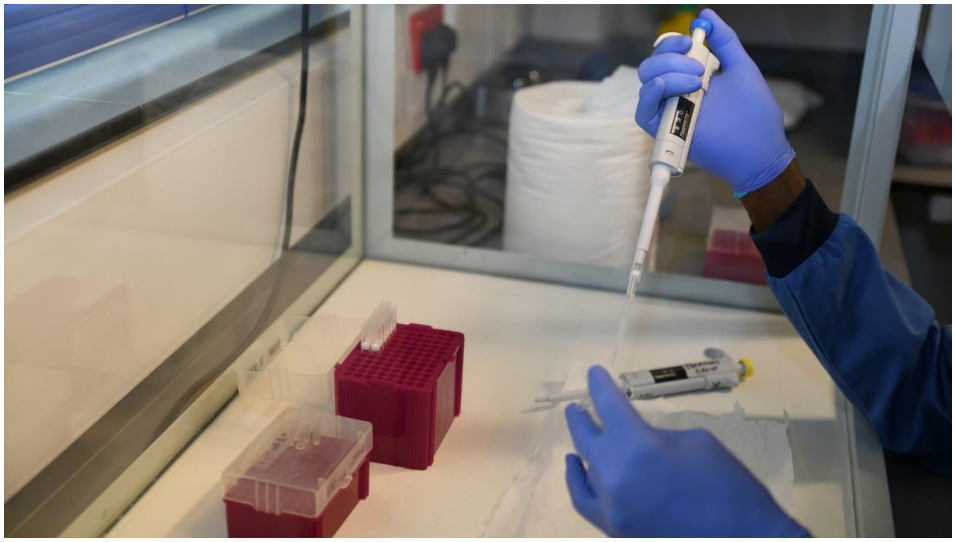
COVID-19 POLICY RESPONSE IN AFRICA: A RAPID EVIDENCE SYNTHESIS ON THE CURRENT STATE OF VACCINE AND DRUG RESEARCH & DEVELOPMENT CAPACITY, REGULATION AND COORDINATION



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Abstract

The rise in drug and vaccine nationalism in the wake of the COVID-19 pandemic has reignited calls for Africa to claim self-reliance for producing drugs, vaccines and other medical products. However, there are several hurdles to creating a thriving pharmaceutical industry. The purpose of this evidence review is to examine the status of drug and vaccine research, development and manufacturing in Africa to inform policies to enhance drug and vaccine production in Africa. The evidence was gathered through two mechanisms: a tele-convening of experts and stakeholders in the drug and vaccine R&D space, and a rapid review of published and relevant grey literature. Thirty-one publications were included in the review after screening an initial pool of 2,609 publications. The results reveal generally low drug and vaccine manufacturing (DVM) capacity in most African countries. Growth of the pharmaceutical industry in Africa is limited by a lack of investment in infrastructure and human resources for DVM. Additionally, the local and global business environment features unfavorable competition, restrictions on cross-border trade and asymmetrical trade treaties, which make the DVM sector in Africa unattractive to investors. Finally, insufficient ethics safeguards and regulatory platforms hamper the rapid introduction of local market innovation. These challenges can be overcome only if DVM capacity to secure the health of citizens is viewed as not only a public good but a fundamental right, and crucial to national security. For the DVM sector to thrive, African governments must commit to sustained R&D infrastructure and human capital investment to establish a conducive business environment for local manufacturers and investors, and to create effective and facilitative ethics structures. African countries must work together to harmonise ethical, regulatory, coordination and pharmacovigilance systems to build synergies.

Background

Coronavirus (COVID-19) has wreaked havoc on livelihoods across the world and resulted in nearly five million deaths. Through July 2021, the virus had infected over seven million people and claimed over 170,000 lives in Africa (1). The global response to COVID-19 includes promotion and enforcement of physical distancing, mask-wearing, frequent handwashing and adjunctive pneumonia therapy for severe cases (2). Despite these measures, the pandemic raged until early 2021 when vaccines were rolled out for public use. By June 2021, nineteen COVID-19 vaccines had been provisionally approved in at least one country (3, 4). So far, these vaccines have been effective, and provide optimism that the pandemic will subside sufficiently in the foreseeable future to enable countries to ease social and economic lockdown measures (4).

The breathtaking speed at which COVID-19 vaccines were developed underscores the power of international cooperation to tackle global health crises – but at the same time, the pandemic highlights the global disparity in access to medical products. While High Income Countries (HIC) account for only 20% of the world's adult population, they secured over 50% of all available vaccine doses, substantially more than they require (4-6). Despite international initiatives such as COVAX to coordinate global development, and equitable access and distribution of COVID-19 diagnostics, vaccines and treatments, less than 2% of the African population is fully vaccinated against COVID-19 (4). In contrast, over 50% of the population of HICs is fully

vaccinated (4-6). This imbalance reflects the diminished purchasing power and limited drug and vaccine manufacturing (DVM) capacity in Lower- and Middle-Income Countries, particularly those in Africa.

The call for Africa to become self-sufficient in developing and providing drugs and vaccines, though long-standing, has been amplified by the huge upsurge in “medical nationalism” attendant to the onset of the COVID-19 pandemic (6). The rush by countries to hoard drugs and other medical products has exposed the continent’s vulnerability to the vagaries of global medical product supply systems. Although frameworks, such as the 2012 Pharmaceutical Manufacturing Plan for Africa (PMPA), were developed to curb over-reliance on imports by promoting the local DVM sector (7), its effects are limited: Africa imports over 90% of her drugs and vaccines. The COVID-19 experience, while tragic, has the potential to be the wakeup call for DVM independence (8).

Drug and vaccine manufacturing requires significant investment in research, technology, human resources and policy support systems. It is therefore important that plans to invigorate the pharmaceutical manufacturing sector in Africa are based on rigorous evidence. The objective of this rapid review, which was commissioned by the African Academy of Sciences, is to evaluate and present the evidence required to inform the establishment of support systems and promote policy coherence regionally and continentally for COVID-19 drug and vaccine manufacturing in Africa. This report evaluates the status of and proposals for strengthening capacity of DVM R&D, manufacturing and regulatory frameworks in Africa.

Methods

Information on the current status of DVM in Africa, and challenges and recommendations, were gathered through two channels: a tele-convening of stakeholders in the drug and vaccine development space, and a rapid review of published and grey literature.

Tele-convening

The tele-convening sought to collect the knowledge, perspectives and experiences of African and international researchers, policymakers, senior African health ministry officials and other stakeholders on both existing coordination and surveillance mechanisms for vaccine and drug development, and how these mechanisms can be integrated in the development and rollout of COVID-19 vaccines. The tele-convening included presentations from subject matter experts and group discussions in breakout sessions.

Rapid Literature Review

The WHO format for rapid reviews was adopted (9) together with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) principles (10). Since the review focused on policy and research systems rather than clinical interventions, the PICO framework was not used. Use of PRISMA enabled a faster review than traditional systematic review. The main limitation of rapid review is the reduced range of literature databases searched; this tradeoff is

worthwhile when high-quality evidence is needed to support decision-making in a resource-efficient and timely manner, such as during a public health emergency (11-13).

Search Strategy

The literature search used the PubMed and Google Scholar databases. In addition, COVID-19 repositories, clinical trial registries and other online resources accessible through WHO, the African Academy of Sciences and Our World in Data were also searched for grey literature.

Search was conducted between 25 July and 5 August 2021 using the following keywords: Africa AND (“vaccines”, or “drugs”, or “pharmaceuticals”) AND (“research and development”, OR “trials”, OR “manufacturing”, OR “coordination”, OR “regulatory”, OR “capacity”). Articles were included only if a full text English version was available and accessible.

Analysis

To synthesise heterogenous literature, a narrative approach (14) was adopted for analysis. One reviewer extracted the data from all selected publications using an extraction form developed for this purpose, and a second reviewer checked the extracted data. The extracted data included the study design and type of resource (for example, research article scoping review or national report), the focus of the study, methodology, location, populations involved, key findings and recommendations. The data was analysed thematically, (15) using capacity and regulatory frameworks and coordination mechanisms for vaccine and drug development in Africa as the main themes.

Quality Assurance

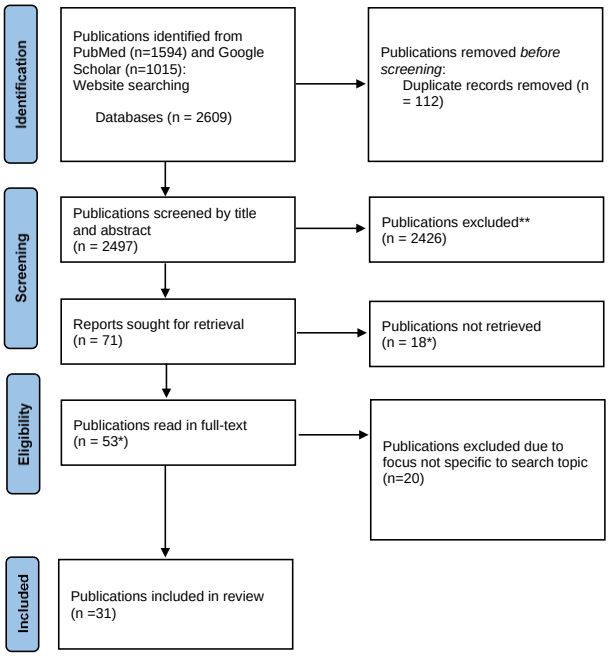
Two reviewers screened the first 30 search results to resolve disparities with a low threshold for inclusion: publications on key themes in English and with focus on Africa and COVID-19. One reviewer screened the resulting search results and selected publications for full screening. A second reviewer screened at least 10% of the publications excluded from the full screening.

Results

Summarised below are the results of the search and the tele-convening under three features of the drug and vaccine development space. A more comprehensive analysis of all the literature is provided in the appended Table 1; a detailed report of the tele-convening is provided in Table 2.

PRISMA

Fig 1. PRISMA search for DVM R&D in Africa



Drug and Vaccine R&D Capacity

Current Status

As of July 2021, there were 11,239 current and past clinical trials in Africa registered in the WHO Clinical Trials Registry (https://www.who.int/clinical-trials-registry-platform). Only five African countries had more than 100 clinical trials registered: Egypt, 7946; South Africa, 5,862; Uganda, 1,002; Kenya, 996; Nigeria, 725 and Ghana, 375. Overall, African trials accounted for only 2% of all the trials globally in the registry. For COVID-19, there were 17 drug and vaccine trials in 12 African countries by November 2020, vs. a global total of nearly 300 trials. Of these, South Africa was involved in seven, and Kenya and Ghana in two each (15). This minimal participation in clinical trials closely mirrors the continent's overall contribution to global health research output (17). This is not surprising, as clinical trials thrive in complex research systems. In fact, only 20 African countries have at least one research institute capable of conducting trials (16).

African governments have made repeated commitments to investing up to 2% of GDP to science, technology, and innovation (STI), but so far STI investment is less than 1% of GDP in all African countries (17). With the exceptions of Egypt and South Africa, clinical trials in Africa are generally externally funded or conducted through partnership with external entities. Even then, funding is not homogeneously distributed: for example, East Africa participates more than

Central Africa and the Sahel countries (17). Similarly, HIV, tuberculosis and malaria research is favoured over research on other high-burden diseases on the continent (18). Countries must therefore rely on pre-existing trial infrastructures for malaria, TB and HIV to conduct COVID-19 vaccine trials. However, these are limited and not necessarily well-suited for trials involving a highly infectious respiratory virus.

Despite the increase in the number of universities and corresponding number of schools of medicine and health sciences, very few graduate programmes train in clinical trials in Africa (18). Without the requisite skills and expertise, Africans are invariably relegated to a support, rather than a leading, role in local clinical trials. The corollary to this is that they share neither scientific credit nor intellectual property rights for the products they are involved in testing (19).

Recommendations

The UNESCO Science Report 2021 indicates that Africa's relative contribution to global science output has stagnated since 2014, largely because of increased output in other regions (17). But the continent can ill-afford to be left behind. It behooves African countries to urgently prioritise the development of an enabling environment for drug and vaccine R&D. To achieve this, African governments must revisit and honor their pledges to increase funding for STI. While in the short-term this may seem difficult, the impact of COVID-19 provides a convincing argument for the value of long-term investment in health research. Ultimately, 'whoever pays the piper calls the tune": Africa will only be in full control of its research agenda if it is the primary funder of research in Africa. This requires building sustainable R&D capacity through investment not just in research supplies and equipment but also in operations such as institutional research management systems.

To upgrade the role of African scientists from providing technical support of clinical trials to leading them, more local universities must develop courses on drug and vaccine development that incorporate clinical trials. Teaching must be reinforced with experiential learning through collaboration with research institutions where students can participate in ongoing clinical trials (17).

Underwriting the lengthy and costly process of pharmaceutical product development and meeting strict regulatory requirements is a challenge for most African public institutions. As elsewhere, public-private partnerships provide an opportunity to confront these challenges. An academia-industry-government model in which different pharmaceutical development stakeholders operate in unity will enhance the drug and vaccine development chain. Academia and industry can conduct joint basic research and clinical trials, while the government guarantees purchase of successful products from the private manufacturer, thus re-injecting money into the product development cycle (20).

Manufacturing Environment

Current Status

Overall, the continent has roughly 375 drug makers, most in North Africa, to serve a population of around 1.3 billion people. Those in sub-Saharan Africa are largely clustered in just nine of 46 countries, and many lack operations that meet international standards. By comparison, China and India, each with a population of roughly 1.4 billion, have as many as 5,000 and 10,500 drug manufacturers respectively (21,22). Most of the pharmaceutical manufacturers in Africa are small, locally owned private companies that primarily serve local markets, although larger, state-owned enterprises are also being established (23). Only seven African countries have companies operating across the vaccine-manufacturing value chain (manufacturing through distribution). Of these, only one exports a WHO pre-qualified vaccine (Institute Pasteur in Dakar), while most do not export at all, and none is engaged in research and development (24).

Grim as these statistics may be, there is nonetheless hope that Africa can develop a thriving DVM sector. A combination of population and economic growth is projected to strongly boost the value of the African pharmaceutical industry in the coming years. In 2003, the industry was valued at $4.7 billion, rising to $20.8 billion by 2013. Its value is now estimated at $40-$65 billion -- about a 9% annual growth rate (22). Of this, the vaccine market, estimated at $1.3 billion, is expected to reach a value of up to $2.35 billion by 2030 (24).

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Challenges

Several modeling studies provide a compelling argument for the economic viability of DVM in Africa (25, 26), but there are challenges to be overcome to create a vibrant DVM sector. These barriers can be categorised into three major areas: 1) limited physical and human resources for DVM; 2) lack of conducive local manufacturing environments, and 3) an unfair global operating environment. Although some of these challenges extend across the whole manufacturing sector in Africa, others are unique to the pharmaceutical industry. This is partly due to the failure of African governments to offer adequate incentives for local pharmaceutical manufacturers (27).

In addition to limited DVM technology and infrastructure (27), most African countries lack a critical mass of specialists required at each step of the DVM chain, making them dependent on engaging expensive expatriates. This, combined with unreliable energy supplies, fragile logistics and storage capacity, the high cost of transport and distribution and long lead times in international procurement, results in significant cost disadvantages for manufacturers in Africa. This, in turn, explains the lack of private investment in the DVM sector in Africa (20).

Heavy dependence on foreign aid and cheap generic drugs, particularly from Asia, coupled with delays in the adoption of WHO's pre-qualification standards for African firms (28), expose local companies to stiff competition, often leading African governments to procure externally produced drugs (23, 27).

These competitive disadvantages are furthermore exacerbated by weak regulation and poor pharmacovigilance that fail to prevent cheap substandard and falsified medical products from flooding the market (28). Moreover, local DVM is disadvantaged by the systemic problem of tax avoidance and endemic international corruption facilitated by some big corporations and

governments (28). Finally, the lack of regional harmonisation and co-ordination of drug and vaccine manufacturing and marketing hamper cross-border trading and limits the market for local manufacturers (27).

Coupled with long-standing economic and political crises in some regions of the continent, the environment for local DVM can be stifling, and can smother the development of even the most promising pharmaceutical product. A cautionary example is the failure of NIPRSAN, a Nigerian herbal therapy with proven efficacy in preventing sickle cell disease (30).

Beyond local challenges, African pharmaceutical companies must also contend with the systemic global disadvantages of asymmetrical trade and intellectual property treaties. Aduse et al (2010) identified patent dysfunctions associated with TRIPS agreement as a major barrier to to pharmaceutical manufacturing in LMICs (19). For instance, the expanded scope of patentable products to include micro-organisms and micro-biological processes, high levels of patent protection for medicinal test data and the uniform application of patent standards globally gloss over differences in national capacities that inherently privileges HICs. The Western patenting philosophy that values the individual's intellectual property rights over public good not only inhibits local innovation and encourages rent-seeking behaviour, but it also denies LMIC access to necessities such as food and drugs. Paradoxically, patent laws in most countries do not grant protection to traditional knowledge, thus facilitating biopiracy and cultural imperialism in the name of bioprospecting (19).

Recommendations

Importing drugs to Africa rather than manufacturing locally may be economically advantageous in the short term, but local production will be cheaper in the long run (25). Furthermore, COVID-19 has demonstrated that the economics of self-reliance on medical products is just one feature of domestic DVM: it is also a public good and critical to national security. As such, African governments must create a DVM ecosystem that integrates the right infrastructure, locally grown expertise and a business-friendly environment that attracts investors and incentivises local manufacturers (31). Such a commitment would include prioritising local manufacturing in public procurement, financial incentives such as soft loans, subsidies and tax breaks, establishment of special economic zones, and talent- and skill-building programmes (21,31).

Also essential is the support of cross-border trade among African countries and enabling local manufacturers to expand their scope to countries without adequate capacity. Cohesive policy frameworks must be established, and regulatory authority and harmonisation of medicine registration is necessary for the integration of continental and regional markets. Such frameworks should focus on supporting regional DVM rather the forming alliances to purchase drugs for Africa from external producers. (28, 21). Private-sector investors, if incentivised, will identify the best commercial opportunities and the role that governments can play in attracting investment. Moreover, collaboration and partnership among pharmaceutical manufacturers and

regulators in African states is crucial to address cross-border coordination and supply of vaccines and drugs to non-producer countries (27).

Cooperation among African countries and multilateral organisations such as WHO are integral to developing DVM capacity. They can assist through technology transfer, guiding relevant frameworks, and investment in the sector. Collaboration among pharmaceutical producers in Africa and upstream suppliers of active pharmaceutical ingredients (APIs) offers an opportunity to jumpstart the initial growth of African DVM industry by facilitating local production of generics and “scaffold hopping” to build capacity across the whole drug and vaccine development chain (29).

To tackle global trade asymmetries that hamper the growth of DVM in Africa, a “regulatory diversity” model should be adopted. The model balances social-economic needs with business interests by accounting for human rights in the patenting of medical products. LMIC governments should consider using compulsory licensing for the domestic manufacture of necessary, essential medicines in the interest of public health, without requiring compliance with preconditions set by the developed world. Such a move would force drugs manufacturers to reduce prices under threat of compulsory licensing by governments in sub-Saharan Africa (19, 31).

Regulation and Ethics

Current Status

Harmonisation of drug and vaccine research ethics and regulatory systems across African countries has long been recognised as necessary for the DVM ecosystem. The African Vaccine Regulatory Forum (AVAREF) was established by WHO in 2006 to build the capacity of regulatory and ethics agencies and improve harmonisation in support of product development (32) and has played a crucial role in the successful development of several vaccines and Ebola virus therapies. More recently, African Medicines Regulatory Harmonization (AMRH) within the Pharmaceutical Manufacturing Plan for Africa (PMPA) of the African Union promotes an enabling regulatory environment for local medicine production by strengthening regulatory capacity, harmonising regulatory requirements and expediting access to good quality, safe and effective drugs (33). This continental instrument is replicated at a regional level through the Economic Community of West African States (ECOWAS), the Intergovernmental Authority on Development (IGAD), the Economic Community of Central African States (ECCAS) and the East African Community (EAC) (34).

Barch et al (2016) mapped national guidelines on the ethical collection of human blood samples (HBS), a key component of most clinical trials. They reveal that only 29 of 49 SSA countries surveyed had some form of national ethics guidance in this area. Of these, only 17 included guidelines specific to HBS, such as consent, ownership, reuse, storage and export/import/transfer. Even among the ten countries that accounted for most of the active clinical trials that collected HBS, only seven had guidelines related to HBS specifically (33).

These data are consistent with the Mapping African Research Ethics Review Capacity (MARC) project portal that reports that by 2016, a maximum of 27 countries had indicated having some level of research ethics committee (36). It is likely that these numbers have increased since 2016, but it is not clear how the capacity of the committees have changed in the intervening period.

There is a general paucity of detailed analysis of ethics review systems at the national level. The most comprehensive review of national ethics guidelines and the National Research Regulatory Authority (NRRA) was conducted in 2018 by the East Africa Research Council in five East African countries. It reports a total of 69 research ethics committees (RECs) which together reviewed nearly 100 protocols per year. Although they received some state or institutional funding, the RECs were largely funded through user fees. Capacity varied across the RECs with only about 60% able to review both local and international research projects. Most of the RECs had education policy but fewer than half had members with training in ethics (37).

National pharmacovigilance (PV) systems monitor the efficacy and safety of newly rolled out drugs and vaccines. PV systems exist in Africa, but many are poorly effective operationally and functionally, which negatively impacts pharmaceutical production (38). A 2012 survey of 46 SSA countries found that over 75% do not have a functional PV system or legislation to monitor adverse events, and fewer than half have a national policy related to medicine safety or a medicine safety advisory committee. Many countries do not have a national PV center and only 28% have a platform or strategy to coordinate in-country stakeholders. Although 74% have adverse event reporting systems, fewer than 50% monitor product quality, medication errors, or treatment failures through existing systems (38). Furthermore, where they do exist, PVs have difficulty gathering and generating evidence-based, transparent active drug or vaccine safety efficacy and monitoring information (39).

Recommendations

African countries must develop strategic plans that account for direct and indirect DVM factors, coordinate stakeholders, and strengthen risk management and communication to improve patient safety and health outcomes (38). The most important policy areas to develop are on 1) harmonisation of policy frameworks and tools; 2) institutionalisation of regional joint review mechanisms; 3) standardisation of training and capacity building, and 4) review of REC operational and financing models.

Summary and Policy Implications

The lessons of COVID-19 clearly amplify the need for Africa to achieve self-reliance for drugs, vaccines and other medical products. Unfortunately, it is unlikely that COVID-19 is going to be the last pandemic; Africa must be better prepared for the next one. The barriers to self-reliance for drug and vaccine development in Africa are significant but not insurmountable if capacity to secure the health of citizens is viewed as a fundamental right, a public good and a matter of national security. The effort must be deliberate, and embrace sustained investments in physical and human resources, creation of conducive local manufacturing environments, and an

equitable global operating environment. The development of R&D infrastructure and human capital must be coupled with the establishment of a conducive business environment for local manufacturers and investors, and the creation of effective and facilitative ethics review and regulatory structures. To build the competitive muscle required to successfully compete in the global pharmaceutical market, African countries must cooperate to harmonise ethics, regulations and pharmacovigilance systems to harness regional and continental synergies.

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Contributions of authors

The rapid review was led by the main author with inputs and collaboration in writing from the other five authors.

Declarations of interest

This is an objective rapid review of evidence and thus no interests to declare.

. **Sources of Support**

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