

Saving mothers' lives: Advancing a novel, affordable uterine balloon tamponade to reduce maternal deaths due to postpartum hemorrhage

PROBLEM

Postpartum hemorrhage: A leading cause of maternal deaths

Postpartum hemorrhage (PPH) continues to be the leading cause of maternal deaths worldwide resulting in an estimated 125,000 deaths per year.¹ The majority of these deaths can be avoided with proper management of the bleeding. The uterine balloon tamponade (UBT) is recognized by WHO as an effective and safe intervention for PPH when standard methods fail or are unavailable. However, commercially available UBTs are expensive and not widely available in low-resource settings.



SOLUTION

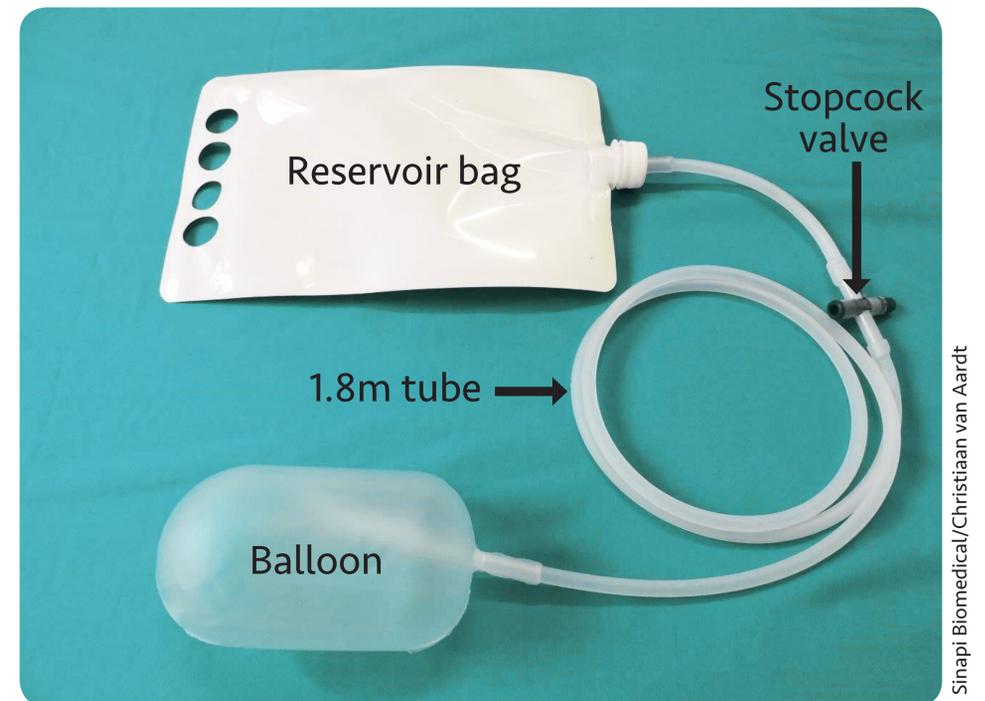
An affordable UBT designed and developed in South Africa with local and global input from maternal health experts

PATH, in collaboration with Sinapi Biomedical in South Africa, designed and developed a novel affordable UBT for the management of severe PPH. The Sinapi UBT design is a result of extensive input from stakeholders and providers treating PPH in Africa. It requires no assembly, is simple to use, and is designed for use at all levels of care by trained providers.

1. World Health Organization (WHO). *MPS Technical Update: Prevention of Postpartum Haemorrhage by Active Management of the Third Stage of Labour*. Geneva: WHO; 2006.

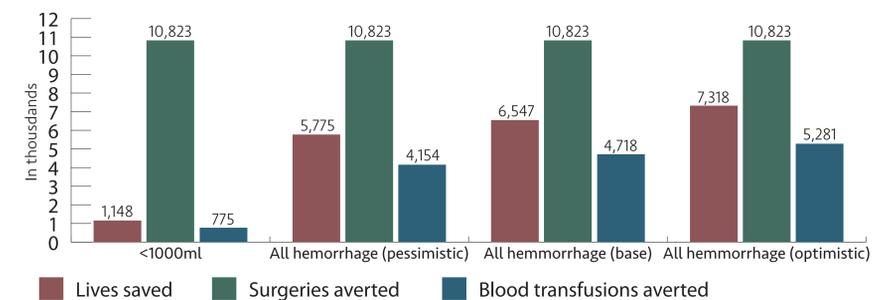
The Sinapi UBT is an affordable and optimized lifesaving device for the management of PPH

- Novel, fully assembled, ready-to-use medical device.
- Integrated system with a gravity-fed filling mechanism for greater control and ease of use.
- Can be inserted and filled in under one minute.
- The Sinapi design bridges the gap between expensive commercially available UBTs and condom catheters that require assembly.



UBT has the potential to significantly reduce maternal mortality and morbidity associated with severe PPH

PATH conducted an analysis to quantify the potential impact of the UBT on women suffering from severe PPH. Model outputs were obtained for the sub-Saharan region for the year 2018. Impact modeling estimated that the UBT could lead to an 11% reduction in maternal deaths and avert 10,823 surgeries and 4,718 blood transfusions annually in the sub-Saharan region.



Proposed activities

Working closely with local partners in South Africa, Sinapi Biomedical and the University of Stellenbosch, PATH proposes to advance an affordable UBT through the following key activities:

- Generate clinical safety data on the Sinapi UBT in a clinical validation trial carried out in a hospital setting under controlled conditions.
- Conduct a final design review incorporating findings from the validation study. Instructions for use will be developed, tested, and incorporated into the final package.
- Develop a sustainable commercialization strategy to ensure adoption and global access of the UBT.