Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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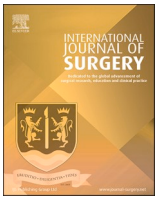

Correspondence

mRNA vaccines and clinical research in Africa - From hope to reality

Dear Editor,

mRNA vaccines are advantageous for Africa. They could potentially be utilized against other African viral and bacterial diseases other than COVID-19 [1]. They are highly effective in preventing symptomatic and severe COVID-19 infection. They are effective, safe, and can be produced in large quantities. Furthermore, they are easily manufactured, take little time, and require no prior familiarity with biological pharmaceutical agents.

In February 2022, six African countries (Egypt, Nigeria, Kenya, Senegal, South Africa, and Tunisia) were chosen to deliver mRNA technology from the WHO mRNA Technology Transfer Hub, which is located at Afrigen, Cape Town, South Africa [2]. Separately to the WHO efforts, Moderna has signed a Memorandum of Understanding (MOU) with Kenya to build a new mRNA plant in Kenya, starting with drug substances and potentially expanding to include fill-finish. Pfizer partner BioNTech intends to send container-based COVID-19 vaccine factories to be installed in some African Union (AU) countries. Malaria and tuberculosis vaccines can be developed using mRNA technology, providing African countries with real opportunities for combating these endemic diseases [3]. Some mRNA vaccines now necessitate ultra-cold chain storage and distribution. Investments in ultra-cold chains for COVID-19 vaccines across Africa can serve multiple purposes if upcycled into future research laboratories and facilities for storing new mRNA vaccines.

Historically, Africa has suffered from a lack of cold chain infrastructure, a lack of highly specialized equipment required to store vaccines at extremely low temperatures, power outages, and freezer equipment failure. During the Ebola outbreak in 2014–2016, a Merck (Ervebo) vaccine had to be maintained at −70 °C. The Arktek Cold Storage Device was first deployed to Sierra Leone in 2014, wherein it helped in the transportation of vaccines that saved the lives of hundreds of thousands of Africans. Arktek containers were recommended as a solution for delivering Merck vaccines at −60 °C [4]. The Arktek Passive Vaccine Storage Device (PVSD) is a super-insulated container that uses only ice packs to keep vaccines safe for up to a month at temperatures ranging from 2 °C to 8 °C. The device was adapted for the Ebola vaccine trials to handle −80 °C, with a payload of roughly 200 vials of vaccine [4]. The modified Arktek devices proved invaluable and dependable for distributing and storing vaccines during power outages or freezer malfunctions. These devices can be critical in spreading mRNA vaccines in Africa against COVID-19 and other viral diseases [2].

Apart from improving the cold chain system within the supply chain, thermostable vaccines have been proposed as a possible way forward in managing these challenges and a feasible solution for increasing vaccination coverage in Low- and Middle-income countries (LMICs) with fluctuating energy supplies [5]. Lyophilization (freeze-drying by removal of the aqueous phase) is one of the approaches that have been urged and successfully employed for mRNA vaccine stabilizing [6]. Higher temperatures may cause denaturation of the vaccine proteins, leaving them useless for all WHO prequalified vaccines that must now be stored in refrigerators or freezers. Making certain vaccines thermostable would eliminate the requirement for a cold chain, making room for vaccines that require cooler or cold temperatures [5]. To get around the high cost of vaccine supply (storage and transportation), and the low accessibility of mRNA vaccines in African countries, the mRNA vaccine must be prepared to be stored at ambient temperature or refrigerated at 4 °C.

Hong and colleagues [7] prepared a lyophilized liposome-based mRNA (EG-COVID) vaccine. They reported that the EG-COVID vaccine is a potent and safe vaccine against SARS-CoV-2 and it could be stored for a prolonged time in a conventional refrigerator. In mice, the EG-COVID elicited a significant humoral and cellular immune response to SARS-CoV-2; additionally, mice sera successfully reduced SARS-CoV-2 viral infection in Vero cells. Alberer and colleagues showed that lyophilized mRNA vaccine against rabies was stable at 5–25 °C for 36 months and at 40 °C for 6 months [8]. Ai and colleagues [9] reported that lyophilized thermostable mRNA-loaded lipid nanoparticles could be stored at room temperature with long-term stability. They prepared three lyophilized vaccines against wild-type SARS-CoV-2, Delta, and Omicron SARS-CoV-2 variants. These vaccines induced a high level of IgG titer and neutralization response. Moreover, the lyophilized mRNA vaccine successfully protected mice from infection with Delta challenge. Muramatsu and colleagues [10] offered additional evidence on the applicability of the lyophilized mRNA vaccine with less need for cooling. They prepared a lyophilized influenza virus hemagglutinin-encoding mRNA-LNP vaccine and stored it at room temperature or 4 °C for three months and six months, respectively. Interestingly, it showed high immunogenicity and high expression in mice.

In February 2022, Afrigen revealed its plans to produce a second-generation COVID-19 vaccine with less mRNA but improved thermostability after successfully producing its own mRNA COVID-19 vaccine [11]. The lyophilization approach [12] offers a compelling opportunity to improve the thermostability of mRNA-LNP vaccines and the accessibility of mRNA-based vaccines and therapeutics, especially in African rural areas. With the entry of Pfizer-BioNTech and Moderna COVID-19 mRNA vaccines in Africa, Africa can start making its own vaccines tailored to it.

1. HIV mRNA vaccines in Africa

Making policy and treatment guidelines based on insufficient data through missing certain populations in clinical research can put patients from these populations at risk of injury or inferior treatment outcomes. Initiatives to promote large-scale trials enhance local scientific

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capabilities to ensure that all trials are done with scientific, ethical, and regulatory rigor under adequate monitoring. For Africa to achieve its regional goal of increasing domestic pharmaceutical and vaccine manufacturing, an efficient clinical research environment is necessary, particularly with the advent of mRNA makers into the African continent [13].

In May 2022, International AIDS Vaccine Initiative (IAVI) and Moderna announced the first participant screenings for a Phase I clinical trial IAVI G003 of an mRNA HIV vaccine antigen (mRNA-1644) in Rwanda and South Africa are about to begin to complement the Phase I clinical trial IAVI G001 that is done on healthy U.S. adults using the HIV immunogen eOD-GT8 60mer as a recombinant protein. HIV immunogen eOD-GT8 60mer was developed by the scientific teams at IAVI and Scripps Research and delivered via Moderna's mRNA platform [14].

Two doses of eOD-GT8 60mer mRNA are to be given to each participant. Enrolled subjects are followed six months after receiving the final dose for safety, and their immune responses are examined in molecular detail to determine whether the intended responses can materialise. Kenyan scientists at the KAVI-Institute for Clinical Research (KAVI-ICR) in Nairobi and Kenya Medical Research Institute-Centre for Geographic Medicine Research-Coast (KEMRI-CGMRC) in Kilifi in Kenya will primarily conduct the majority of the trial endpoint analysis for IAVI G003, and in part by scientists at the CAVD-Central Services Facility, the IAVI's Neutralizing Antibody Center (IAVI NAC) at Scripps Research, La Jolla, California, and Vaccine Immunology Statistical Center (VISC). Promisingly, this groundbreaking partnership will foster cutting-edge research and a new generation of African scientists to advance the development HIV mRNA vaccine.

2. Africa and its internal threats

Over the past century, viral zoonotic pandemics have increasingly cost more money and more lives [15]. The cycle of zoonotic pathogens is complete on the existence of a suitable environment for spillover, the absence of sufficient and effective surveillance, and the lack of awareness and resources. Since then, the cycle begins to reshape the emerging and re-emerging diseases once such zoonotic diseases arrive in cities. Contact of African people with animals is indispensable for different purposes like livelihood (hunting and eating bush meat) [1]. Africa is the second most populous continent after Asia, with 1.3 billion people, and the wildlife of Africa is renowned for its tremendous diversity and richness. In addition to climate change, increasing urbanisation and encroachment on wildlife habitats, the chance of zoonotic disease outbreaks spreading from rural, sparsely populated areas to major cities is greater due to improved road, rail, boat, and air connections throughout Africa.

In the decade from 2012 to 2022 when compared to 2001–2011, there has been a 63% rise in the number of zoonotic outbreaks in the African region [16] and the numbers of these zoonotic outbreaks have increased especially over the past two decades. Nearly 70% of these outbreaks are caused by the Ebola virus disease and other viral hemorrhagic fevers, with the remaining 30% being caused by dengue fever, anthrax, plague, monkeypox, and various other diseases. 50% of public health events recorded in the African region between 2019 and 2020 were zoonotic. The 14th Ebola outbreak in the Democratic Republic of the Congo has just recently ended as a result of the partnership and working together by the Food and Agriculture Organization of the United Nations (FAO), the World Organization for Animal Health (OIE), and WHO which began since 2008 [16].

Enhancing surveillance and laboratory testing capacity in the African countries is crucial for monkeypox and other zoonotic diseases (discovered and undiscovered). When containment measures start in Africa, it can save the possibilities for spread of transboundary diseases, such as monkeypox disease. A one-health strategy calls for cooperation among many communities, specialties, and sectors (environment, animal, and human) through exchanging routine disease surveillance data and response activities for both animal and human health.

I am just wondering why wealthier countries fight the fire before getting inside. Africa alone cannot prevent the splash and flare-up of future pandemic pathogens from its lands, in the light of limited-available resources. The first lessons that should be learned from the COVID-19 pandemic (Omicron variant) [17] and the ongoing monkeypox outbreak [18] are health security and assurance in Africa will reflect on the whole world, and neglecting these issues will worsen the global health situation.

Ethical approval

This article does not include any human/animal subjects to acquire such approval.

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Author contribution

AbdulRahman A. Saied: Conceptualization, Data Curation, Visualization, Writing - Original Draft, Writing -review & editing.

Research registration

1Name of the registry:
2Unique Identifying number or registration ID:
3Hyperlink to your specific registration (must be publicly accessible and will be checked):

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Declaration of competing interest

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijsu.2022.106833.

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