were able to vaccinate their populations rapidly against COVID-19. However, governments in most low- and middle-income countries could not vaccinate their populations so quickly as they did

not have timely access to COVID-19 vaccines.¹ In some cases, vaccines were not available until 2 years after the World Health Organization (WHO) declared COVID-19 a pandemic in March 2020. The reasons for these inequities are varied. However, from the public health perspective, the importance of having domestic vaccine research and development and production capacity in all regions of the world, especially for the versatile messenger ribonucleic acid (mRNA) technology, have become evident.

It is in this context that WHO created the mRNA technology transfer programme in mid-2021 to meet requests from low- and middle-income countries for support in developing their local vaccine manufacturing capacity and responding to the COVID-19 pandemic. The programme was initially set up as a technology development hub in South Africa that would transfer the technology to partner companies in 15 middle-income countries (Fig. 1). The goal was to enable these countries to enhance their response to local health needs, build resilience for epidemic preparedness and reverse global inequities related to access to life-saving vaccines.

Despite its novelty, mRNA technology is uniquely suited for decentralized capacitybuilding in low- and middle-income countries. In addition to the versatility and adaptability of mRNA technology as a technology platform (with potential applicability in multiple disease areas), small- to medium-scale manufacturing infrastructure and capability can be quite easily built without the complex set-ups needed for traditional biological vaccines. Building mRNA vaccine development capabilities in the partner firms has the potential to serve not only their respective national markets, but also regional markets. In fact, most partner companies saw this programme as addressing regional public health needs, especially to achieve a minimum viable scale of production. The programme was set up to produce COVID-19 vaccines. However, as new COVID-19 vaccines are not needed on the scale in 2020 and 2021, this capacity is unlikely to be used in the near future, by which time the AfriVac 2121 COVID-19 vaccine being developed at Afrigen (the so-called hub) will be available. However, the development and production of this vaccine would be a validation of the successful transfer of technology, which could then be used for the development of other vaccines, such as those for influenza, dengue, tuberculosis and human immunodeficiency virus, among others.

The WHO Council on the Economics of Health for All was tasked by the WHO Director-General to reimagine economic principles, with health, well-being and equity at the centre. The Council commissioned a case study, conducted from November 2022 to May 2023, to evaluate the mRNA technology transfer programme in terms of rethinking value, Publication: Bulletin of the World Health Organization; Type: Policy & practice Article ID: BLT.24.291388 finance, innovation and capacity in the economy This paper contextualizes the development of the programme within the global vaccine market, and summarizes the case study on the

Methods

programme and its findings.

The case study was informed by literature reviews including reports of the WHO Council on the Economics of Health for All and other sources of progressive health economic thinking and global health policy, and unstructured interviews with stakeholders in the mRNA technology transfer programme. These stakeholders included staff of WHO, the Medicines Patent Pool, Afrigen (the South African vaccine manufacturing firm at the centre of the technology transfer programme), representatives of seven participating vaccine manufacturers and civil society stakeholders, among others.² The focus of the discussions was how sustainability in vaccine production was being conceptualized in the mRNA technology transfer programme and whether and how the programme should be re-thought to achieve its public health objectives. The policy environment needed to facilitate the success of the technology transfer programme was also an important part of the conversations with stakeholders.

The objectives of the mRNA technology transfer programme are to build resilience and sustainable capabilities for mRNA technology research and development and manufacturing to address local health needs in low- and middle-income countries. The case study suggested that the programme be viewed as a collective effort among stakeholders towards resilient epidemic preparedness and response capacity for the common good,² driven by collaboration between developing countries as well as pursuing the shared mission of health security, centred around equity and local resilience.³ If the programme is to achieve its objectives, it must not replicate the market dynamics that underlie the current segmented vaccine market. Instead, the programme should establish a mission-oriented policy framework for an end-to-end ecosystem for health innovation for the common good.^{4,5} This approach would require reshaping health industry research, developing and manufacturing ecosystems for health equity, doing more than just fixing market failures, and putting the concept of the common good at the centre.^{6–8}

Vaccine market landscape

The global vaccine market is segmented. Vaccines in high-income countries are supplied by global pharmaceutical corporations which can achieve substantial profit margins by charging

high prices for newer vaccines and moderate and differential prices for the older routine vaccines. On the other hand, low- and middle-income countries are supplied largely by developing country vaccine manufacturers, which operate on a low-price, high-volume and low-profit-margin model, especially for older routine vaccines. The low profit margin makes substantial investment in research and development difficult. Newer vaccines are mostly only available at high prices in these markets, albeit the prices are lower than in high-income countries.⁹ In general, governments play a significant role in vaccine supply and delivery, but the support is greater in high-income countries where governments have more fiscal capacity. Vaccine markets in low- and middle-income countries are largely supported by donors, especially in countries that are eligible to receive support from GAVI, the Vaccine Alliance.⁹

Governments in high-income countries have created a policy environment that is conducive to the development and production of new vaccines by pharmaceutical companies.¹⁰ Notably, governments in the United Kingdom of Great Britain and Northern Ireland, the United States of America and the European Union typically fund the high-risk early phases of research and development and invest in basic and applied research, including clinical trials. These governments also use procurement policies to ensure that pharmaceutical companies have a guaranteed market. In addition, the profits¹¹ of these companies are further protected by a generous intellectual property framework that grants them broad and upstream (that is, patented by components, rather than final product) patents to privatize the results of government-supported research with no conditions attached.¹² In other words, governments in high-income countries have many tools to shape vaccine research and development to deliver medical innovation and create profitable market opportunities for pharmaceutical companies.^{10,13,14} However, these government interventions are not designed for, and often get in the way of, global public health and equity, as they do not facilitate, and can impede, equitable access to affordable life-saving treatments and vaccines globally.^{15,16}

Before COVID-19, the vaccine market was considered balanced in terms of market demand and supply to fulfil vaccine orders. In 2019, a total of 5.5 billion doses of vaccines were produced and purchased, representing a market value of 33 billion United States dollars (US\$).¹⁷ However, the market is unbalanced in terms of monetary value distribution, with an estimated 68% of the market by value being in high-income countries for just 13% of the doses. Self-procuring middle-income countries, including China and India, represent 25% of the market by value for 49% of the doses. The procurement for lower-income countries

Publication: Bulletin of the World Health Organization; Type: Policy & practice Article ID: BLT.24.291388 subsidized by GAVI and the United Nations Children's Fund (UNICEF) represents only 3% of the market's monetary value for 33% of all doses.

In 2021, 16 billion doses of vaccine were produced and procured, of which 10.8 billion were for COVID-19, representing a market size of US\$ 99 billion. The market for non-COVID vaccines – 5.3 billion doses worth US\$ 42 billion – remained roughly unchanged.¹⁸ Consequently, donors such as GAVI and UNICEF drive much of the market dynamic and activities focused on fixing market failures for vaccine supply to low- and middle-income countries and rely on a handful of large-volume, low-cost producers.

Balancing supply and demand of the market does not necessarily translate into health equity and access. Important gaps remain in vaccination coverage in low- and lower-middle-income countries,¹⁹ even for routine vaccines that are part of WHO's Essential Programme on Immunization and are in principle available at low cost. Vaccine inequities are greater for the newer generation, more expensive vaccines, such as the human papilloma virus, pneumococcal conjugate and rotavirus vaccines.²⁰ In addition, regular shortages occur, especially for outbreak vaccines with limited and unpredictable markets. For example, a shortage of cholera vaccines occurred recently after one of only three producers decreased its vaccine production just when the frequency of cholera outbreaks was increasing.²¹ This situation results in part because it is not profitable to maintain reserve capacity for vaccines, especially for diseases that predominantly afflict people in low- and middle-income countries. Therefore, as a matter of course, the market for vaccines does not maximize vaccine coverage, nor does it serve public health well.¹⁸

Reshaping research and development

The mRNA technology transfer programme was set up as a WHO-led technological capacitybuilding project for individual manufacturers in low- and middle-income countries.

Conversations with stakeholders did not reveal a uniform view on economic sustainability. At a minimum, donor support could be used to establish mRNA capacity in each partner company so that they can incorporate the technology as part of their operations as they continue to attract investors and compete in the market. Sustainability in that sense would mean that all, or as many as possible, partner companies could produce and supply mRNA products in an economically viable way. This view seems to underlie WHO's sustainability work as presented at the WHO and Medicines Patent Pool mRNA meeting in Cape Town, South Africa in 2023.²²

However, an alternative and more ambitious view of economic sustainability towards health for all would consider the collaborative network of manufacturing partners, and their mission-oriented government support, as the operational entity that delivers public health. In this view, a one-off catalytic investment in technology transfer would not be enough for sustainable development of production capacity. Instead, the continued development and sharing of technology and a collaborative research and development pipeline could serve as the core asset around which to sustain the development and production of epidemic countermeasures for the common good.³ For the mRNA technology transfer programme, this approach would mean that participating vaccine manufacturers would combine knowledge and resources (intellectual, human and financial) around a shared and collectively owned technology platform. A different governance structure would also be needed for this initiative, with equity, knowledge-sharing and regional resilience at its core. Participating countries would also be required to prioritize the strengthening of regulatory capacity, including working with WHO and international experts to clarify the most appropriate regulatory pathways for the next generation of mRNA products.

To make such an end-to-end platform for epidemic preparedness sustainable, the countries and regions hosting and supporting the platform must design conducive policies for the platform to achieve its goals.⁷ Such policies should apply the vision laid out by the WHO Council on the Economics of Health for All to build an economy for health,²³ using its four work streams of value,²⁴ finance,²⁵ innovation²⁶ and capacity²⁷ as guidance. This approach focuses on how value in health is measured, produced and distributed across the economy, and how innovation is governed to provide low- and middle-income countries with the ability to invest in initiatives such as the hub, and the capacity, both public and private, to make it happen.

Valuing what matters

Markets value goods and services in terms of prices, but this system is not a good indicator of the value of public goods such as health.^{7,28,29} For instance, the value of a vaccine includes individual health benefits and broader socioeconomic and indirect impact(s) that the vaccine or vaccination might have, as reflected in WHO's full vaccine value assessment, an analysis to inform priority-setting for investment in and uptake of vaccines.³⁰ For epidemic preparedness and response in particular, the capacity of countries or regions to rapidly develop and make available health technologies to control outbreaks when and where they occur is an important asset for health security. This capacity needs to be valued as such, even

if it is not profitable for individual companies.³¹ Other drivers of local resilience and equity are technological capability and autonomy to develop innovative solutions to address local health needs.³² The mRNA technology transfer programme would need to be reconfigured such that these drivers of public health, reliance and health security are valued, even if the traditional metrics of price and profits dictate otherwise.

To this end, the programme should measure success not just by the revenue streams generated by the partner companies, but by a mix of factors that includes: collaboration between firms and health-care providers to co-create vaccine candidates for an emerging health threat; ability to produce vaccines and related products and obtain national regulatory approval within a reasonable time frame; establishment of multiple small- to medium-scale production units that can produce epidemic countermeasures at acceptable cost-of-goods, and are ready for activation when needed; ability to establish reserve capacity that can be rapidly activated in case of need or to supply stockpiles; and increased access to relevant vaccines, and adequate and timely coverage.

Financing what is valued

If both the societal value of vaccines (based on the full vaccine value assessment) and the strategic value of an end-to-end system for epidemic preparedness and resilience are recognized as goals of the mRNA technology transfer programme, appropriate channels need to be used to mobilize the required financing.

The programme currently receives its funding from donors mostly from high-income countries as part of their development cooperation (Table 1). As of May 2023, the programme has US\$ 128.9 million in commitments, with about three quarters allocated to the South African Consortium (Hub) around Afrigen, BioVac and the South African Medical Research Council and a quarter to the partner companies.

Equipping the whole network of manufacturing partners with state-of-the-art infrastructure for efficient small- to medium-scale production will require further investments for the manufacturers, through additional donor funding and domestic finance, especially if governments can access capital affordably. However, not all partners will be able to individually raise the finance needed, given the uncertainty about whether the market for a vaccine candidate would exist and the lack of procurement guarantees from governments or multilateral organizations. Current budget estimates are modest to set up the needed infrastructure and capability, develop mRNA technology and transfer it to the 15–20 manufacturers and expect them to be sustainable.

Therefore, greater financing needs to be secured for the programme from international financial institutions, regional development banks and potentially private financial sources.^{33–} ³⁵ However, the funds to finance an end-to-end approach for health security would have to be carefully selected and directed with appropriate conditions.³⁶ Unlike typical public–private partnership funding, the arrangement should not only minimize risk to the investments of private sector partners and investors, but also ensure the collective effort is structured around shared objectives of all stakeholders to achieve health security, resilience and sustainability.

Governing innovation

The shortcomings of the current commercial health innovation system to serve public health objectives are well documented,²⁶ and are particularly apparent for epidemic preparedness and response.^{37,38} With intellectual property monopolies as the main mechanism to maximize financial returns, research and development priorities are geared to market opportunities rather than health needs. This model allows billions of dollars in profits for large pharmaceutical companies while not disclosing the know-how and technologies that could transform pandemic preparedness and response in low- and middle-income countries.³⁹ At the same time, new health products command increasingly high prices, even though most such goods show little or no clinical benefit compared with products that already exist.²⁹ These dynamics also result in insufficient research and development investment in treatments and vaccines for diseases that affect people in low- and middle-income countries, where the population does not have the means to pay high prices.⁴⁰

The mRNA technology transfer programme should be designed as a collectively owned research and technology platform for epidemic preparedness and response which is managed for the common good.^{3,31} An appropriate legal structure and organizational form should be designed in which the shared technology platform and research and development portfolio are considered important common-good assets for public health. Access and user rights should be defined around this platform and portfolio and linked to commitments to continued investments in sustainability and equitable access to the resulting health products when and where needed.²

Success of the mRNA technology transfer programme requires the implementation of measures to ensure freedom to operate without intellectual property constraints in developing, manufacturing, commercializing (including for export) and using health products produced with mRNA technology.³ As such, individual government action, or regional and/or global

Publication: Bulletin of the World Health Organization; Type: Policy & practice Article ID: BLT.24.291388 approaches, may be required, including the use of legal mechanisms under international law if advocacy and good-faith negotiations fail to secure essential tools for public health.

Building government capacity

Countries that host a local manufacturer participating in the mRNA technology transfer programme have in principle committed to support the manufacturing partners. Concrete ways to support the programme include: (i) ensuring that the country's intellectual property laws include flexibilities within the Trade-Related Aspects of Intellectual Property Rights to overcome any intellectual property barriers to protecting public health, and the willingness to use these laws if needed to achieve the goals of the mRNA technology transfer programme; (ii) strengthening regulatory oversight and authorization capacity and the ability to make judgements about benefits or risks based on the local context – or building international collaboration to support this function; (iii) ensuring the timely adoption of evidence-based vaccination guidelines, and closely coordinating with vaccine procurement (locally and internationally); (iv) investing in building local research and development capacity and regional collaboration and open science initiatives; and (vi) mobilizing domestic and international finance to support the mRNA technology transfer programme as investment in both local and global health security and equity.

Conclusion

The mRNA technology transfer programme is a timely, important and ambitious project to shift the balance of global vaccine production so that researchers and developers in low- and middle-income countries can produce life-saving health technologies and provide equitable access to them in a timely way. Establishing resilient global health security infrastructure and capability and supporting the freedom for research, development and manufacture of vital health technologies are essential building blocks towards that goal. However, ensuring success requires rethinking the definition of sustainability and reshaping the health–industry system for health equity. This change involves moving beyond the concept of competitive markets and market-fixing to enable individual producers to thrive as businesses. Therefore, a new narrative and value proposition must be adopted that focuses on mission-oriented economic sustainability for health from a country, regional and global perspective. To build a new narrative and achieve the desired outcomes for health, a range of inputs, policies and operational mechanisms need to be considered which include access to suitable technologies and know-how, adequate financing, skilled human resources, and collaboration and

coordination between developing countries. While parts of this overall vision have started to be incorporated into the evolving design and operationalization of the mRNA technology transfer programme, other aspects – especially the common good approach to health security through technological capability and freedom to operate – have yet to be seriously applied. Stronger leadership and a global public health vision from the partners in low- and middle-income countries and their governments are needed to move from a vertical technical assistance project piloted by WHO and Medicines Patent Pool to a truly and locally owned collaborative health security effort for the common good, rooted in regional resilience and autonomy.

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Competing interests:

None declared.

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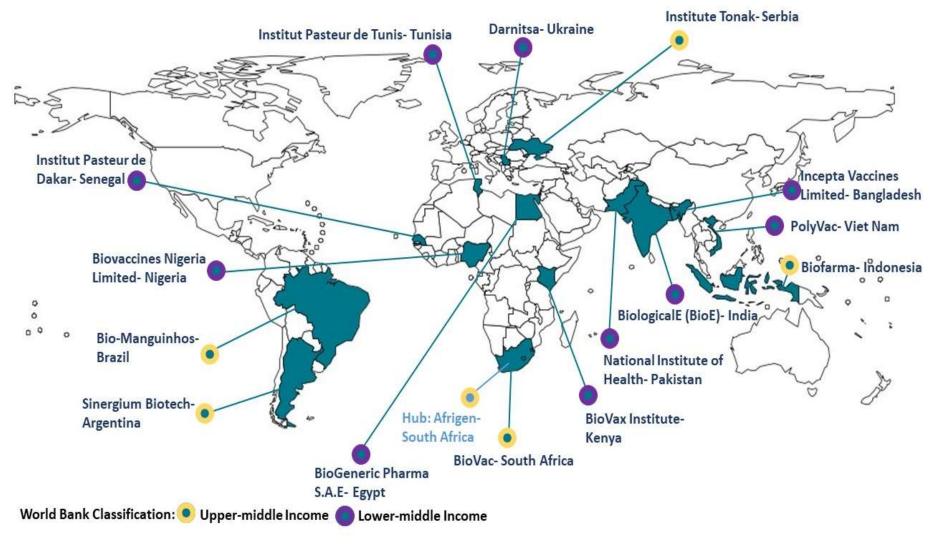
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Funder	Amount, in million US\$
French government	54.4
Canadian government	33.9
European Commission	12.0
German government	6.6
African Union	7.0
South African government	4.5
Belgian government	4.3
Norwegian government	4.5
Other	1.7
Total	128.9

Table 1. Funding committed for the mRNA technology transfer programme, bydonor country, May 2023

mRNA: messenger ribonucleic acid; US\$: United States dollars.

Fig. 1. mRNA technology transfer hub and manufacturing partners



mRNA: messenger ribonucleic acid.