

The Ellavi Uterine balloon tamponade with a free flow system for management of refractory PPH

From Research to Implementation and Impact

Uncontrolled postpartum hemorrhage (PPH) is a life-threatening emergency and the most common cause of maternal death and disability worldwide. Women in resource-poor settings are at greatest risk of dying from PPH. Uterine balloon tamponade (UBT) is recommended for the treatment of PPH due to uterine atony in women who do not respond to standard first line treatment, however, quality assured UBTs are not widely available in many of these settings due to cost.

To address this gap, PATH established a strong partnership with Sinapi biomedical, manufacturer of the Ellavi UBT, to ensure that the product is available for the public sector in low and middle income countries at an affordable cost of no more than US\$7.50 at Ex-Works (the price when the product left the factory). The Ellavi UBT product is fully assembled in a sterile package that is ready to use. A comprehensive training packet, available online at ellavi.com, and a poster with detailed user instructions, are made available to all providers and facilities procuring the Ellavi. Device characteristics such as the unique free flow mechanism of action and the supporting package of materials are critical elements to the successful roll out of the Ellavi UBT.

The D₃AWN PDP used implementation research in Kenya and Ghana to assess the feasibility and acceptability of integrating and sustaining use of the Ellavi UBT in the national PPH management package of care. In Kenya, we established a strong research partnership with the Ministry of Health, University of Nairobi, and Kenyatta Hospital, Department of Obstetrics and Gynaecology. In Ghana, we worked closely with the Ghana Health Service, Family Health Division, and leading maternal health experts. We trained over 450 providers on the use of the Ellavi UBT (215 physicians, nurses and midwives in Kenya



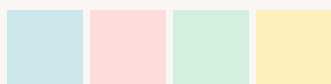
Implementation Research Results

In both countries, the Ellavi UBT stopped the bleeding in reported cases of PPH, 38 out of 44 cases in Ghana and 13 out of 19 cases in Kenya. All but one of the remaining cases in each country were resolved by surgery. The two remaining cases were not appropriate for use of the Ellavi UBT. More than 90% of providers in Kenya and Ghana who used the Ellavi UBT were:

- confident they used the device correctly,
- satisfied the Ellavi UBT serviced the needs of their patient and,
- would like to use the Ellavi UBT in the future.

Results from the implementation research showed that the training package and timesaving, innovative design of the Ellavi facilitated its adoption, acceptability, and feasibility. The Ellavi is appropriate and easy for use among obstetric staff working at different facility levels of care and can be successfully integrated into the Kenyan and Ghanaian maternal health care package.





ELLAVI UBT PIPELINE STATUS

Exited from the portfolio into wide-scale implementation

Research ► Translation ► Development ► Implementation

and 236 providers in Ghana). We conducted the implementation research in three facilities representing various levels of care (tertiary referral hospital, district hospital and maternity clinic) in each country.

PATH and local partners held a national dissemination workshop in each country; 93 key stakeholders attended the workshops and participated in creating the action plan to roll out the Ellavi UBT.

In Ghana, the meeting was presided over by Dr. Kofi Issa, Director of the Family Health Division of the Ghana Health Service, and was attended by officials from Ghana Health Service, NGOs, academic institutions, and representatives from Mangel Klicks, distributor of Ellavi in Ghana), and Sinapi Biomedical [manufacturer of Ellavi]).

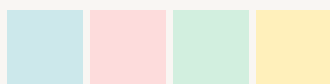
In Kenya, the meeting was presided over by Dr. Issak Bashir, Head of the MOH Department of Family Health and was attended by officials from the Ministry of Health, County Health Management Teams, NGOs, and representatives from Prota Limited, the Ellavi distributor in Kenya.

Key actions being undertaken in each country include:

- Adding Ellavi into procurement channels like the Kenya Medical Supplies Authority (KEMSA), Mission for Essential Drugs and Supplies (MEDS) in Kenya, and the National Procurement Authority and central and regional medical stores in Ghana to increase availability and access.
- Conducting budget advocacy at subnational levels to build capacity on financing and procurement options.
- Providing compelling cost-effectiveness data to inform Inclusion of the Ellavi into national health insurance schemes.
- Including Ellavi into skills building in pre-service and in-service training
- Creating additional indicators in health management information systems to include refractory PPH management and ensure effective monitoring of Ellavi use.

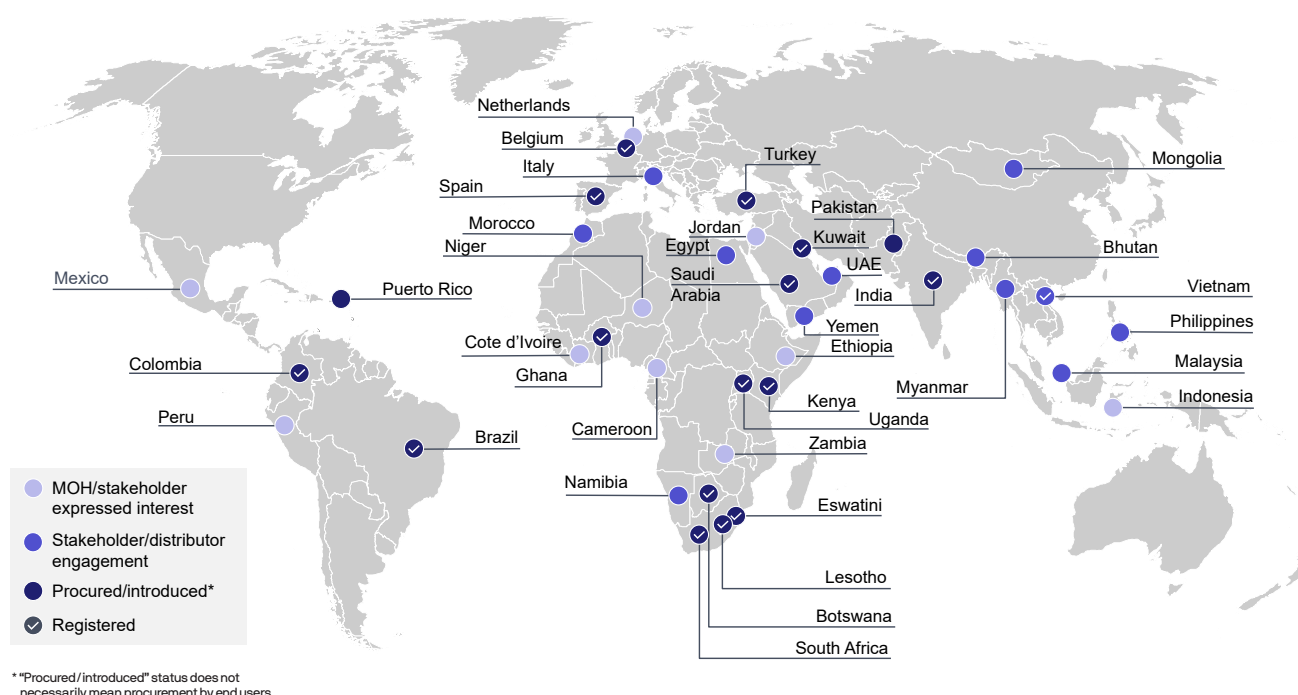


Ellavi UBT provider training sessions in Ghana (above) and Kenya (below).



Status of introduction for Ellavi as of August 2022

Since the Ellavi received CE marking in 2019, it has been registered in 16 countries and more than 25,000 devices have been sold, ensuring that health care providers have a new option to help save the lives of women. Uptake of the Ellavi UBT continues to be widespread and robust to address health equity; for example, Partners In Health, Medical Aid International, ALIMA, Maternal & Childhealth Advocacy International, and Medicines Sans Frontières have procured the Ellavi for programs in several countries. The Johnson and Johnson Foundation also supported training rollout in 5 countries.



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All images: PATH, unless otherwise indicated

