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# The strategic importance of mRNA vaccine technologies in Africa for achieving public health independence

Patrick B. Arbuthnot, Kristie M. Bloom, Dylan M. Kairuz, Connor Stockley, Robin Klintworth, Charles B. de Koning & Abdullah Ely



To build mRNA vaccine manufacturing capacity in Africa, significant progress has been made with human, technical and regulatory capacity development. Here we highlight these developments and summarise hurdles that need to be overcome before a self-sustaining mRNA vaccine production ecosystem is established in the continent.

Vaccines remain a cornerstone of global health security and have enabled milestones such as eradication of smallpox and near-elimination of poliovirus. However, existing vaccines may have limited efficacy against threats posed by emerging and current pathogens. Importantly, global vaccine distribution has remained inequitable, particularly in Africa, where there are substantial public health needs and limited local manufacturing capacity. Climate change, ease of travel and urbanisation exacerbate the challenges posed by infectious diseases[1]. Vaccine self-reliance, which involves securing reliable local access to vaccines and reducing dependence on external supply chains, is important for Africa to respond to public health threats. Africa presently only produces approximately 1% of the vaccines it consumes, and the goal of the Africa Centres for Disease Control and Prevention (Africa CDC) is to increase this figure to 60% by 2040[2]. Access to new vaccine technologies is therefore essential for achieving the Africa CDC goals.

## The COVID-19 pandemic exposed Africa's vaccine vulnerability

Within months of the start of the COVID-19 pandemic, SARS-CoV-2 spread worldwide[3]. As a result, healthcare infrastructures were overwhelmed, economies disrupted, and inadequacies of health security were starkly revealed. The crisis spurred scientific collaboration, which resulted in the fastest development and rollout of vaccines in history[4]. This feat was largely enabled by harnessing adaptable mRNA and viral-vector technologies. Countries with strong vaccination programmes experienced rapid declines in severe disease and mortality[5], which highlighted the importance of vaccines for mitigating the health and socioeconomic impacts of COVID-19. However, low- and middle-income countries (LMICs), which had limited resources, remained vulnerably dependent on external supplies[5]. Another complication was the emergence of variants of concern (VOCs), which could evade immunity induced by first generation vaccines. These VOCs often arose in LMICs, raising concerns that gains from implementing efficient vaccination programmes could be undermined by the new variants[6]. This further emphasised the global importance of robust local vaccine manufacturing programmes in LMICs.

## Building mRNA vaccine capacity through technology transfer

The success of mRNA vaccines during COVID-19 indicated the feasibility of this technology for rapidly strengthening manufacturing capacity in LMICs. Unlike traditional platforms, which often require complicated methods or specialised facilities, mRNA vaccine production uses modular, rapidly adaptable and scalable cell-free enzymatic synthesis. The World Health Organization (WHO) and Medicines Patent Pool (MPP) recognised the strategic opportunity offered by mRNA-based approaches[7,8]. Based on this insight the WHO/MPP mRNA Technology Transfer (TT) Programme was set up. By enabling mastery of the full spectrum of mRNA vaccine development, the initiative aimed to build self-reliance and resilience in LMICs. The programme was supported by multiple national governments, the European Union, the African Union and the ELMA Foundation. The investment was intended to support pandemic preparedness and nurture human capacity development.

Establishing a complete mRNA vaccine pipeline requires coordinated advances in several different fields. Initially, the WHO/MPP mRNA TT Programme drew on the technical experience of the Antiviral Gene Therapy Research Unit (AGTRU) of the University of the Witwatersrand (Wits) and the South African Medical Research Council (SAMRC). AGTRU's experience with therapeutic mRNA was rapidly adapted for vaccine production and transferred to Afrigen Biologics and Vaccines in Cape Town, the WHO/MPP-designated hub, before dissemination to partner countries through a "hub-and-spoke" model. This mechanism rapidly enabled partners to produce high-quality research-grade mRNA and was a precursor to establishing current Good Manufacturing Practice- (cGMP-) compliant manufacturing procedures that are needed for use of mRNA in humans. Expertise in mRNA lipid nanoparticle (LNP) formulation, scale-up through process expansion followed, albeit at an uneven pace, throughout Africa[8].

The complex intellectual property (IP) landscape of mRNA vaccines, which includes patents covering mRNA design, LNP delivery systems and manufacturing processes, may impede vaccine rollout in LMICs. These difficulties potentially create barriers to freedom to operate (FTO), increase costs and delay development of vaccine manufacturing capacity. Therefore, the mRNA TT Programme also aimed to assist LMICs to overcome intellectual property (IP) barriers. Ideally, to avoid costly license agreements and infringing others' patents, local vaccine manufacturing industries should be based on use of proprietary IP in LMICs. This FTO is, however, not easily achieved. An interesting alternative approach that resulted in new African-led IP entailed the synthesis of novel ionisable lipids derived from rare phenolic compounds extracted from cashew nutshell liquid (CNSL)[9,10].

Ionisable lipids are essential for mRNA LNP formulation, but supply is dominated by a small number of patent holders, which may restrict FTO and increase licensing complexity. Cashew nuts are abundantly produced in Africa, and the nutshells are an agricultural waste product. Use of CNSL-derived phenolic compounds also avoids dependence on precursors derived from the petroleum industry. The ionisable lipids, generated by teams from the Wits Synthetic Organic Chemistry group and AGTRU, function very efficiently in preclinical vaccine formulations[10]. In addition to providing FTO, these lipids are considerably cheaper to synthesise than currently licensed compounds, which is advantageous for manufacture of affordable mRNA vaccines in Africa.

## Remaining scientific, regulatory and manufacturing challenges

Rapid clinical translation of candidate mRNA vaccines in Africa requires coordinated input from multiple stakeholders (Fig. 1). Although substantial progress has been made, important gaps remain before a fully accredited end-to-end mRNA vaccine manufacturing capability is achieved. A key requirement for clinical translation is the availability of small-scale cGMP manufacturing to support affordable entry into early Phase 1 and Phase 2 clinical trials, which typically require approximately 1000 doses per study. Ideally, an integrated manufacturing ecosystem should include both small-scale cGMP capability for early clinical evaluation, and larger-scale cGMP needed for advanced clinical trials and population rollout. Small-scale cGMP manufacture reduces development costs and enables early evaluation and optimisation of vaccine candidates before commitment to large-scale production. Construction of African facilities for cGMP manufacture of mRNA vaccines is progressing well, and a significant milestone has been accreditation of the facilities of Afrigen Biologics and Vaccines in Cape Town[11]. This authorisation was obtained from the South African Health Products Regulatory Authority (SAHPRA) and similar approval by National Regulatory Authorities (NRAs) of other countries seems imminent[8,12,13].

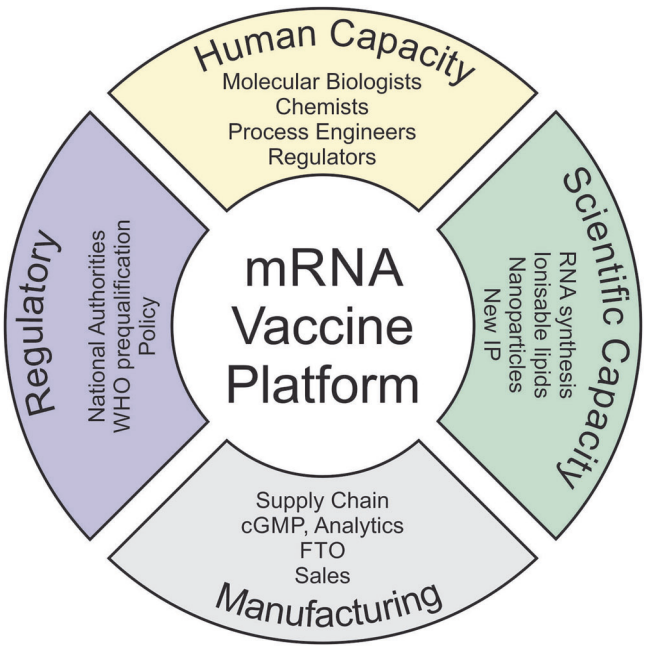


**Fig. 1 |** Essential interrelated components required to advance mRNA vaccine production to becoming autonomous and sustainable.

Advancing readiness of NRAs in Africa has also been a priority. WHO Global Benchmarking Tool-defined maturity level 3 (ML3), which signifies a stable, well-functioning and integrated regulatory authority, has now been achieved by the NRAs of eight African countries[14]. Four of these are from countries that are partners of the WHO/MPP mRNA TT platform: South Africa, Egypt, Nigeria and Senegal. None of the African NRAs has yet achieved ML4, the most advanced level maintained by the US FDA, European Medicines Agency and Japanese Pharmaceuticals and Medical Devices Agency, but agencies from Ghana and South Africa are approaching ML4. By harmonising processes, the African Medicines Agency is further strengthening the regulatory framework which augurs well for African mRNA vaccine production facilities achieving internationally accepted standards.

Automated mRNA production platforms, such as the Quantoom and BioNTainer systems, offer important advantages for Africa[15–17]. These include the lowering of infrastructure requirements and simplification of technology transfer. Moreover, the integrated nature of the platforms is suited to building scalable frameworks that enable a streamlined path to cGMP compliance. These systems have already been deployed or are being installed in several African countries, including South Africa, Rwanda, Senegal and Egypt. Although these automated systems accelerate access to manufacturing infrastructure, they may leave African manufacturers removed from the fundamentals of the underlying scientific and technical processes. This capability is important for Africa to achieve true technological sovereignty.

## Building a sustainable mRNA vaccine ecosystem

Successfully realising the aims of the WHO/MPP-sponsored mRNA TT programme offers the prospect of transformative benefits for countries across Africa. By building regional mRNA vaccine production capacity, the initiative has the potential to reduce Africa's dependence on external supplies. By extension, such an achievement should also promote global health security. These goals align well with the Africa CDC's aim that the continent should produce 60% of the vaccines it uses by the year 2040. However, achieving these ambitions is dependent on overcoming substantial challenges. Foremost is ensuring long-term sustainability beyond initial donor support. To prevent dissipation of hard-won gains, clearly defined pathways for commercialisation should be put in place. This will be vital for financial viability and embedding the enterprises within functioning markets. Although several African partners of the mRNA vaccine programme are commercial entities, the broader biotechnology ecosystem in Africa is at an early stage of its development. Establishing strategic partnerships with global companies and continued financial investment will be vital. Generating valuable intellectual property to secure FTO, negotiating favourable licensing arrangements and securing government procurement contracts should remain priorities. Currently, there is a commitment to achieve these goals, and the supportive goodwill is nurturing a resilient, self-sustaining mRNA vaccine production ecosystem in Africa.

## Data availability

No new data were generated or analysed for this Commentary. All data referenced are derived from publicly available sources and previously published studies cited in the manuscript.

**Patrick B. Arbuthnot [1,2] ✉, Kristie M. Bloom [1,2], Dylan M. Kairuz [1,2], Connor Stockley [2,3], Robin Klintworth [2,3], Charles B. de Koning [2,3] & Abdullah Ely [1,2] ✉**

[1]Wits/SAMRC Antiviral Gene Therapy Research Unit, School of Pathology, Infectious Diseases and Oncology Research Institute (IDORI), Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa. [2]Green Lipids (Pty) Ltd, Johannesburg, South Africa. [3]School of Chemistry, University of the Witwatersrand, Johannesburg, South Africa. ✉e-mail: Patrick.Arbuthnot@wits.ac.za; Abdullah.Ely@wits.ac.za

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## Author contributions

P.B.A. compiled the first draft of the article, which was then finalised after input from K.M.B., D.M.K., C.S., R.K., C.B.dK and A.E.

## Competing interests

The authors are founders of Green Lipids (Pty) Ltd, Johannesburg, South Africa.

## Additional information

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**Correspondence** and requests for materials should be addressed to Patrick B. Arbuthnot or Abdullah Ely.

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