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Introduction of the Ellavi uterine balloon tamponade into the Kenyan and Ghanaian maternal healthcare package for improved postpartum haemorrhage management: an implementation research study

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ABSTRACT

Objectives Use of intrauterine balloon tamponades for refractory postpartum haemorrhage (PPH) management has triggered recent debate since effectiveness studies have yielded conflicting results. Implementation research is needed to identify factors influencing successful integration into maternal healthcare packages. The Ellavi uterine balloon tamponade (UBT) (Ellavi) is a new low-cost, preassembled device for treating refractory PPH.

Design A mixed-methods, prospective, implementation research study examining the adoption, sustainability, fidelity, acceptability and feasibility of introducing a newly registered UBT. Cross-sectional surveys were administered post-training and post-use over 10 months.

Setting Three Ghanaian (district, regional) and three Kenyan (levels 4–6) healthcare facilities.

Participants Obstetric staff (n=451) working within participating facilities.

Intervention PPH management training courses were conducted with obstetric staff.

Primary and secondary outcome measures Facility measures of adoption, sustainability and fidelity and individual measures of acceptability and feasibility.

Results All participating hospitals adopted the device during the study period and the majority (52%–62%) of the employed obstetric staff were trained on the Ellavi; sustainability and fidelity to training content were moderate. The Ellavi was suited for this context due to high delivery and PPH burden. Dynamic training curriculums led by local UBT champions and clear instructions on the packaging yielded positive attitudes and perceptions, and high user confidence, resulting in overall high acceptability. Post-training and post-use, ≥79% of the trainees reported that the Ellavi was easy to use. Potential barriers to use included the lack of adjustable drip stands and difficulties calculating bag height according to blood pressure. Overall, the Ellavi can be feasibly integrated into PPH care and was preferred over condom catheters.

Conclusions The training package and time saving Ellavi design facilitated its adoption, acceptability and feasibility. The Ellavi is appropriate and feasible for use among obstetric staff and can be successfully integrated into the Kenyan and Ghanaian maternal healthcare package.

Trial registration numbers NCT04502173; NCT05340777.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study was the first large-scale implementation research trial to examine the Ellavi uterine balloon tamponade (Ellavi) as a novel, free-flow, preassembled system for refractory postpartum haemorrhage (PPH) care.
⇒ Results from the implementation research showed that the training package and time saving, innovative design of the Ellavi facilitated its adoption, acceptability and feasibility.
⇒ A longer study duration would have fostered greater use-case observations as refractory PPH is a rare outcome and practitioners became more comfortable with the device over time; busy practitioners also requested shorter questionnaires.
⇒ Our article highlights the need for other studies to examine fidelity to training content during use and enable team simulations and individual practice prior to PPH events to increase user confidence.
⇒ The Ellavi is appropriate and feasible for use among obstetric staff working at different facility levels of care and can be successfully integrated into the Kenyan and Ghanaian maternal healthcare package.

INTRODUCTION

Postpartum haemorrhage (PPH) is defined by the WHO as a cumulative blood loss of at least 500 mL following vaginal birth, or 1000 mL following caesarean section, within 24 hours after birth.[1 2] The most common cause of PPH is uterine atony, or failure of the uterus to contract after placenta delivery. Globally, PPH affects 5% of all deliveries, remains the leading cause of maternal mortality and morbidity, and is responsible for nearly 25% of all maternal pregnancy-related deaths.[2 3] In Ghana, PPH is responsible for 22% of the direct obstetric deaths with a cause-specific case fatality rate of 1.3%.[4] In Kenya, 49% of the maternal deaths are due to obstetric haemorrhage and half (49%) of those obstetric haemorrhage deaths are due to uterine atony.[5 6]

To treat PPH, WHO recommends a first-response bundle of interventions that includes administering uterotonics, isotonic crystalloids (intravenous fluids), tranexamic acid and uterine massage.[7] Between 10% and 20% of PPH cases are refractory[8] and are not responsive to these first-line interventions,[9] and the patients continue to bleed. One-third to half of such refractory PPH cases are caused by uterine atony. Second-line bundles recommended for refractory PPH include a care package of interventions including aortic compression or bimanual uterine compression, uterine balloon tamponades (UBTs) and non-pneumatic anti-shock garments. Finally, invasive surgical procedures can be used, considering first those that preserve the uterus.[7 10 11]

UBTs for the management of refractory PPH have triggered much interest and debate over the past few years. Various commercially available UBT options exist, including volume-controlled UBTs such as the Bakri balloon, the ESM-UBT and the Ebb balloon, and pressure-controlled UBTs such as the Ellavi UBT. Multiple observational and prospective case series have documented and highlighted the effectiveness of UBTs in managing severe PPH.[12–16] UBT success rates, ranging from 84% to 97%, have been reported with the different types of UBTs[11 17–23] including volume-controlled UBTs such as the Bakri balloon and the ESM-UBT, and the pressure-controlled Ellavi UBT. Evidence suggests that UBT use is associated with a significant reduction in the rate of PPH-related invasive procedures such as artery ligation, uterine compression sutures, hysterectomy and arterial embolisation.[24–26] The evidence on UBT efficacy and effectiveness from randomised studies in low-income and middle-income countries is conflicting. Results from a randomised controlled trial using UBTs conducted in Mali and Benin[27] and a cluster randomised trial in Egypt, Senegal and Uganda,[28] using prepackaged condom catheter UBT kits, showed unfavourable outcomes with higher rates of blood loss and maternal deaths for women who had UBT treatment. Although these studies had serious limitations, their findings have raised concern by suggesting that UBTs may not be as effective in managing refractory PPH as reported in observational studies and emphasised the need for rigorous evidence evaluating efficacy, safety, and the process of implementation.[29]

In 2021, WHO published a new recommendation on the use of UBTs for treatment of PPH due to uterine atony after vaginal birth in women who do not respond to first-line treatments.[30 31] The recommendation further states that UBTs should be used only where access to other PPH treatments and supportive systems is already in place.

Alongside the need for establishing strong evidence of UBT efficacy through randomised controlled trials, we must also determine effective operational strategies for UBT use, especially in low-income and middle-income countries.[32] To this end, we have conducted this multi-country implementation research study to identify the factors influencing uptake of the Ellavi UBT (a free flow-controlled system) by providers and facilities in Ghana and Kenya. By studying the adoption, fidelity, sustainability, appropriateness, acceptability and feasibility of Ellavi UBTs in six facilities, we aimed to inform future integration of the Ellavi UBT into national maternal healthcare packages.

METHODS

This implementation study was guided by the Proctor *et al* Implementation Outcomes Framework.[33] We aimed to examine adoption of the Ellavi UBT into facilities (percentage of facilities that incorporated the device in PPH management, percentage of hospital staff trained on Ellavi UBT), sustainability (sustained use) of the device over a 6 month period, PPH burden within the participating facilities and fidelity to the training. We also aimed to evaluate the factors determining appropriateness, acceptability and feasibility of using the Ellavi UBT among obstetric healthcare workers by exploring comprehension of the usage steps, accuracy of use, perceptions and attitudes toward the device, usability and user confidence, facilitators of use and barriers to use, use-patterns, and insights into training effectiveness.

Study design

This was a longitudinal, mixed-methods, implementation research study. We administered cross-sectional surveys to study participants immediately post-training (N=378) at baseline and then post-use (N=63) after refractory PPH treatment, over the following 10 months. We collected facility data on total births, PPH cases, PPH mortality and maternal mortality.

The post-training survey (see online supplemental Appendix 1) recorded information on comprehension of usage steps, feedback on the training methods used, perceptions and attitudes toward the device, usability and user confidence and appropriateness of the device for the context. The case management form (see online supplemental Appendix 2) and post-use survey (see online supplemental Appendix 3) were completed up to 24 and 72 hours after each PPH management experience; these tools examined staff experience and correct use of

the device. One contact at each hospital was responsible for connecting staff to the PATH principal investigator after each PPH event to complete the study forms. Only one staff member was interviewed for each refractory PPH event, but teams of up to five staff worked together to resolve cases. This study was not powered to detect significance, only descriptive findings on implementation (process) outcomes and usability. Considering the local practicalities (eg, delivery rates, efficacy of first-line PPH interventions and the rarity of refractory PPH), we planned to observe a sample of 90 use-cases across both sites over the 10 months. However, thematic redundancy from qualitative usability data was expected to be achieved from a sample of 40.

Inclusion criteria

The study population included obstetric care workers (eg, obstetricians, medical officers, midwives and nurses) practicing at the six participating hospitals. All were encouraged to attend an Ellavi UBT training session and encouraged to use the device in practice. Only healthcare providers were included as study participants, and only if they signed a consent form to participate. If staff missed the training and managed a refractory PPH case, they filled out a consent form prior to completing surveys. Maternal PPH cases were not participants in this study.

Ellavi UBT device

The Ellavi UBT device is manufactured at the Sinapi Biomedical ISO-certified factory in Stellenbosch, South Africa. The preassembled device consists of a fillable water supply bag and a tube with a valve that connects the supply bag to the tamponade balloon (figure 1). The supply bag holds up to 1000 mL of water; indication levels are printed on the front and detailed, illustrated user instructions are printed on the back. The tubing displays height level markings that correspond to patient systolic blood pressure. Sinapi received a CE Mark for the device in 2019, and it was registered with the Kenya Pharmacy and Poisons Board and the Ghana Food and Drug Administration to treat refractory PPH by atony by 2020.

Study sites

Three Kenyan hospitals (Kenyatta National Hospital (KNH), Mbagathi County Hospital (MCH) and St. Mary's Mission Hospital (SMMH)) and three Ghanaian hospitals (Tema General Hospital, Kasoa Polyclinic, and Ridge Hospital) were purposively selected for this study based on their urban location, large catchment population and PPH burden, facility level representation and access to UBT master trainers. All six facilities follow national guidelines for the management of PPH, including use of second-line interventions for refractory PPH (including use of UBTs).

Training sessions (intervention)

In both countries, the trainings were held at the workplace, with attendance capped at 25 participants to maximise social distancing for COVID-19 prevention. Other COVID-19 protocols (facemasks, hand-washing, temperature checks) were strictly followed.

Training content included a review of refractory PPH management, application of the Ellavi UBT, an outline of the study objectives, onboarding criteria and tools, implementation guidance and study contacts. The Ellavi UBT use presentation included an instructional video from the manufacturer. Additionally, teams of learners practiced using the device with humanistic foam postpartum pelvic models in a simulated PPH event.

In Kenya, 15 trainings were conducted at SMMH (1 and 18 December 2020), MCH (9 March 2021 and 7 July 2021) and KNH (29 January 2021; 8, 10, 11 and 12 March 2021; 6–7 May 2021; 17–18 June 2021; 26–27 August 2021). The trainings were led by four obstetricians from the University of Nairobi Medical School and the KNH obstetrics/gynaecology department, with assistance from PATH. Ten trainings were offered in Ghana at Tema General Hospital (9–11 December 2020), Kasoa Polyclinic (18–20 November 2020) and Ridge Hospital (29 November 2020 to 2 December 2020). These trainings were led by an obstetrician and UBT expert, with assistance from PATH. For the purpose of this study,

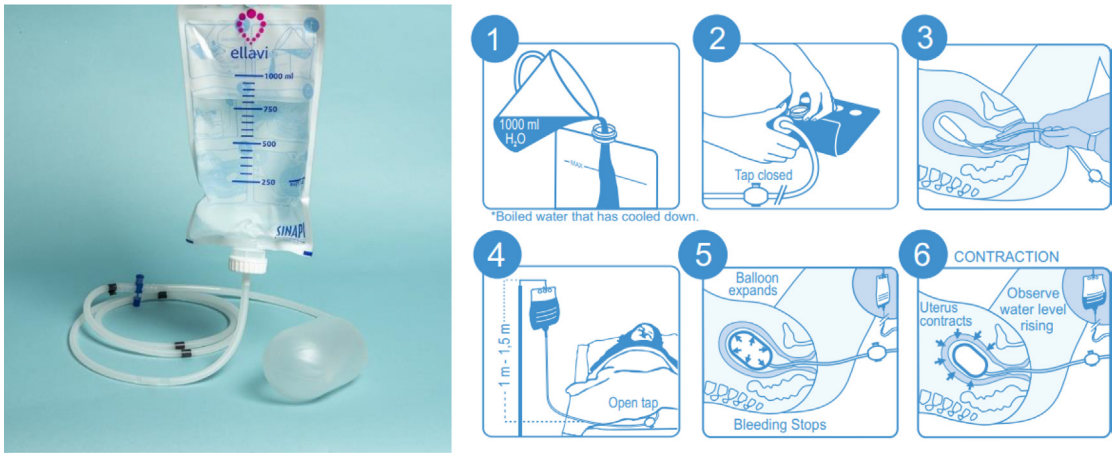

Figure 1 The Ellavi uterine balloon tamponade device and quick setup reference instructions.

PATH purchased 500 Ellavi UBT units for the participating hospitals.

Patient and public involvement

Patients were involved in the conduct of this research since the Ellavi UBT is registered in both Ghana and Kenya and used as part of the standard maternal care package, where available, to treat refractory PPH. Study participants (obstetric ward staff) participated in conduct of the study but were not involved in the study design; they received the study results via dissemination events led by the local principal investigator working at their facility. The public was not involved in study design or conduct of the study, but public dissemination events were held in both Ghana and Kenya at local health conferences, national obstetrical gynaecological society meetings, and meetings with the Ministries of Health.

Data management and analysis

Paper survey data were entered into an Excel database on Box, a cloud-based content management system, and processed by Power Query. The study team back-checked 30% of data entry records to ensure accuracy. Simple frequency tables were generated to assess the quality of the data prior to statistical analysis in Stata V.12 (StataCorp, College Station, Texas, USA). Descriptive statistics were calculated in Stata to report on implementation outcomes and the qualitative data responses were coded in Excel to examine predominant themes. The data generated by our team of coauthors are publicly available on Figshare and were used in the writing of this article.[34]

IRB approvals

This study conformed to the principles embodied in the Declaration of Helsinki. This study was also registered with the Kenya Pharmacy and Poisons Board, Kenya's National Commission for Science, Technology and Innovation and ClinicalTrials.gov.

RESULTS

PPH burden

Participating Kenyan and Ghanaian facilities oversaw 11 188 and 15 262 deliveries and managed 278 and 343 PPH events, respectively. Most PPH events were controlled using conventional management strategies. During the 7-month data collection period in Kenya and 10-month period in Ghana, at least 118 patients were referred for some surgical procedure (table 1). Of the 23 Kenyan refractory PPH cases reported during the study, the Ellavi UBT was deployed in 19 (93%) cases; 13 provided definitive management, 5 were resolved by surgical intervention and 1 was resolved by condom catheter (20-week miscarriage). In Ghana, the Ellavi UBT was deployed every time a refractory PPH case was reported to our staff (n=44); 38 provided definitive management,

Table 1 Facility-level data from the six participating hospitals

	Kenya				Ghana*			
	KNH	MCH	SMMH	Total	Ridge	TGH	Kasoa	Total
Adoption (training)								
Total obstetrics staff (employed†+registrars)	296	54	30	380	176	128	76	380
Staff (employed+registrars) completed Ellavi UBT training	152	30	15	197	99	69	68	236
% of staff trained	51	56	50	52	56	54	89	62
Adoption (facility uptake)								
Facilities using the device	Yes	Yes	Yes	100%	Yes	Yes	Yes	100%
# of staff who reported using Ellavi UBT‡	16	1	1	18	11	6	6	23
# of Ellavi UBT used	17	4	3	24	52	41	15	108
Sustainability				**Total**				**Total**
Used Ellavi UBT 1+ times, ≥4 months after training	Yes	Yes	No	67%	Yes	Yes	Yes	100%
Used Ellavi UBT every month, for 6 months	Yes	No	No	33%	Yes	No	Yes	67%
Facility PPH burden								
# of births	5282	4439	1467	11 188	6031	4332	4899	15 262
# of PPH events§	170	71	37	278	224	46	73	343
# of PPH requiring surgery¶	96	10	4	110	8	N/A**	N/A**	8

*Data collection period was 10 months for each Ghanaian facility (Ridge: 1 December 2020 to 30 September 2021; TGH 1 December 2020 to 30 September 2021; Kasoa: 1 December 2020 to 30 September 2021).
†Employed obstetric staff included obstetricians, medical officers, midwives and nurses.
‡Only one team member could complete the survey.
§PPH events included refractory and non-refractory events. Blood volume loss is visually estimated.
¶Surgery options included B-lynch or other compression sutures, artery ligation (uterine or internal iliac) and partial or total hysterectomy.
**Data not available.
Kasoa, Kasoa Polyclinic; KNH, Kenyatta National Hospital; MCH, Mbagathi County Hospital; PPH, postpartum haemorrhage; Ridge, Ridge Hospital; SMMH, St. Mary's Mission Hospital; TGH, Tema General Hospital; UBT, uterine balloon tamponade.

4 were resolved surgically, 1 by condom catheter (case of uterine fibroids) and 1 was referred for specialised care.

Ellavi UBT adoption

All six facilities adopted the Ellavi UBT (100% adoption), meaning facilities trained relevant providers and placed the devices in the labour wards, maternity wards, delivery rooms, operating theatres, postnatal wards and main stores for easy access during the study period (table 1). In Kenya, 52% of the 380 total obstetric staff were trained on the Ellavi UBT; trained staff primarily consisted of registrars (66%) and midwives or nurses (33%) (table 1). In Ghana, 62% of the 380 obstetric staff were trained and the majority were midwives (78%). All facilities (100%) used the Ellavi UBT to manage at least one refractory PPH case. Over the study period, at least 7% (14/215) of the trained providers in Kenya and 8% (19/236) in Ghana used the UBT to treat a refractory PPH case (only one staff was surveyed per obstetric care team and untrained staff could use the device).

Sustainability

A sizeable majority (83%) of the study facilities used the device at least once, 4 or more months after the training. Half (50%) of the facilities used an Ellavi UBT every month for six consecutive months.

Provider post-training perceptions

Appropriateness and acceptability of the Ellavi UBT

Following training, obstetric staff were asked what they most liked and disliked about the Ellavi UBT. Overall, the Kenyan staff (N=189) perceived the device to be an effective intervention for PPH management. Two-thirds appreciated its innovative design (65%), one-third remarked on its simplicity and ease of use (31%) and others liked its preassembled nature (14%), appropriateness for the context (14%), and user controls (eg, T-valve) (9%). Similarly, in Ghana, obstetric staff (N=184) appreciated its easy-to-use design (85%), durability (11%), ability to provide effective care (22%) and preassembled nature (28%), saving precious time to easily insert (15%) and provide patient care (22%). Appreciative quotes from obstetric staff included:

> It's preassembled. It's effective and fast to use since everything is in one pack.
>
> —Kenyan Nurse
>
> The free flow system allows fluid movement, but it also has controls (T-valve) to adjust the intrauterine volume pressure to systolic BP.
>
> —Kenyan Registrar
>
> It's safe in the hands of various levels of health providers.
>
> —Ghanaian Registrar
>
> It's easy to assemble. No stress in tying the tubes with ligatures.
>
> —Ghanaian Midwife
>
> It's easy to insert manually. It's preassembled so it saves time.
>
> —Ghanaian Physician's assistant

When asked about dislikes, less than two-fifths (N=71) of the Kenyan staff gave responses. Of respondents, one-third voiced concerns about it requiring an adjustable drip stand (35%) and its sustainability beyond the project (14%); others disliked certain usability issues (40%) (eg, height calculation for supply bag) and the need for continued capacity-building (11%). Similarly, less than one-quarter (24%) of Ghanaian obstetric workers had dislikes. Among them, some (39%) expressed concerns about its perceived cost, and fewer expressed concerns for its single-use nature (5%), the need for adjustable drip stands (6%), inflexible tubing (5%), potential allergies (5%) and assistance requirement (5%). Quotes expressed by obstetric workers about the above concerns included:

> Blood pressure—the height calculation of the bag above the patient is not straight forward, beds are adjustable. —Kenyan Registrar
>
> If you don't have an adjustable drip stand, the water won't flow easily.
>
> —Ghanaian Midwife
>
> It needs an assistant so it will be very difficult to use if (you are) left alone.
>
> —Ghanaian Midwife
>
> [Myself, I] … need more practice before a real PPH event.
>
> —Kenyan Midwife

Acceptability of the Ellavi UBT training

Over 80% of the trainees reported the Ellavi UBT was easy to use and many stated its clear advantages over condom catheters, the standard of care. Approximately 90% of the trainees said they could use the Ellavi UBT by themselves if required but typically PPH events were managed with a colleague (78%–83%) or in a team (2%–16%) of colleagues, rather than alone (10%) (table 2). Obstetric staff perceived the most effective training methods to have been the team drills practicing PPH treatment, use of foam models to simulate treatment and instructional videos. However, more than half (54%) reported wanting more time to practice using the device.

Provider post-use perceptions

Acceptability and feasibility of the Ellavi UBT device

Sixty-three cases were managed with Ellavi UBTs (19 in Kenya and 44 in Ghana) by 18 and 22 obstetric staff in Kenya and Ghana, respectively. Survey results were compared between post-training and post-use responses (table 3). Post-use, obstetric staff remained confident in their ability to correctly use an Ellavi UBT to manage PPH (100%) and most (>85%) had no requests for improvements to instructions for use (IFU). Kenyan users more

Table 2 Indicators of study participants' understanding of use and attitudes toward the device post-training.

	Kenya	Ghana
Comprehension of the usage steps	**N=188**	**N=185**
Had to refer back to instructions for use*	56 (30%)	44 (24%)†
Steps of use flowed in a logical sequence	184 (96%)‡	181 (97%)§
Reported Ellavi UBT was easy to use*	168 (89%)	150 (81%)
Requested improvements to the instructions	N=144	N=63
No changes needed Larger font sizes More pictures	85 (59%) 17 (12%) 16 (11%)	37 (59%) 14 (22%) 7 (11%)
Attitudes toward the device	**N=191**	**N=187**
Feel I have enough knowledge to confidently use an Ellavi UBT	187 (98%)‡	185 (99%)
Feel confident I can correctly use an Ellavi UBT to manage a life-threatening PPH*	185 (97%)‡	185 (99%)
Advantages of Ellavi UBT over condom catheters	**N=181**	**N=147**
Preassembled, time-saving Easier to use, insert Free flow system with valve Better quality and design More sterile	70 (39%) 41 (23%) 35 (19%) 35 (19%) 12 (7%)	61 (41%) 72 (49%) 3 (2%) 28 (19%) 5 (3%)
Usability and user confidence	**N=190**	**N=189**
Easy to fill the device¶	184 (97%)	187 (99%)
Easy to insert the device¶	167 (88%)	176 (93%)
Easy to monitor if device is working¶	179 (95%)**	185 (98%)
Easy to remove the device¶	183 (96%)	189 (100%)
Need the support of a more technical person to use the Ellavi UBT	39 (21%)	32 (17%)††
Concerns regarding ability to operate the Ellavi UBT	**N=181**	**N=101**
None Availability of adjustable drip stands Difficulties calculating bag height More practice Requires a team Pain management Availability of Ellavi UBT Perception of affordability	57 (32%) 33 (18%) 12 (7%) 13 (7%) 9 (5%) 5 (3%) 33 (18%) 5 (3%)	27 (27%) 1 (1%) 1 (1%) 3 (3%) 2 (2%) 0 (0%) 23 (23%) 21 (21%)
Imagine most could learn how to use the Ellavi UBT quickly	178 (94%)**	187 (99%)‡‡
Could use the Ellavi UBT alone, if needed	169 (89%)**	171 (90%)**
Perceived challenges with using Ellavi UBT alone	**N=179**	**N=116**
No challenge Adjusting the drip stand height Maintaining sterility Patient monitoring Requires teamwork Need help stabilising the balloon/patient Need assistance holding cervix open Filling water bag Need assistance to save time	15 (8%) 26 (15%) 47 (26%) 12 (7%) 40 (22%) 26 (15%) 45 (25%) 0 (0%) 0 (0%)	36 (31%) 22 (19%) 15 (13%) 7 (6%) 18 (16%) 4 (3%) 3 (3%) 7 (6%) 9 (8%)
Insights into training effectiveness		
Perceived efficacy of training methods for UBT	**N=189**	**N=178**
Team practice simulations Model simulators (foam) Team drills Visual aids Videos Formal lectures	101 (53%) 109 (58%) 61 (32%) 27 (14%) 68 (36%) 29 (15%)	87 (49%) 113 (63%) 27 (15%) 57 (32%) 81 (46%) 68 (38%)
Desired more during training	**N=180**	**N=150**
Practice using device Information on how to use Information on when to use Information on effectiveness Nothing additional	98 (54%) 14 (8%) 10 (6%) 44 (24%) 34 (19%)	81 (54%) 22 (15%) 12 (8%) 18 (12%) 41 (27%)

Continued

Table 2 Continued

	Kenya	Ghana
Appropriateness		
Number of deliveries involved in, per month	**N=174**	**N=123**
Average (SD)	110 (193)	78 (117)
Number of PPH events (all severities) involved in, per month	**N=174**	**N=125**
Average (SD)	12 (25)	8 (18)
During a regular PPH, I usually manage the event	**N=188**	**N=168**
Alone With a colleague With a team	18 (10%) 146 (78%) 24 (12%)	17 (10%) 140 (83%) 3 (2%)
Perceived effectiveness	**N=185**	**N=185**
Overall impression of Ellavi UBT effectiveness to treat severe PPH		
Very effective Somewhat effective	117 (62%)‡‡ 51 (27%)‡‡	153 (83%)†† 8 (4%)††
Ellavi UBT effectiveness in comparison to other PPH treatments		
Very effective Somewhat effective	121 (65%)†† 47 (25%)††	146 (80%)§§ 12 (7%)§§

*This response includes agree/strongly agree or confident/very confident.
†The sample size is 183.
‡The sample size is 191.
§The sample size is 186.
¶This response includes easy and very easy.
**The sample size is 189.
††The sample size is 185.
‡‡The sample size is 188.
§§The sample size is 182.
PPH, postpartum haemorrhage; UBT, uterine balloon tamponade.

commonly reported referring back to IFU (56% vs 2%) but were more likely to report that Ellavi was easy to use (94% vs 79%). Usability indicators (insertion, monitoring, removal) remained high (>71%) and need for the presence of a more technical person declined (<12%). Almost all users, post-use, maintained that they could use the Ellavi UBT alone, if needed (94%–95%). Users perceived simulation models (65%–88%) and practice exercises (53%–70%) with teammates to be the most effective training methods; some still desired more time practicing with the device (50%–64%) prior to patient care. Overall impressions of Ellavi UBT's effectiveness was high (72%–92%) but decreased post-use among Kenyan obstetric staff and increased among Ghanaian staff.

Experiences managing refractory PPH

Following the management of the included refractory PPH events, we assessed fidelity to the training and accuracy of use, accessibility of Ellavi UBT and other experiences of use (table 4). The Ellavi UBT was used by medical officers, registrars, midwives and nurses for both vaginal deliveries and caesarian sections. Most refractory PPH cases were caused by atony (88% in Ghana and 79% in Kenya). Oxytocin was used in all but one case along with other uterotonics (eg, misoprostol, carbetocin); intravenous fluids, uterine massage and tranexamic acid were also used as per training on the primary bundle. The Ellavi UBT is designed to be used between systolic blood pressures of 60 to 120; however, the device still controlled haemorrhage in 24 of the 29 cases with BP above 120. Devices were largely stored in the delivery room, maternity ward and operating theatres for easy access and inserted into patients within 1 hour of refractory PPH recognition. Obstetric staff felt encouraged by facility leaders and colleagues to use the Ellavi UBT.

Fidelity

Accuracy of use, according to training course instructions and initial height placement of the supply bag at the start of PPH management, was very high (94% Kenya and 100% Ghana) but adjustment of the supply bag's height during treatment was low (61% Kenya and 54% Ghana). Trainees were instructed to remove the UBT after 30–60 min if unable to stop the haemorrhage; check for continued bleeding 6–8 hours after insertion and if bleeding recurs, hang the supply bag back at appropriate height up to a maximum of 24 hours. In Kenya, trainees were instructed to readjust every 15 min during the first hour, every 30 min during the second hour and hourly thereafter. In Ghana, these instructions were adapted based on feedback from midwife trainees; the modifications dictated positioning the bag 1.5 m above the patient and adjusting the height only if the patient had discomfort. On average, the device was inserted into the patient 1 hour after recognition of PPH in Ghana and Kenya (table 1). Among the patients for whom the Ellavi UBT did not stop the haemorrhage (32% Kenya and 9% Ghana), the device

Table 3 Observations in comprehension, attitudes, usability and user confidence, and insights into training effectiveness between users' post-training and post-use scores

	Post-training		Post-use	
	Kenya	Ghana	Kenya	Ghana
Unique study IDs	**12**	**13**	**18**	**22**
Comprehension of the usage steps	**N=12**	**N=13**	**N=18**	**N=43**
Had to refer back to instructions for use*	3 (25%)	1 (8%)	9 (56%)†	1 (2%)
Reported Ellavi UBT was easy to use*	10 (91%)‡	12 (92%)	17 (94%)	34 (79%)
Requested improvements to instructions				
No changes needed	6 (67%)§	11 (85%)	17 (94%)	37 (86%)
Larger font sizes	0 (0%)	1 (8%)	0 (0%)	4 (9%)
More pictures	1 (11%)	0 (0%)	0 (0%)	2 (5%)
Wording	0 (0%)	0 (0%)	1 (6%)	0 (0%)
Picture of tube with calibrations and BP	2 (22%)	0 (0%)	0 (0%)	0 (0%)
Attitudes toward the device	**N=12**	**N=13**	**N=18**	**N=43**
Feel confident I can correctly use an Ellavi UBT to manage a life-threatening PPH*	12 (100%)	13 (100%)	18 (100%)	43 (100%)
Usability and user confidence	**N=12**	**N=13**	**N=18**	**N=43**
Easy to insert the device¶	12 (100%)	13 (100%)	13 (72%)	43 (100%)
Easy to monitor if device is working¶	12 (100%)	13 (100%)	16 (89%)	34 (81%)**
Easy to remove the device¶	11 (92%)	13 (100%)	15 (100%)††	39 (98%)‡‡
Need the support of a more technical person to use the Ellavi UBT	3 (25%)	2 (15%)	2 (11%)	2 (5%)**
Could use the Ellavi UBT alone, if needed	12 (100%)	11 (85%)	17 (94%)	41 (95%)
Insights into training effectiveness				
Perceived efficacy of training methods for UBT	**N=12**	**N=13**	**N=17**	**N=40**
Team practice simulations	4 (33%)	5 (38%)	9 (53%)	28 (70%)
Model simulators (foam)	7 (58%)	7 (54%)	11 (65%)	35 (88%)
Team drills	3 (25%)	2 (15%)	2 (12%)	12 (30%)
Visual aids	1 (8%)	2 (15%)	5 (29%)	12 (30%)
Videos	2 (17%)	7 (54%)	5 (29%)	19 (48%)
Formal lectures	2 (17%)	2 (15%)	4 (24%)	22 (55%)
Desired more during training	**N=11**	**N=12**	**N=16**	**N=39**
Practice using device	5 (45%)	6 (50%)	8 (50%)	25 (64%)
Information on how to use	1 (9%)	2 (17%)	2 (13%)	3 (8%)
Information on when to use	1 (9%)	1 (8%)	2 (13%)	4 (10%)
Information on effectiveness	4 (36%)	3 (25%)	3 (19%)	0 (0%)
Nothing additional	2 (18%)	4 (33%)	4 (25%)	10 (26%)
Perceived effectiveness	**N=12**	**N=12**	**N=18**	**N=41**
Overall impression of Ellavi UBT effectiveness to treat severe PPH				
Very effective	11 (92%)	9 (75%)	14 (78%)	34 (83%)
Somewhat effective	0 (0%)	2 (17%)	2 (11%)	6 (15%)
Ellavi UBT effectiveness in comparison to other PPH treatments				
Very effective	11 (92%)	9 (75%)	13 (72%)	33 (83%)‡‡
Somewhat effective	1 (8%)	3 (25%)	2 (11%)	5 (13%)

*This response includes agree/strongly agree or confident/very confident.
†Sample size is 16.
‡Sample size is 11.
§Sample size is 9.
¶This response includes easy and very easy.
**Sample size is 42.
††Sample size is 15.
‡‡Sample size is 40.
BP, blood pressure; PPH, postpartum haemorrhage; UBT, uterine balloon tamponade.

was removed about an hour after insertion in Kenya (50 min) and Ghana (44 min) but some unsuccessful use cases went as long as 2.8 hours. Successful use cases typically had the Ellavi UBT removed after 5.3 hours to 6.5 hours; about one-quarter (29% Ghana and 22% Kenya) had the UBT inserted for more than 8 hour; no staff allowed the device to be inserted for more than 24 hours.

Table 4 Fidelity to training: use patterns

	Kenya		Ghana	
	UBT did not stop PPH	**UBT stopped PPH**	**UBT did not stop PPH**	**UBT stopped PPH**
Obstetric staff role	**N=6**	**N=13**	**N=6**	**N=38**
Obstetrician	1 (17%)	1 (8%)	0 (0%)	0 (0%)
Medical officer	1 (17%)	0 (0%)	3 (50%)	20 (53%)
Registrar	1 (17%)	7 (54%)	0 (0%)	0 (0%)
Midwife	0 (0%)	3 (23%)	3 (50%)	18 (47%)
Nurse	3 (50%)	2 (15%)	0 (0%)	0 (0%)
Mode of delivery				
Vaginal	2 (33%)	5 (38%)	6 (100%)	37 (97%)
Caesarean section	4 (67%)	8 (62%)	0 (0%)	1 (3%)
Reported causes of PPH	**N=6**	**N=13**	**N=6**	**N=35**
(Suspected) Atony	4 (67%)	11 (85%)	3 (50%)	33 (94%)
Retained placenta	1 (17%)	3 (23%)	1 (17%)	2 (6%)
Abnormal placentation	0 (0%)	2 (15%)	0 (0%)	2 (6%)
Trauma (uterine)	1 (17%)	1 (8%)	4 (67%)	3 (9%)
Trauma (vaginal)	0 (0%)	1 (8%)	1 (17%)	0 (0%)
Placental site bleeding	1 (17%)	0 (0%)	0 (0%)	0 (0%)
Coagulation problems	0 (0%)	2 (16%)	1 (17%)	2 (6%)
Interventions used prior to Ellavi UBT	**N=6**	**N=13**	**N=6**	**N=38**
Oxytocin	6 (100%)	13 (100%)	6 (100%)	37 (97%)
Misoprostol	5 (83%)	13 (100%)	4 (67%)	28 (74%)
Ergometrin	1 (17%)	0 (0%)	2 (33%)	12 (32%)
Oxytocin/ergometrin	0 (0%)	2 (15%)	0 (0%)	3 (8%)
Uterine massage	6 (100%)	12 (92%)	5 (83%)	26 (68%)
Bimanual compression	4 (67%)	5 (39%)	2 (33%)	4 (11%)
Aortic compression	3 (50%)	0 (0%)	0 (0%)	1 (3%)
Tranexamic acid	4 (67%)	11 (85%)	3 (50%)	20 (53%)
Manual removal of placenta	1 (17%)	2 (15%)	0 (0%)	3 (8%)
Intravenous fluids	4 (67%)	12 (92%)	3 (50%)	29 (76%)
Carbetocin	2 (33%)	8 (62%)	2 (33%)	2 (5%)
Treatment of lacerations	1 (17%)	1 (7%)	1 (17%)	5 (13%)
B-lynch sutures	1 (17%)	0 (0%)	0 (0%)	0 (0%)
Duration between PPH recognition and Ellavi UBT insertion	**N=5**	**N=11**	**N=4**	**N=33**
Mean (SD)	49 min (1.2 hours)	1.2 hour (2 hours)	26 min (14 min)	56 min (1.5 hours)
Approximate blood loss at PPH recognition (mL)	**N=5**	**N=10**	**N=6**	**N=36**
Mean (SD)	1260 (371)	650 (213)	1450 (1,037)	1342 (993)
Range	1000–1800	300–950	700–3500	400–5000
Blood pressure	**N=6**	**N=13**	**N=4**	**N=34**
% <60 systolic BP	0 (0%)	0 (0%)	0 (0%)	0 (0%)
% >120 systolic BP	2 (33%)	12 (92%)	3 (75%)	12 (35%)
Patient locale when Ellavi UBT used	**N=5**	**N=13**	**N=6**	**N=38**
Operating theatre	4 (80%)	8 (62%)	1 (17%)	3 (8%)
Labour ward	0 (0%)	4 (31%)	5 (83%)	33 (87%)
Post-anaesthesia care unit	1 (20%)	1 (8%)	0 (0%)	0 (0%)
Delivery suit	0 (0%)	0 (0%)	0 (0%)	1 (3%)
Post-delivery ward	0 (0%)	0 (0%)	0 (0%)	1 (3%)
Ellavi UBT was easily accessible	**N=5**	**N=12**	**N=5**	**N=38**
Yes	5 (100%)	12 (100%)	5 (100%)	37 (97%)
Location of UBT storage	**N=5**	**N=11**	**N=5**	**N=38**
Delivery room	0 (0%)	0 (0%)	4 (80%)	20 (53%)
Maternity ward	3 (60%)	7 (64%)	3 (60%)	17 (45%)
Operating theatre	1 (20%)	4 (36%)	1 (20%)	13 (34%)
Main store	1 (20%)	0 (0%)	0 (0%)	0 (0%)
Labour ward	0 (0%)	0 (0%)	0 (0%)	1 (3%)
Postnatal ward	0 (0%)	0 (0%)	1 (20%)	5 (13%)
Feedback on storage location	**N=5**	**N=12**	**N=5**	**N=38**
No change	3 (60%)	7 (58%)	3 (60%)	28 (74%)
Make available in maternity ward	0 (0%)	1 (8%)	0 (0%)	5 (13%)
Make available in operating theatre	2 (40%)	1 (8%)	1 (20%)	1 (3%)
Make available in delivery room	0 (0%)	3 (25%)	1 (20%)	8 (21%)
Fidelity to training				
Accuracy of use	**N=5**	**N=13**	**N=6**	**N=38**

Continued

Table 4 Continued

	Kenya		Ghana	
	UBT did not stop PPH	UBT stopped PPH	UBT did not stop PPH	UBT stopped PPH
Fluid bag placed correctly above the patient at start of PPH management	4 (80%)	13 (100%)	6 (100%)	38 (100%)
Fluid bag height adjusted during PPH management	3 (60%)	8 (62%)	3 (50%)	21 (55%)
Ellavi UBT duration of use (inserted)	**N=5**	**N=9**	**N=5**	**N=35**
Mean (SD)	50 min (0.47 hours)	5.3 hour (3.5 hours)	44 min (1.2 hours)	6.5 hour (7.6 hours)
Range (min, max)	0.3 hours, 1.3 hours	0.5 hours, 12 hours	0 hour, 2.8 hours	0 hour, 24 hours
Provider used Ellavi UBT	**N=5**	**N=12**	**N=5**	**N=38**
Alone Had assistance	2 (40%) 3 (60%)	3 (25%) 9 (75%)	0 (0%) 5 (100%)	8 (21%) 30 (80%)
Had authority to use independently	**N=5**	**N=11**	**N=5**	**N=36**
Yes No, received order	5 (100%) 0 (0%)	10 (91%) 1 (9%)	5 (100%) 0 (0%)	31 (86%) 5 (14%)
Facility leaders encouraged Ellavi UBT use	**N=5**	**N=11**	**N=5**	**N=36**
Yes No Neither	4 (80%) 0 (0%) 1 (20%)	9 (82%) 0 (0%) 2 (18%)	5 (100%) 0 (0%) 0 (0%)	30 (83%) 0 (0%) 6 (17%)
Colleagues encouraged Ellavi UBT use	**N=5**	**N=11**	**N=5**	**N=36**
Yes, encouraged No, discouraged Neither	5 (100%) 0 (0%) 0 (0%)	7 (64%) 0 (0%) 4 (36%)	4 (80%) 0 (0%) 1 (20%)	25 (69%) 0 (0%) 11 (31%)
Completed training course	**N=5**	**N=12**	**N=5**	**N=38**
Yes	5 (100%)	8 (67%)	4 (80%)	35 (92%)

BP, blood pressure; PPH, postpartum haemorrhage; UBT, uterine balloon tamponade.

DISCUSSION

This study was conducted to examine implementation outcomes associated with introducing an improved device (the Ellavi UBT) to manage refractory PPH cases in Ghana and Kenya. It highlights the need to address gaps in understanding implementation challenges en route to improving treatment effectiveness.[27 28] Implementation outcomes provide indicators of implementation success, proximal indicators of implementation processes and offer intermediate outcomes to consider in relation to service outcomes (eg, efficiency, safety, effectiveness, timeliness) and client outcomes (eg, satisfaction).[33] Our study focused on implementation effectiveness, rather than clinical intervention effectiveness. This article highlights the need for researchers to examine training rates and fidelity to training content, as well as acceptability and feasibility, while building evidence around UBT efficacy within future interventions.

We observed moderate levels of adoption and sustainability over the 6 months of our study. All facilities adopted the Ellavi UBT device. The majority of the obstetrics staff participated in trainings and half of the facilities used the device at least once every month. Although we observed relatively few use-cases and a small percentage of providers who used the devices over the 6 months, these data reflect the rarity of refractory PPH events, the fact that only one team member was surveyed post each PPH event, and given our other indicators, does not reflect low provider motivation to use. In fact, Ellavi UBTs were used in the majority of refractory PPH cases, and providers reported it was appropriate and acceptable. The 2021 total PPH rate reported herein was similar to the 2020 total PPH rate reported from the year prior (data not presented). Our observed PPH rate may have been lower than the expected 5% rate because blood loss volumes were visually estimated within study facilities and thus likely underestimated due to poor measuring and documentation practices. To foster adoption and sustained used of new devices, we recommend identifying UBT champions and tasking them to promote use, conducting team simulation exercises during trainings, enabling more practice time with models prior to PPH events, strategically placing the device within facilities, ensuring trained providers are present on each shift and fostering interest and engagement among hospital leadership.

Given the complex and emergency nature of PPH cases, defining and observing correct use-cases for UBTs can be challenging. It is important to note that obstetric staff were able to stop all cases of severe PPH with an Ellavi UBT (among cases that did not require surgery) except for two which employed condom catheters. The staff feedback received from these cases indicated that the Ellavi UBT was too large for a second trimester miscarriage (small uterus) and too thick to be helpful with uterine fibroids. Further research is needed to determine if these conditions should be excluded from the future definition of appropriate use-cases, however, a constrictive ring can be added to reduce the Ellavi balloon size for smaller uteri. We assessed fidelity to specific training content indicators when using the Ellavi UBT via survey and not observation.

Adjustment of the fluid bag was the component with the lowest fidelity. In our study, we introduced the Ellavi UBT at six sites by using a dynamic training programme that incorporated multiple learning methods.[35] Future studies should explore additional strategies to improve both implementation and service outcomes for the UBT. For example, improvements in training rates, fidelity to learnt methods and sustained use may be achieved with pre-service and in-service curriculums incorporating UBT devices, facility-based mentorship programmes supporting individual UBT-use, group refresher trainings (especially at low-volume facilities or where staff turnover is high), high-fidelity team practice simulations prior to emergency situations, advocacy for UBT use by local champions and Ministry of Health supervisor visits to monitor use and storage.[7 36–39] Both Ghana and Kenya have illustrated a strong commitment to equip health providers with the proper tools to strengthen skills via training and supportive mentorship.

Among the facility levels where we tested implementation, the Ellavi UBT appeared appropriate due to the high volume of deliveries and the need for all refractory PPH bundle components. The device was also highly accepted; post-training, the majority of providers praised the device and expressed a preference for the Ellavi UBT over condom catheters due to its preassembled design (which hastens the process to deliver critical care), ease of use, free flow system with T-valve, sterile packaging and perceived effectiveness of the device to treat PPH. Before the Ellavi UBT was introduced, only condom catheters were used as a non-surgical intervention. Post-training, obstetric staff instead consistently chose to use the Ellavi UBT and without financial incentives. Maxwell also found the Ellavi UBT was the preferred device among third-year and fourth-year students from Harvard Medical School in terms of simplicity, ease of use and speed to deploy when tested for usability against the ESM-UBT, an improvised condom balloon, Bakri balloon and Ebb balloon.[40] Post-use, acceptability remained high and providers reported it was feasible to use in routine care. Most participants reported high usability and user confidence when using the device to treat severe PPH; they perceived the device could effectively treat severe PPH and was effective in comparison to other PPH treatments. The facilitators of acceptability and feasibility included a preference for the Ellavi UBT over the current standard (condom catheters) due to enhanced usability and time saved, the use of effective and preferred training methods delivered by local UBT champions, encouragement from facility leaders and colleagues, team management of PPH cases and strategic placement of the device and job aid posters in the wards. Relatively few barriers to use were mentioned during the study but included a lack of adjustable drip stands (>1.5 m), difficulties calculating the supply bag height according to systolic BP, challenges maintaining sterility if working alone (without a team) and the desire for further training to increase self-confidence.

To further the feasibility of the Ellavi UBT, Sinapi registered the device in both Ghana and Kenya, and contracted local distributors in both geographies. To date it has been registered in 17 countries, including 7 in sub-Saharan Africa. To ensure sustainability, it is critical that the Ellavi UBT be included in procurement and distribution channels and in national financing schemes to remove access barriers. Sinapi developed a comprehensive training package that includes a lecture, videos and job aid posters. These user-friendly tools are available free of charge and accessible online to support local capacity-building programmes (ellavi.com).

For this study, we were limited in the number of trainings we could offer, and patient care took precedence within obstetric staff's schedules; thus, adoption could have been enhanced. Modifications to the training instructions were also improvised (bag height adjustment and frequency, removal before 6–8 hours) in both settings but further implementation research may be needed for optimisation. Although we evaluated sustainability of the Ellavi in the targeted hospitals, PPH is a rare event and our study duration was <10 months; longer durations may be more appropriate to evaluate this outcome. Providers had limited time to complete our study surveys and requested they be shortened; this may have reduced the number of post-use accounts recorded. Further, social desirability may have played a role in providers' survey responses, and feasibility was assessed only by providers who used the Ellavi UBT. It is important to note that while the Ellavi may have been preferred by our study participants, this implementation study focused on system integration and did not address clinical efficacy outcomes, thus the non-inferiority of the Ellavi UBT to condom catheters was not demonstrated. The WHO is currently conducting a PPH management study in Vietnam to compare the clinical efficacy outcomes of five uterine devices, the Ellavi UBT was included.

CONCLUSION

Overall, all cadres of obstetric staff were satisfied with the Ellavi UBT as a refractory PPH intervention. This study was one of the first large-scale implementation research trials to examine the Ellavi UBT as a novel, free-flow, preassembled system for refractory PPH care. We found the device was appropriate, acceptable and feasible within maternal healthcare packages at all facility levels tested.

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Contributors MEP, EA-H, CM, ZQ, SD and MM designed the research study. ZQ, GG, AO, OO, JS, SD, PD and PC led the trainings and conducted the informed consent process. JS, GG, JO, SK and ZQ assisted with data collection in Kenya. PC, PD, RO, MB, ES, PA, SD, CF and GS-M assisted with data collection in Ghana. MEP, CM, RO and AS conducted the analysis. MEP and EA-H drafted manuscript content. All authors participated in routine study calls and dissemination events and provided technical review of the manuscript prior to submission. MEP is responsible for the overall content as guarantor.

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Competing interests Over the last decade, MP, JS, PC, PD, RO, AS, MM and EA-H have been directly involved in the development, introduction and scale of the Ellavi uterine balloon tamponade as part of their employment at PATH, which constitutes a non-financial conflict of interest. PATH, an international non-governmental organisation, did not receive any funding from Sinapi Biomedical to conduct this multisite study. The remaining authors have no conflicts of interest to declare.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by PATH Research Ethics Committee #1514537; PATH Research Ethics Committee #1512602; Kenyatta National Hospital Ethics Review Committee (none); Ghana Health Service Ethics Review Committee (GHS-ERC014-01-20). Participants gave informed consent to participate in the study before taking part.

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REFERENCES

1 WHO. Who recommendations for the prevention and treatment of postpartum haemorrhage. Geneva: who, 2012. Available: https://apps.who.int/iris/bitstream/handle/10665/75411/9789241548502_eng.pdf;jsessionid=30FC0ACFA7B1DBAB72BB668EACD3015C?sequence=1 [Accessed 24 June 2022].
2 WHO. Who recommendations: Uterotonics for the prevention of postpartum haemorrhage. Geneva: who, 2018. Available: https://apps.who.int/iris/bitstream/handle/10665/277276/9789241550420-eng.pdf?ua=1 [Accessed 24 June 2022].
3 Say L, Chou D, Gemmill A, *et al*. Global causes of maternal death: a who systematic analysis. *Lancet Glob Health* 2014;2:e323–33.
4 Ghana Ministry of Health (MOH). *Ghana Adapted FIGO Post-Partum Haemorrhage Protocol and Care Pathways*. Ministry of Health, Republic of Ghana, 2021.
5 Kenya MOH. *National annual maternal and perinatal death surveillance and response report. first report*. Nairobi, Kenya: Kenya National MPDSR Secretariat, Division of Reproductive and Maternal Health, Department of Family Health, Ministry of Health Afya House, 2020.
6 Kenya MOH. Saving Mothers' Lives 2017. First Confidential Report into Maternal Deaths in Kenya, 2017. Available: https://familyhealth.go.ke/wp-content/uploads/2018/02/CEMD-Main-Report-Sept-3-FINAL-Full-Report.pdf [Accessed 10 July 2022].
7 Althabe F, Therrien MNS, Pingray V, *et al*. Postpartum hemorrhage care bundles to improve adherence to guidelines: a who technical consultation. *Int J Gynaecol Obstet* 2020;148:290–9.
8 Widmer M, Piaggio G, Hofmeyr GJ, *et al*. Maternal characteristics and causes associated with refractory postpartum haemorrhage after vaginal birth: a secondary analysis of the who champion trial data. *BJOG* 2020;127:628–34.
9 Pingray V, Widmer M, Ciapponi A, *et al*. Effectiveness of uterine tamponade devices for refractory postpartum haemorrhage after vaginal birth: a systematic review. *BJOG* 2021;128:1732–43.
10 Doumouchtsis SK, Papageorghiou AT, Arulkumaran S. Systematic review of conservative management of postpartum hemorrhage: what to do when medical treatment fails. *Obstet Gynecol Surv* 2007;62:540–7.
11 Liljestrand. Save Mothers, Stop PPH [blog post], 2020. Available: https://www.figo.org/news/save-mothers-stop-pph [Accessed 22 June 2022].
12 Katesmark M, Brown R, Raju KS. Successful use of a Sengstaken-Blakemore tube to control massive postpartum haemorrhage. *Br J Obstet Gynaecol* 1994;101:259–60.
13 Doumouchtsis SK, Papageorghiou AT, Vernier C, *et al*. Management of postpartum hemorrhage by uterine balloon tamponade: prospective evaluation of effectiveness. *Acta Obstet Gynecol Scand* 2008;87:849–55.
14 Bakri YN, Amri A, Abdul Jabbar F. Tamponade-balloon for obstetrical bleeding. *Int J Gynaecol Obstet* 2001;74:139–42.
15 Keriakos R, Mukhopadhyay A. The use of the Rusch balloon for management of severe postpartum haemorrhage. *J Obstet Gynaecol* 2006;26:335–8.
16 Uygur D, Altun Ensari T, Ozgu-Erdinc AS, *et al*. Successful use of BT-Cath(®) balloon tamponade in the management of postpartum haemorrhage due to placenta previa. *Eur J Obstet Gynecol Reprod Biol* 2014;181:223–8.
17 Theron GB, Mpumlwana V. A case series of post-partum haemorrhage managed using Ellavi uterine balloon tamponade in a rural regional hospital. *South African Family Practice* 2021;63:a5266.
18 Burke TF, Shivkumar PV, Priyadarshani P, *et al*. Impact of the introduction of a low-cost uterine balloon tamponade (ESM-UBT) device for managing severe postpartum hemorrhage in India: a comparative before-and-after study. *Int J Gynaecol Obstet* 2022;159:466–73.
19 Tindell K, Garfinkel R, Abu-Haydar E, *et al*. Uterine balloon tamponade for the treatment of postpartum haemorrhage in resource-poor settings: a systematic review. *BJOG* 2013;120:5–14.
20 Suarez S, Conde-Agudelo A, Borovac-Pinheiro A, *et al*. Uterine balloon tamponade for the treatment of postpartum hemorrhage: a systematic review and meta-analysis. *Am J Obstet Gynecol* 2020;222:293.e1–293.e52.
21 Burke TF, Ahn R, Nelson BD, *et al*. A postpartum haemorrhage package with condom uterine balloon tamponade: a prospective multi-centre case series in Kenya, Sierra Leone, Senegal, and Nepal. *BJOG* 2016;123:1532–40.
22 Nelson BD, Stoklosa H, Ahn R, *et al*. Use of uterine balloon tamponade for control of postpartum hemorrhage by community-based health providers in South Sudan. *Int J Gynaecol Obstet* 2013;122:27–32.
23 Burke TF, Danso-Bamfo S, Guha M, *et al*. Shock progression and survival after use of a condom uterine balloon tamponade package in women with uncontrolled postpartum hemorrhage. *Int J Gynaecol Obstet* 2017;139:34–8.

24 Laas E, Bui C, Popowski T, *et al*. Trends in the rate of invasive procedures after the addition of the intrauterine tamponade test to a protocol for management of severe postpartum hemorrhage. *Am J Obstet Gynecol* 2012;207:281.e1–281.e7.
25 Revert M, Rozenberg P, Cottenet J, *et al*. Intrauterine balloon tamponade for severe postpartum hemorrhage. *Obstet Gynecol* 2018;131:143–9.
26 Gauchotte E, De La Torre M, Perdriolle-Galet E, *et al*. Impact of uterine balloon tamponade on the use of invasive procedures in severe postpartum hemorrhage. *Acta Obstet Gynecol Scand* 2017;96:877–82.
27 Dumont A, Bodin C, Hounkpatin B, *et al*. Uterine balloon tamponade as an adjunct to misoprostol for the treatment of uncontrolled postpartum haemorrhage: a randomised controlled trial in Benin and Mali. *BMJ Open* 2017;7:e016590.
28 Anger HA, Dabash R, Durocher J, *et al*. The effectiveness and safety of introducing condom-catheter uterine balloon tamponade for postpartum haemorrhage at secondary level hospitals in Uganda, Egypt and Senegal: a stepped wedge, cluster-randomised trial. *BJOG* 2019;126:1612–21.
29 Hofmeyr GJ. Time to test tamponade. *BJOG* 2018;125:538–9.
30 WHO. Who recommendation on uterine balloon tamponade for the treatment of postpartum haemorrhage. Geneva: who, 2021. Available: https://apps.who.int/iris/handle/10665/340796 [Accessed 24 June 2022].
31 Weeks AD, Akinola OI, Amorim M, *et al*. World Health organization recommendation for using uterine balloon tamponade to treat postpartum hemorrhage. *Obstet Gynecol* 2022;139:458–62.
32 Liu C, Gao J, Liu J, *et al*. Predictors of failed intrauterine balloon tamponade in the management of severe postpartum hemorrhage. *Front Med* 2021;8:656422.
33 Proctor E, Silmere H, Raghavan R, *et al*. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health* 2011;38:65–76.
34 Parker ME, Qureshi Z, Deganus S. Introduction of the Ellavi uterine balloon tamponade into the Kenyan and Ghanaian maternal health care package for improved postpartum hemorrhage management: an implementation research study. Figshare, 2022. Available: https://figshare.com/articles/dataset/Introduction_of_the_Ellavi_Uterine_Balloon_Tamponade_into_the_Kenyan_and_Ghanaian_maternal_health_care_package_for_improved_postpartum_hemorrhage_management_an_implementation_research_study/21507843 [Accessed 6 Nov].
35 Powell BJ, Waltz TJ, Chinman MJ, *et al*. A refined compilation of implementation strategies: results from the expert recommendations for implementing change (ERIC) project. *Implement Sci* 2015;10:21.
36 Adegoke O, Danso-Bamfo S, Sheehy M, *et al*. A condom uterine balloon device among referral facilities in Dar ES Salaam: an assessment of perceptions, barriers and facilitators one year after implementation. *BMC Pregnancy Childbirth* 2020;20:34.
37 Posever N, Sipahi S, Shivkumar PV, *et al*. Every Second Matters - uterine balloon tamponade implementation across ten medical colleges in Maharashtra and Madhya Pradesh in India: A qualitative study. *Int J Gynaecol Obstet* 2022;159:817–24.
38 Nelissen E, Ersdal H, Mduma E, *et al*. Clinical performance and patient outcome after simulation-based training in prevention and management of postpartum haemorrhage: an educational intervention study in a low-resource setting. *BMC Pregnancy Childbirth* 2017;17:301.
39 Egenberg S, Masenga G, Bru LE, *et al*. Impact of multi-professional, scenario-based training on postpartum hemorrhage in Tanzania: a quasi-experimental, pre- vs. post-intervention study. *BMC Pregnancy Childbirth* 2017;17:287.
40 Maxwell EPB. A comparative analysis of user experience with uterine balloon devices during standardized postpartum hemorrhage simulations. doctoral dissertation, Harvard medical school, 2020. Available: https://nrs.harvard.edu/URN-3:HUL.INSTREPOS:37364975 [Accessed 27 June 2022].