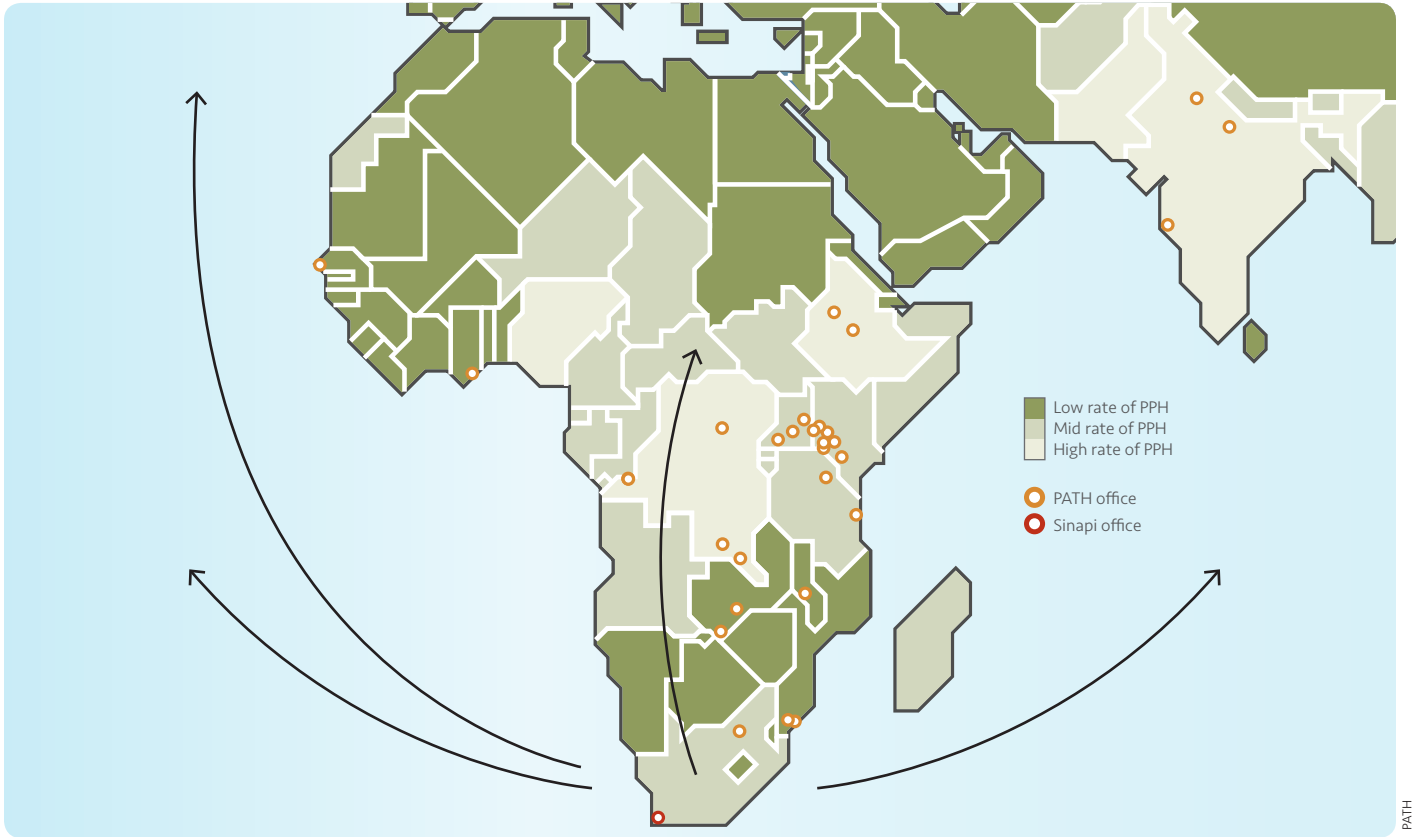


FIGURE 2 PATH and Sinapi addressing global postpartum hemorrhage from South Africa



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PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. Learn more at www.path.org.

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Advancing the Ellavi uterine balloon tamponade (UBT)

A low-cost UBT designed specifically for treatment of postpartum hemorrhage

A LIFESAVING SOLUTION FOR MOTHERS IN LOW-RESOURCE SETTINGS

Excessive bleeding after childbirth, or postpartum hemorrhage (PPH), is globally the single most common cause of maternal mortality, accounting for approximately 25 percent of maternal deaths.¹ PPH is dangerous, life-threatening, and can lead to long-lasting health effects, including severe anemia.

No woman should die from PPH. PPH can be treated if the bleeding is immediately controlled and managed. Deaths and serious complications from PPH are most likely to occur in sites lacking trained providers and appropriate interventions.

The consequences of PPH are devastating to families and costly to health care systems. Women who survive can face serious adverse effects including hysterectomies, and in the year following PPH, women are more likely to die from complications related to extreme blood loss.³

PPH is the leading cause of maternal deaths

- PPH can happen to any pregnant woman.
- Severe PPH can kill in less than two hours.
- Ninety-nine percent of deaths from PPH occur in low-resource settings—mainly sub-Saharan Africa.²

First-line treatments for PPH include uterine massage and administration of oxytocin, a drug that helps the uterus contract. When these treatments don't work, and the woman continues to lose blood, a uterine balloon tamponade (UBT) can be inserted into the uterus. The UBT is filled with water, exerting pressure until the bleeding stops. These devices work rapidly and effectively (stopping the bleeding in 5 to 15 minutes), reducing blood loss and the need for risky and costly surgical interventions and blood transfusions.

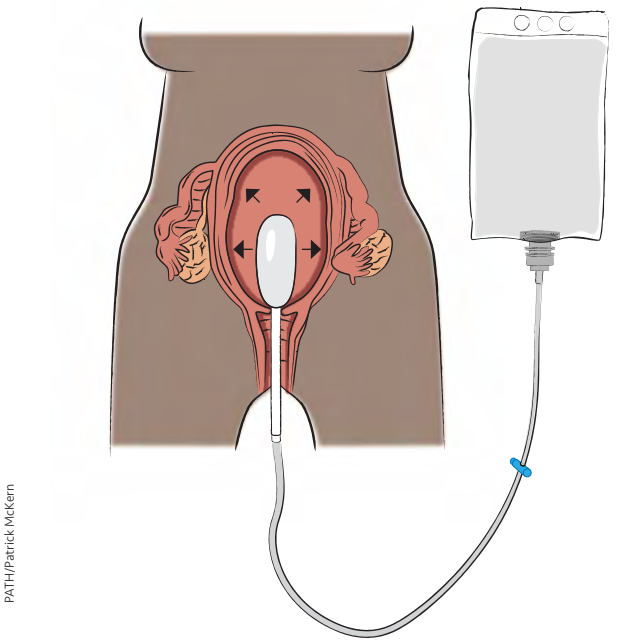
Global endorsements of UBTs

The World Health Organization, the International Federation of Gynecology and Obstetrics, and the International Confederation of Midwives recognize the potential of UBTs to significantly impact the management of intractable PPH.

2017 WHO Guideline Revision

In 2017, WHO’s Managing Complications in Pregnancy and Childbirth manual was updated to include use of uterine balloon tamponades as important tools for treatment of severe postpartum hemorrhage. This revision recommends a balloon tamponade designed specifically for the treatment of PPH.

FIGURE 1 The Ellavi UBT is a gravity-filled open system designed to apply optimal pressure to stop bleeding fast.



ADDRESSING BARRIERS TO ACCESS AND COST

Health care professionals in wealthy countries have used UBTs for years, and there are several approved UBT medical devices on the market. However, these typically cost hundreds of dollars. Evidence of UBTs’ availability in African countries is scarce, but there is anecdotal evidence of limited use, restricted mostly to higher-level facilities due to high cost. Some health facilities unable to afford these devices rely on improvised equipment assembled at the point of care, such as condom catheters.

Achieving the United Nations Sustainable Development Goals will require addressing the main causes of maternal

death by increasing access to effective services and interventions. PATH estimates that adding an affordable UBT to providers’ toolkits can lead to an 11 percent reduction in maternal mortality, attributable to the use of a low-cost UBT. Annually, an affordable UBT could save up to 6,500 lives and avert nearly 11,000 surgeries in sub-Saharan Africa alone.⁴ Most maternal lives saved will be among women with severe blood loss, the most likely to die from PPH.

Saving lives on a global scale

According to the Innovation Countdown 2030 report, widespread use of the UBT could save the lives of 169,000 women by 2030.⁴

ADVANCING THE FIRST LOW-COST UBT DESIGNED SPECIFICALLY FOR TREATMENT OF PPH

After many years of in-country research and collaboration with many local and global organizations, PATH identified the need for an easy-to-use, inexpensive, and accessible UBT. Health care workers and global experts have indicated the need for an affordable preassembled UBT, which would save time during those critical first moments.

We completed a situational analysis of current UBT practices in low-resource settings,⁵ an analysis of optimal manufacturing approaches, and an assessment of user needs and requirements. Study results provided information on usage patterns, cost issues, availability, and acceptability. The results also informed the design and development of PATH’s proof-of-concept prototype.

PATH conducted a scan of manufacturers, focusing on Africa-based companies experienced in low-cost, high-quality medical device production. PATH selected Sinapi biomedical as a manufacturing and commercialization partner to co-develop a new UBT device that would address the specific needs and requirements of a low-cost, preassembled, effective UBT—appropriate for use in any medical setting, from urban central-level facilities to rural primary health care centers, and by all cadres of health providers.

THE ELLAVI UBT: DESIGNED AND MANUFACTURED IN AFRICA

Together, PATH and Sinapi biomedical have developed the first UBT specifically designed for the management of severe PPH in low- and middle-income countries—the Ellavi UBT.

The Ellavi UBT is an easy-to-use, fully assembled system that is uniquely designed to apply optimal pressure to stop

bleeding fast. Designed to address the cost, quality, and assembly issues of other devices, the Ellavi UBT has many advantages, including:

- High safety and efficacy for management and treatment of PPH when standard treatment fails or is unavailable.
- Open system allows the uterus to contract and retract to arrest the bleeding.
- Designed to the shape of the uterus.
- Fully assembled system.
- Can be inserted, filled, and begin working in less than a minute.
- Gravity filled: enables hands-free care.

COST EFFECTIVE, SCALABLE, AND IMPACTFUL

The availability of a UBT manufactured and commercialized in Africa will offer lower-income countries the option to add a regulated medical device to their PPH toolkits at an affordable price. At an estimated cost of US\$5–15 (a fraction of the cost of existing commercial UBT products), the Ellavi UBT is designed to be highly cost effective. A clinical study (pending publication) of the Ellavi UBT in South Africa demonstrated high acceptability, safety, and efficiency. Due to its unique design and high quality, the Ellavi UBT has the potential to scale from African to international markets, including high-income nations; the Sinapi Ellavi UBT is the first UBT designed for use in every medical setting.

ANTICIPATED AVAILABILITY

Clinical trials took place in South Africa from 2016–2017, and CE Mark registration is expected by the end of 2017. We anticipate that the Ellavi UBT device will be available for pilot introductions and pivotal studies in Africa, India, and Southeast Asia in early 2018. Sinapi expects commercial market launch early in 2018.

GOING FORWARD

PATH is currently conducting a series of activities to plan for introduction and scale of the Ellavi UBT in Africa and India. This includes identifying requirements and potential hurdles for public-sector adoption; supporting Sinapi’s marketing plan, including pricing, distribution, and regulatory approvals; and developing an introduction package.

At the local and national levels, PATH is advocating for policy change to support inclusion of UBTs in national guidelines, essential commodities lists, and country PPH management strategies.

Globally, PATH is engaging with organizations such as the World Health Organization, the United Nations

PARTNER PROFILE

Sinapi biomedical

Sinapi biomedical (Pty Ltd) is a South Africa–based biomedical engineering company with extensive expertise in developing and manufacturing medical devices. A high-quality manufacturer of products similar to the UBT, Sinapi makes and sells a chest drain, a more complex sterile product, for US\$10.

With a staff of 90 and growing, Sinapi has proven sustainability as an ISO-certified manufacturer of medical devices. The company is profitable: 30 percent of sales are to European Union markets and it sells in volume to the private and public sectors in South Africa.



The Sinapi Ellavi UBT

Children’s Fund, and the United Nations Population Fund to improve supply and ultimately the availability of UBTs around the world. Momentum is building, the need is high, and the value of the UBT as an effective, safe, and easy-to-use intervention is evident. With country-level interest and demand for UBTs growing, PATH is pursuing funding opportunities to increase access to UBTs in additional countries.