

EFFICIENCY FOR ACCESS RESEARCH AND DEVELOPMENT FUND: INNOVATOR SERIES

Innovating Neonatal Care in Low-Resource Settings



Sona, Sheilah and Vivian (left to right) from Neopenda, with their neoGuard product

In healthcare settings across the Global North, continuous vital signs monitoring technology is a basic and critical part of specialised care. However, in the Global South, where access to electricity is often limited, or unreliable, applying this technology in intensive care units poses significant challenges.

In such low-resource environments, the use of conventional patient monitors, and maintaining complex medical equipment, presents challenges such as high costs. In settings involving critically ill newborns, this makes it extremely difficult to adhere to protocols for vital signs monitoring. This impacts survival rates, raises complication rates, and prolongs hospital stays.

Assessing vital signs in hospitalised newborns is crucial for evaluating their clinical status and detecting early warning signs of deterioration.

However, in off- and weak-grid settings, nurses typically take physical vital sign measurements and manually record them on clinical charts. This raises the risk of missed early warning signs, and ultimately increases mortality rates.

To overcome this constraint in newborn care, introducing wearable devices for continuous monitoring can help with early detection of acute and chronic physiological events. This, in turn, enables quicker and more effective treatment of patients.

DID YOU KNOW?

Nearly 80% of newborn deaths result from preventable causes that could be effectively treated if clinicians had the necessary resources, training and equipment.

NEOPENDA

Neopenda is a medical device start-up based in Chicago, Illinois. Their mission is to pioneer innovative health technology in emerging markets, designing and bringing needs-based solutions to underserved populations in an impactful and sustainable way. Since its establishment in 2015, Neopenda has expanded to a global team of 12 across five countries: Columbia, Kenya, Nigeria, Uganda and the US.

With support from the Efficiency for Access Research and Development Fund, Neopenda was able to identify and test the product-market fit of their vital signs monitoring device, known as neoGuard, through pilot testing in healthcare facilities in Kenya, Nigeria, Uganda and Tanzania.

WHAT IS NEOGUARD?

To address the medical concerns and improve patient care in off- and weak grid settings, Neopenda developed neoGuard, a battery-powered patient monitoring system. The technology is designed to operate in dynamic clinical environments with space constraints, unreliable power supplies and limited numbers of health staff.

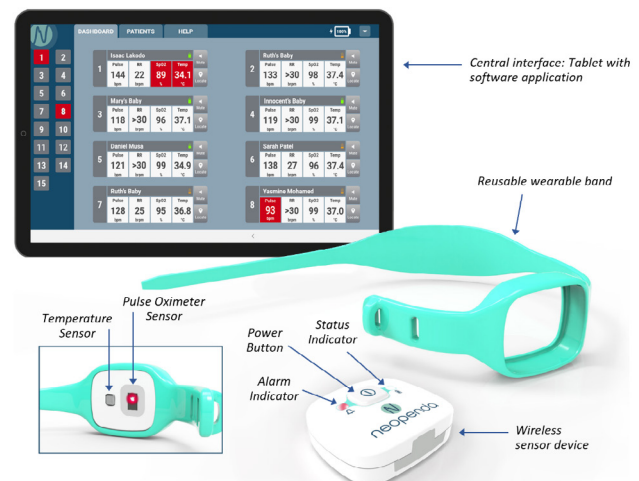
neoGuard consists of the following components:

- wireless sensor devices
- reusable wearable bands
- a software application on a tablet that receives, displays, and stores data from the sensor devices.

The sensor devices use reflectance pulse oximeter and temperature sensors to measure pulse rate, blood oxygen saturation (SpO₂), respiration rate, and temperature from the patient.

The neoGuard device is attached to the patient's forehead with a reusable band and powered by a rechargeable, 36-hour lasting battery. Data is transferred from the device to the software application using Bluetooth over a 30-metre radius. The app is a central interface, showing digital values of pulse rate, oxygen levels (SpO₂), breathing rate, and temperature in real-time. It includes a dashboard view of the patient's vital signs and patient information for a maximum of 15 patients. It also stores data in the back end.

Using archived data, healthcare providers can study trends in patients' vital signs to inform future treatment decisions. The reporting feature provides valuable insights for hospital administrators, ministries of health and non-profit international partners.



The neoGuard vital signs monitoring system

Developed through an immersive human-centred design process, involving feedback from over 400 health workers, primarily in East Africa, neoGuard addresses the pressing concerns of people in low-resource healthcare facilities. Its development involved multiple stages of lab and field testing, as well as market research.

Compared to traditional monitoring devices that experience problems with power instability, internet access and availability of spare parts in off-grid settings, neoGuard is tailored to suit these challenges, reimagining clinical vital signs monitoring for local communities.

BRINGING NEOGUARD TO THE GLOBAL SOUTH

In off- and weak-grid contexts, vital signs monitoring in most Intensive Care Units relies on intermittent, manual measurements. Nurses must manually count heart beats or breaths every few hours, or share the limited functioning devices, such as pulse oximeters, which only intermittently measure oxygen saturation and pulse. This practice falls short of early detection of distress and optimal management of critical care patients. Neopenda's neoGuard aims to enhance patient care beyond the standard-of-care, by providing a solution for continuous monitoring of vital signs.

Gold standard monitors, while common in high-resource areas, are costly, poorly suited to low-resource settings, and difficult to maintain. They struggle with environmental constraints, like an unstable power supply, lack of internet access, and heat and humidity becoming obsolete within short periods of use.



10 neoGuard devices packaged for distribution

Existing products in the global health space are limited in their monitoring capabilities, only measuring one or two parameters, and diagnosing specific conditions (e.g. pneumonia diagnostics). Patient monitors currently available on the market are priced at around \$3,500. In contrast, the neoGuard technology is priced significantly lower at around \$300 each, offering a more affordable and sustainable solution.

WHAT DID THE PROJECT ACHIEVE?

During this project Neopenda completed product testing of the neoGuard, acquired CE mark and ISO 13458:2016 certification, built distribution channels with local partners, and introduced the product to 11 newborn health facilities in Kenya, Nigeria and Tanzania.

Upon successful completion of clinical validation and safety testing, Neopenda set up commercial production, shipping and piloting 120 neoGuard devices in 11 health facilities. This included five clinical study sites, two trial placements and four direct sales. Neopenda finalised product registration in Kenya and signed a distribution contract with Mediquip Global Supplies. It also initiated product registration in Tanzania and is in conversation with three potential distribution partners.

In 2023, the product was registered in Tanzania, although Neopenda has yet to secure a distribution partner in the country.

However, they have support from a local technical representative, Center for Reforms Innovation, Health Policies and Implementation Research (CeRIHI), responsible for overseeing importation and regulatory needs related to distributing the product.

Since the completion of the R&D project, Neopenda have distributed 80 neoGuard devices to other health facilities in Kenya.

FEASIBILITY STUDIES

Neopenda carried out its first formal feasibility study in Western Kenya, assessing the performance of the neoGuard product at two rural health centres: Bungoma Regional Referral Hospital and Kakamega Regional Referral Hospital. They gathered feedback from nurses and clinicians and interviewed the parents of newborns to gauge its suitability.

The second formal feasibility study took place in Northern Nigeria, where they tested the neoGuard product at three health facilities, also involving interviews with nurses, clinicians and parents of newborns. These studies played a vital role in informing Neopenda's business strategy and product improvements.

As a result of the project, Neopenda was able to bring its vital signs monitoring solution to many health providers in remote areas that commonly struggle to access sustainable health equipment. Additionally, Neopenda engaged in meaningful discussions with key decision makers in government, non-profit and private sectors. This helped to refine the product-market fit and harness more value out of the neoGuard product.



neoGuard in use at a healthcare facility

LESSONS LEARNED

Challenges of manufacturing and shipping at a commercial scale

It took several months for Neopenda to obtain all the components required for the neoGuard device. Due to the COVID-19 pandemic, and the challenges of scaling up production to commercial levels for the first time, Neopenda experienced delays in shipping and manufacturing. The company also had to navigate different regulations in each country for research approvals to conduct feasibility studies, and for import permits to distribute the product.

In-field testing and performance enhancement

In-field testing is essential for identifying performance issues and making improvements. Neopenda initially encountered unexpected performance issues reported by neonatal health providers, despite high initial test results. However, the product was generally well-received, and the feedback gathered helped refine Neopenda's algorithms to better meet user needs.

Feasibility studies revealed significant performance variations in real-world conditions, emphasising the importance of testing products in diverse environments with a wide range of users before launch.

IMPLEMENTING NEOGUARD

Neopenda is supporting early adopters as they use neoGuard in order to generate more real-world evidence regarding its performance and impact in low-resource settings.

They aim to gather key metrics such as total hours of usage, the daily, weekly and monthly numbers of monitored patients, basis, and how the neoGuard product affects their clinical outcomes. Various feasibility, acceptability, reliability and clinical impact studies of neoGuard have been carried out in Uganda, Kenya and Nigeria.

Alongside the ongoing monitoring and evaluation processes, Neopenda's business team will continue to market the neoGuard product to acquire new customers in Uganda and Kenya. Neopenda currently has a commercial presence in Ghana, Kenya, Tanzania and Uganda, it is also in the early stages of identifying distributors and commercially expanding to Nigeria.

In the medium-to-long term, Neopenda is committed to ensuring that users get the most out of their experience with the neoGuard product. It has secured a \$630,000 award from the Wellcome Trust Flagship Innovations Program, which will be used to upgrade the product hardware in the next version of neoGuard to improve product performance.

GET IN TOUCH

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Training of the neoGuard product at Lwala Community Alliance, Kenya

