MEDICAL DEVICES AND HEALTH TECHNOLOGIES

RELI Delivery System

Devices, Diagnostics, and Drugs to Address Women's Needs Product Development Partnership (D₂AWN PDP)



Globally, approximately 300,000 women die in childbirth every year; more than half of these deaths occur in sub-Saharan Africa. These deaths are often preventable when health providers have access to necessary medical devices and medicines that enable higher-quality obstetric care.

Health need: Highly controlled drug and fluid delivery for maternal and neonatal emergency and continuing care

The World Health Organization recommends controlled intravenous (IV) delivery of common medications, such as antibiotics, fluid therapy, and nutrition for critically ill newborns, as well as magnesium sulfate, oxytocin, and anesthesia for obstetric emergencies. However, clinicians in low- and middle-income countries (LMICs) do not always have access to the IV delivery equipment that they need. Barriers to access to infusion pumps are related to the high cost of purchase, repair, parts, and training, as well as a lack of electricity.

Technology solution

The RELI Delivery System is a reusable, electricity-free, low-cost infusion pump that is appropriate for treating pediatric and obstetric emergencies in LMICs. With no electronic components, the RELI Delivery System has a simple user interface that is easy to learn, use, and understand. Since it requires no electricity or batteries to operate, it is dependable in settings with unreliable power. The robust design is also inexpensive to maintain and does not require expensive or proprietary consumables to operate.

The RELI Delivery System is powered by an air tank that is connected to a hydraulic circuit for flow-rate control.³ To operate the device, the user pumps up the air tank, selects the flow rate, and begins the infusion. The target pumping interval is every 8 hours, and the device functions with syringes of varying sizes.

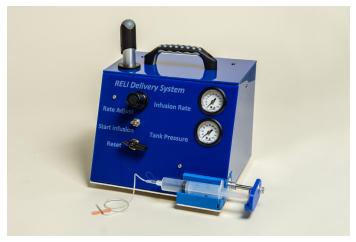


Photo: PATH/Patrick McKern

Potential health impact

An estimated 59 percent of health care facilities in LMICs lack access to reliable electricity,⁴ but standard infusion pumps are dependent on electricity. Non-electric options for controlled fluid delivery require expensive, proprietary disposable tubing that prevents easy titration and introduces cost and supply chain challenges. A lack of access to appropriate equipment for controlled IV delivery can introduce patient safety concerns or limit the treatments a clinician can provide.

Health system use case

Interviews with maternal, newborn, and child health care providers, ministry of health officials, program managers, and other key stakeholders in Rwanda and Uganda provided insight on the need for infusion pumps, as well as use scenarios. There was confirmation in both countries that there are not enough infusion pumps to meet the need. In a survey of 133 clinicians from LMICs, only 32 percent responded that they had complete access to adequate equipment and supplies for IV delivery of drugs, nutrition, and fluids (unpublished data).

Newborns, mothers, and children are at risk of dying in facilities that cannot provide them with the drugs they need in the forms and dosages they require.

Stakeholders in both countries expressed a strong

need for infusion pumps that are safe, easy to use, and durable, and that provide precise delivery. Potential users provided input on size, shape, portability, gauge design, pump design, and syringe sizes and positions that will be incorporated into future design iterations to ensure an appropriate product for the locations of use.

The RELI Delivery System combines the low cost and simplicity of non-electric disposable pumps with the functionality and accuracy of electronic devices, without the need for proprietary consumables.

Go-to-Market Plan (G2MP)

This is a moderate-risk Class IIb device per Rule 11 of the Medical Device Directive 93/42/EEC.

This product is currently under development at PATH. We have produced a functional prototype and are in the process of refining the functionality and user interface of the product. We are currently seeking manufacturing and commercialization partners who are based in target markets for future market entry.

Partners and funding support

Our project partners include Dr. Anthony Roche, University of Washington School of Medicine, Department of Anesthesiology and Pain Medicine; Department of Global Health and Dr. Karl Weyrauch, Pygmy Survival Alliance.

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D₃AWN PDP: Addressing the leading causes of maternal mortality with an innovative portfolio of products

The new, four-year Devices, Diagnostics, and Drugs to Address Women's Needs Product Development Partnership (D₃AWN PDP) is tapping into PATH's deep PDP expertise to develop and introduce a portfolio of devices, diagnostics, and drugs to prevent or manage preeclampsia/eclampsia (PE/E) and postpartum hemorrhage (PPH).

To address this critical health need, the D₃AWN PDP is advancing affordable, accessible, safe, and effective tools for sub-Saharan communities. Solutions include:

- heat-stable fast-dissolving tablet for PPH prevention;
- reusable, electricity-free infusion pump for the delivery of lifesaving nutrients, fluids, and medicines;
- balloon tamponade for the management of PPH;
- urinary dipstick test for improved diagnoses of PE/E.

These lifesaving technologies are being developed in partnership with research institutions, manufacturers, and companies in Africa, accelerated through PATH's product development process and introduced into key African markets.

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