QUALITY ASSURANCE

How medical device inventors are grappling with unclear local standards

Necessity is considered the mother of invention. On a continent where health indices have repeatedly fallen short of local and global expectations, research shows that "rampant corruption in medical products and technologies procurement systems, unreliable supply systems, unaffordable prices, irrational use, [and] wide variance in quality and safety" are exacerbating Africa's health challenges. Still, local health technologists have persevered by finding ways to devise solutions to address pressing health issues like maternal deaths and malaria.

Despite the need for such innovation, many say countries in Africa have not done a good job of creating an ecosystem to support the mass production and use of innovative medical devices made with an eye to addressing health issues. A 2016 survey by WHO that looked at improving access to medical devices through local production zeroed in on four sub-Saharan countries - Nigeria, South Africa, Ethiopia and Tanzania - and found that the most commonly reported obstacles to medical device development included 'limited financial resources for development, inadequate local facilities and tools, and a lack of financial incentive/ market appeal/potential return on investment."

The labyrinth of regulations needed for these devices to be used safely in the continent has also proved challenging for health innovators in Africa. A literature review of the regulatory status for medical devices in the College of Surgeons of East, Central and Southern Africa countries and South Africa revealed that some regulatory bodies provide a loosely defined scope of regulation for medical devices, while some even fail to provide guidance about the registration process for medical devices.

When it comes to the enforcement capacity of these regulatory authorities, the report used Botswana as an example, noting that the country's Medicines Regulatory Authority only has regulatory procedures in place for drugs and related substances but not devices. According to the report, while 11 of 14 member countries

Left: the Oculus device for diagosing cerebral malaria, Right: the HearScope by HearX. Cipher; HearX.

of the College of Surgeons of East, Central, and Southern Africa have legislation mandating the regulation of medical devices, only half are currently developing medical device regulatory processes and half do not have a formal process.

"By principle, [the countries] have regulatory bodies," says Julius Mugaga, an assistant lecturer at Makerere University in Uganda and one of the paper's co-authors. But in practice, Mugaga says that there is a lack of guidance and policy framework that prevents locally developed medical devices from entering the market.

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When it comes to malaria, Nigeria has the highest disease burden in the world. According to WHO's 2020 world malaria report, Nigeria accounted for approximately 27% of malaria deaths worldwide, the highest of any other country. While malaria is often easily diagnosed and treated with antimalarial drugs, there are many cases where malaria can turn fatal.

Emmanuel Ugwu's Oculus diagnostic tool hopes to prevent fatal outcomes by changing the way cerebral malaria, one of the more fatal types of the disease, is diagnosed. During his research, Ugwu found that cerebral malaria is often diagnosed using a spinal fluid that is extracted with a long needle, but in rural communities where healthcare facilities are often understaffed or lack resources, this is almost impossible.

So, Ugwu decided to create a tool to help healthcare workers diagnose cerebral malaria more easily. Oculus is an attachment, almost resembling an ophthalmoscope, that can be used to see the patient's retina, optic nerve, and even the back of the patient's eye. Ugwu says Oculus will then review the image for changes in the eye like discoloration and hemorrhaging and identify them. Ultimately, the health worker will use the information to make the final diagnoses as Ugwu makes sure to mention that the app isn't intended to replace a medical diagnosis but mainly to support the work health workers do, especially in resource-strapped environments.

While undergoing clinical trials in Nigeria, Ugwu says his experience getting approval to begin the trials was mired by bureaucracy and what was supposed to take three to four months took more than a year. "The whole process was so tedious," says Ugwu. "In the end, I got the approvals but it took longer than expected, it actually delayed the project timeline [so much] that it had to be extended."

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Even in countries like South Africa that have been lauded by WHO as a country with a capacity to support a strong local production environment of medical devices, things are not easy. The process of getting a medical device startup up and running in South Africa is an expensive endeavour, says Nic Klopper, CEO of hearX, a South African-based startup that aims to provide affordable access to hearing healthcare using digital solutions. During hearX's early days, the company had to obtain a CE Mark to confirm that its products met European health, safety, and environmental protection standards. In addition, the company had to obtain the International Organization for Standardization for medical devices (ISO 13485), a process Klopper says took the company two and a half years and "millions."

"For a young startup that is extremely difficult," says Klopper. The CEO says the company had to employ a full-time regulatory officer to assist and because the auditors needed to ensure

the products met the ISO certification weren't local, Klopper says the company flew in auditors from outside the continent. As the company worked to obtain their CE mark, Britain began the process of leaving the European Union, which led to the introduction of the UKCA marking as the CE mark equivalent for relevant goods to be sold in the UK. Klopper says this was another setback for the company.

"We were almost four years in with our product design lifecycle before we actually obtained [our] CE mark," says Klopper.

In 2018, South African Health Products Regulatory Authority (SAHPRA) was created to regulate all health products, including the production of medical technology in South Africa. Currently, the country still relies on European certification standards for medical devices, something Klopper says, despite the work involved in obtaining it, is helpful to young entrepreneurs looking to build a global product. He notes that more cumbersome country-specific certification processes could have the opposite effect on innovation.

"I have my reservations around country-specific regulatory requirements for products," says Klopper. "Because if you have one product, you have to comply with 270 countries' adaptation of the same protocol, [that] makes it almost impossible, right? So the approach that South Africa took initially to lean much more heavily on the European standards, I think was a good thing."

What Klopper says health tech startups on the continent need is more financial support as they work to take their products to market. "I think there's a big lack of support, specifically when it comes to funding from governmental institutions to support these types of young entrepreneurs getting their products to market."

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Some say that the medical device market on the continent just hasn't reached its full potential. According to Mugaga, increased health funding from governments, in addition to supporting the development of health technology are just a few steps countries can take to better support medical device production. Overall, Mugaga says that as a result of COVID-19 and the limitations it imposed on all aspects of Uganda, there is a renewed desire to support local industries. "Previously, the political will was not there. But now it has changed," says Mugaga.

Ibrahim Yekinni, a Medical Device Innovation Fellow at the University of Minnesota's Earl E Bakken Medical Devices Centre, says that what makes the industry attractive to some medical device developers is the financial viability of these medical devices.

For example, in Nigeria, where WHO estimates more than 75% of Nigerians pay health expenses out of pocket, and research shows that out of pocket payments can make households become impoverished, only a select few can afford to purchase medical devices. "The patients are the ones paying, so they can't really afford the technology," says Yekinni.

Using countries in North America as an example, Yekinni notes that where more people are insured and are able to cover health costs associated with the use of a medical device more comfortably, then those producing the devices will be encouraged by the uptake.

"If there's a system in place that makes that possible, then people will be motivated to innovate," says Yekinni.