

Ellavi Uterine Balloon Tamponade

Devices, Diagnostics, and Drugs to Address Women's Needs Product Development Partnership (D₃AWN PDP)



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

Health need: Closing gaps in the PPH continuum of care

Postpartum hemorrhage (PPH) is globally the single most common cause of maternal mortality, accounting for approximately 25 percent of maternal deaths. Deaths from PPH are preventable with timely and appropriate management. First-line treatments for PPH include administration of oxytocin, a uterotonic drug that causes the uterus to contract, and uterine massage. When uterotonics fail or are unavailable, the use of a uterine balloon tamponade (UBT) is a very effective second-line intervention.

However, in low-resource settings, the use of the UBT is limited due to cost constraints and lack of awareness and availability. Commercially available, quality-assured UBTs that have received regulatory approval are prohibitively expensive. Condom or glove catheters (a condom or a glove that is tied to a catheter and syringe used for filling the condom) are improvised at the point of care to fill this gap to some extent. But it can be difficult to gather essential materials and assemble them at the same time a woman is experiencing uncontrolled PPH. And condom catheters are not regulatory-approved medical devices, which creates challenges with quality control and standardization of protocols for their use. Preassembled, quality-assured, and reasonably priced UBTs are in great need.

Technology solution

PATH—in collaboration with Sinapi Biomedical (Pty) Ltd based in Stellenbosch, South Africa—are advancing the use of the Ellavi uterine balloon tamponade. The Ellavi UBT is a preassembled medical device that is manufactured by Sinapi at their ISO 9001 and 13485 certified factory.



Photo: Sinapi Biomedical.

The Ellavi has a unique mechanism of action and several advantages over UBT products on the market (for ex: Bakri and Ebb balloons) and existing stop-gap measures such as the condom catheter:

- Pre-assembled, ready to use medical device.
- Free-flow pressure controlled system—allows the water to be expelled from the balloon to reduce pressure and allow the uterus to contract and retract to arrest the bleeding.
- Quick deployment—fills in under one minute and acts swiftly to stop bleeding.
- Gravity filled—enables hands-free care.

Potential health impact

PATH estimates that adding an affordable UBT to providers' toolkits could save up to 6,500 lives and avert nearly 11,000 surgeries annually in sub-Saharan Africa alone according to the Innovation Countdown 2030 report, and widespread use of the UBT could save the lives of 169,000 women by 2030.¹

Health system use case

A clinical study of the Ellavi UBT in South Africa demonstrated high acceptability, safety, and efficiency² and pilot introductions in two provinces are under way. PATH is serving on a WHO technical advisory group on UBT aimed at ensuring strong clinical evidence of efficacy is available.

Go-to-Market Plan (G2MP)

The Ellavi UBT is considered to be a Class II moderate risk device. In February 2018, Sinapi Biomedical obtained a certificate of free sale from the South African National Department of Health to sell the Ellavi UBT in South Africa and to export it to other countries. In February 2019, Sinapi Biomedical obtained CE marking with requirements for post-market clinical feedback, which allows Sinapi to sell the Ellavi UBT in countries where CE marking is recognized. Product registrations in Ghana and Kenya are underway and expected in 2020.

Sinapi has agreed to provide the Ellavi UBT to the public sector for \$7.50 per unit out of their factory (does not include costs associated with shipping, distribution, and import). This is a fraction of the price of current commercial UBT devices, which will improve availability for PPH control programs.

Currently, PATH and Sinapi Biomedical are introducing the Ellavi UBT into existing national PPH-control programs in sub-Saharan Africa, starting with Kenya and Ghana where use of UBTs is already included in national guidelines. Implementation research will be conducted in Ghana and Kenya, in collaboration with ministries of health to generate operational evidence and facilitate product uptake. Training on use of the Ellavi UBT will be integrated into existing PPH strategy. PATH and partners will explore and leverage existing pre-service and in-service PPH training programs in countries for sustainable scale-up. In-country financing options to support sustainable product procurement and integration into national procurement and supply lists will be identified. Inclusion of UBT devices in supply catalogs of global procurement agencies will be sought.

Support

This project was funded with UK aid from the UK government.

Previous support for PATH's development of a low-cost UBT includes the Bill & Melinda Gates Foundation and the United States Agency for International Development.

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.

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;
- Ellavi uterine balloon tamponade for the management of severe 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.

Contact

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References

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