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# The Usability, Acceptability, and Performance of the Maternal PPH Wrap Device in Controlling Postpartum Hemorrhage: A Pilot Study at Kawempe National Referral Hospital, Uganda

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This work involved human subjects or animals in its research. Approval of all ethical and experimental procedures and protocols was granted by the School of Medicine Research and Ethics Committee (SOMREC), Makerere University, under Application No. REC REF 2019-129, and also by the Kawempe National Referral Hospital and the Uganda National Council of Science and Technology (UNCST).

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**ABSTRACT** Timely intervention for atonic postpartum hemorrhage (PPH) significantly reduces the incidence of death from PPH. However, technological solutions geared towards this have not received substantial adoption by the health community in sub-Saharan Africa due to limiting factors such as; cumbersome application, being costly, requiring skilled personnel, needing cold chain storage, and the associated side effects. This pilot study aimed to assess the usability, acceptability, and performance of the Maternal PPH Wrap, a first-aid device designed to control atonic PPH after childbirth. Forty subjects were recruited for the study. Twenty of these were women who sought maternity care at Kawempe National Referral Hospital (KNRH). The women wore the device for 120 minutes while their vitals were recorded every 20 minutes. The device's acceptability and performance were evaluated on the women. The remaining twenty were licensed midwives working at KNRH. The device's usability was assessed on all the midwives recruited for the pilot study using a usability questionnaire. There was a non-significant reduction in blood loss associated with the use of the Maternal PPH Wrap alongside the standard of care as opposed to the standard of care alone. This reduction in blood loss was detected between the 80<sup>th</sup> and 120<sup>th</sup> minute of the device application onto the mothers. The acceptability and usability scores from the study participants also scored favorably. The Maternal PPH Wrap demonstrated potential to control PPH and product satisfaction, and these results will support the device's redesign leading into a phase I clinical trial.

**INDEX TERMS** Medical device, obstetric first-aid, pilot study, postpartum hemorrhage, uterine atony.

## Clinical and translational impact statement

The clinical evaluation results show that the Maternal PPH Wrap can control PPH in mothers after birth at health centers, during transportation, and delays in receiving treatment at referral hospitals.

## I. INTRODUCTION

The Department of Economic and Social Affairs of the United Nations Secretariat estimates that 800 women die every day

from childbirth-related complications worldwide, a 38 % reduction in maternal deaths from the levels of 2000 [1], [2]. This significant reduction in maternal deaths has been mostly

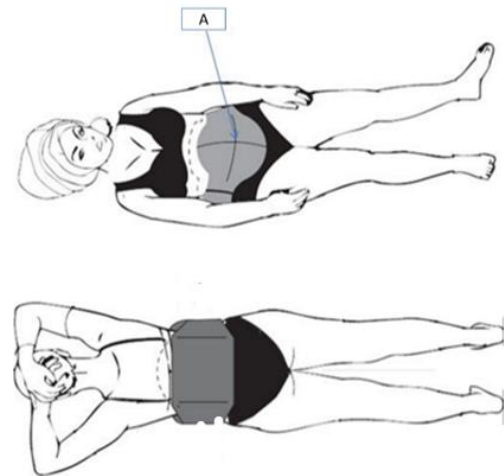
attributed to the global adoption of the Millennium Development Goals 2015. Despite this reduction, maternal mortality remains higher in low-and middle-income countries (LMICs) than the high-income countries, with sub-Saharan Africa and South Asia alone accounting for 86% of the global burden of maternal mortality [1].

Postpartum hemorrhage (PPH), defined as blood loss of  $\geq 500$  ml after vaginal delivery or  $\geq 1000$  ml after a cesarean section within 24 hours after birth [3], is one of the leading causes of maternal deaths globally, accounting for 25% of all maternal deaths [4], [5]. The high incidences of maternal mortality due to PPH in LMICs are attributed to; limited access to infrastructure, limited availability of trained delivery attendants, and low quality of uterotonic agents for the management of the third stage of labor or untimely intervention in case obstetric emergencies arise.

Active management of the third stage of labor (AMTSL) recommended by the World Health Organization (WHO) is the most effective strategy in the prevention of PPH as it reduces it by 60% [8], [9]. It is composed of administration of uterotonic drugs (such as oxytocin, ergometrine, and misoprostol), controlled cord traction, and uterine massage after placental delivery. Despite the implementation of AMTSL, uterine atony, remains the most common cause of PPH, contributing to over 75% of all PPH-related cases [4], [6], [7]. Treatment of PPH due to uterine atony entails additional administration of uterotonics and other maneuvers like bimanual compression of the uterus, uterine balloon tamponade, and application of Non-Pneumatic Anti-Shock Garment (NASG) [9], [12]. However, the application of NASG is a bulky device to use because it has nine segments, of which each has a particular part of the lower body it must fit and thus requires skilled personnel to apply it on the patients [13], [14].

To search for more ways to treat PPH due to uterine atony, we designed a Maternal PPH Wrap. The Maternal PPH Wrap is a low-technology, re-usable, non-invasive pneumatic first-aid device that exerts pressure on the uterus, similar to bimanual compression of the uterus. It is projected to cost only US \$20. The device comprises polyurethane-coated nylon fabrics with an inflatable air bladder, squeeze bulb, and an anaerobe gauge. It is strapped around the bleeding mother's lower abdomen by the birth attendant, skilled or not (eliminates the necessity of a skilled person to give first aid) and inflated using a squeeze bulb to the order of 120mmHg that is maintained within the bladder as monitored using a pressure gauge attached. The bladder exerts radial pressure transmitted through the abdominal muscles to the atonic uterine wall muscles stimulating their contraction, thus reducing blood flow from the open vessels at the placental site and the bleeding from the mother's uterus.

To assess the usability, acceptability, performance, and safety of the Maternal PPH Wrap, we conducted a pilot study among the hospital population in a national referral hospital in Uganda.



**FIGURE 1.** Shows the Maternal PPH Wrap placed around the mother's abdomen. The figure on top is a front view showing the positioning of the belt, with the center of the concave disc at point A. The figure at the bottom shows the hind view of mother wearing the Maternal PPH Wrap.

## II. METHODS AND PROCEDURES

### A. ETHICAL CONSIDERATION

This study was approved by the Makerere University School of Medicine Research and Ethics Committee (SOMREC) under protocol number **REC REF 2019-129** and was cleared by the Uganda National Council of Science and Technology (UNCST). All eligible study subjects received all the information about the study and provided written informed consent to participate in the study and to have a picture consent allowing for their pictures to be taken when the Wrap was applied. Consent was done in the language best understood by the prospective study participant. Careful consideration was taken to ensure that the photos did not disclose the participant's identity. In addition, to ensure anonymity, all the study participants' personal information, such as names, were translated into codes for analysis and publications.

### B. THE STUDY SITE, NUMBER OF PARTICIPANTS, AND RECRUITMENT

The pilot study was undertaken at Kawempe National Referral Hospital (KNRH), a teaching and government hospital in Kampala, Uganda [18]. The hospital delivers approximately 21,000 pregnant women per year, and 25% are by caesarean section. The hospital follows WHO recommended AMTSL protocol for the prevention of PPH as a standard of care. Additionally, the hospital was equipped with blood transfusion services and surgical facilities for cases that require surgery of severe PPH.

Forty participants (women and health providers) were recruited in the pilot study. Twenty women had vaginal birth at KNRH, and these were subdivided into two groups. The first ten women were those with normal bleeding after delivery, while the remaining ten women had mild PPH after vaginal birth. The mild PPH group was further

equally subdivided into two smaller groups. The active group received the Maternal PPH Wrap as the intervention for mild PPH after delivery of the placenta, whereas the control group received the standard of care only.

We also recruited health providers who were midwives working at KNRH. These were in two groups. The first five midwives applied the Maternal PPH Wrap onto mothers after birth, the other fifteen midwives observed its application to the mothers and practiced the use of the device on the mannequin.

### C. INCLUSION AND EXCLUSION CRITERIA

The pilot study included participants being 18 years and above, in labor (4-6 cm cervical dilatation) expecting vaginal birth. In addition, vital signs were stable (systolic blood pressure greater than 90mmHg and heart rate less than 110 beats per minute). For Group 1, we included women with normal bleeding after delivering the placenta. In this group, a woman was excluded if she experienced PPH after birth. For Group 2, we included women who had mild PPH (500-1000 ml blood loss) caused by uterine atony as diagnosed by the attending provider. A woman was excluded from group 2 if blood loss exceeded 1000 ml or the cause of PPH is not uterine atony.

The inclusion criteria for health provider was practicing midwife at the Kawempe national referral hospital and consented to participate in the study.

### D. PROCEDURE

After the attending clinician had admitted the expectant woman in labor, the study team reviewed the clinical charts to determine if they are eligible to participate in the study. Those that met the eligibility criteria were approached and given information about the study, requested to participate in the study. Women who agreed were taken through the consenting process and they provided written informed consent. The labor was monitored using a partograph until delivery of the baby and placenta. The Maternal PPH Wrap device was applied onto the women's lower abdomen after delivering the placenta, and calibrated under-buttock drapes were used to collect blood loss per vagina. The device's usability was evaluated on all the midwives that participated in the pilot study using the usability questionnaire (*see supplementary information D*). The acceptability of the device was evaluated on all the women that participated in the study using the acceptability questionnaire (*see supplementary information C*), while the preliminary performance of the Maternal PPH Wrap was assessed on the women who had mild PPH. Randomization was done using identical opaque envelopes containing group allocations of active and control groups. If a mother picked an envelope containing the letter A, they were assigned to the active group and if they picked an envelope containing the letter C, they were assigned to the control group. Mothers in the active group had the Maternal PPH Wrap applied on them together with standard AMTSL and the mothers in the control group had only standard AMTSL as the intervention.

### E. DATA COLLECTION

The data collected from the women in groups 1 and 2 of the study included age, gravidity, gestation age of the pregnancy, blood glucose levels, and baby status at birth. Others were systolic and diastolic blood pressures, the volume of blood collected in calibrated under-buttock drapes indicating blood loss, pulse, temperature, oxygen saturation (SpO<sub>2</sub>), pain (scale of 1-10), and respiratory rate monitored for 120 minutes after delivery of baby. The presence of discomfort, itching, and heat build-up because of wrapping the device was also collected.

### F. DATA ANALYSIS

Data on acceptability and usability of the Maternal PPH Wrap was analyzed quantitatively based on replies on a Likert scale from strongly agree to strongly disagree on several variables as reported by women and health providers. The preliminary performance of the device was evaluated by comparing the average amounts of blood loss in women (as collected in the under-buttock drapes) in the intervention arm and control. All the data collected from the study was entered, queried, cleaned, and analyzed using the STATA v.14 statistical packages. Mann Whitney test was used to compare groups to determine usability and acceptability. A t-test was used to compare the outcome between the two groups at a single time point. Thereafter a mixed effects linear regression model was adopted to compare the two groups. Data are reported as mean  $\pm$  standard deviation unless otherwise stated.

## III. RESULTS AND CLINICAL OUTCOME ANALYSIS

### A. CHARACTERISTICS OF THE PARTICIPANTS

The mothers' social, demographic, and clinical characteristics (Table 1) were comparable between the active and control groups. That is, no significant differences were observed between the two groups,  $p > 0.05$ . The average volume of blood loss (volume of blood collected in the under-buttock drapes), mother's age, gravidity, and gestation pregnancy age was lower among mothers in the active group than those in the control group.

Additionally, the mean systolic blood pressure at both baseline and follow-up among women in the active group was higher than that of mothers in the control group. The mean diastolic blood pressure at baseline among women in the active group was lower than that of the mothers in the control group, whereas the mean diastolic blood pressure at follow-up among mothers in the active group was higher than that of mothers in the control group. The weight of babies given birth to by the mothers was higher in the active group than in the control group.

The mean blood glucose levels and amount of oxytocin (Table 2) used to treat PPH were similar among women in the active and control groups. The mother's average pulse rate and amount of misoprostol (Table 2) used to treat PPH were lower in the active group than in the control group. In contrast, the mean temperature, oxygen saturation, respiratory rate,

**TABLE 1.** Summary statistics of mothers' social, demographic, and clinical characteristics. CI stands for Confidence Intervals and SD for standard deviation (n = 10, with five mothers in active and control group). \*\* P < 0.25, \* P < 0.05.

Characteristic	Active Group (N=5)		Control Group (N=5)	
	Mean (SD)	95% CI	Mean (SD)	95% CI
Blood volume collected in drape (ml)	737.0 (129.2)	(606.3, 867.7)	778.0 (164.1)	(612.0, 944.0)
Age (years)	26.4 (7.7)	(24.0, 28.8)	31.0 (6.7)	(28.9, 33.0)
Mean gravidity	2.6 (1.9)	(2.0, 3.2)	3.2 (1.6)	(2.7, 3.8)
Gestation age of pregnancy (weeks)	36.0 (3.0)	(35.0, 37.0)	36.8 (2.7)	(35.9, 37.7)
Systolic blood pressure (mmHg) at baseline	133.2 (17.2)	(127.4, 139.0)	121.6 (19.1)	(115.2, 128.0)
Systolic Blood pressure (mmHg) at follow up	116.5 (13.9)	(111.7, 121.3)	108.3 (17.5)	(102.4, 114.2)
Diastolic blood pressure (mmHg) at baseline	79.8 (9.3)	(76.7, 83.0)	88.2 (13.6)	(83.6, 92.8)
Diastolic Blood Pressure (mmHg) at follow up	76.0 (9.6)	(72.7, 79.2)	72.2 (14.7)	(67.2, 77.1)
Weight of the baby (grams)	3150.0 (816.7)	(2879.6, 3425.4)	2968.0 (736.2)	(2719.8, 3216.3)
Mother's Blood Glucose (mmol/L)	5.8 (1.6)	(5.3, 6.4)	5.8 (0.3)	(5.6, 5.9)
Mother's Pulse rate (beats per minute, bpm)	100.9 (18.4)	(94.8, 107.1)	106.2 (15.3)	(101.1, 111.4)
Mother's Temperature (°C)	37.3 (0.9)	(37.0, 37.6)	36.5 (0.5)	(36.3, 36.8)
Mother's SpO <sub>2</sub> (%)	97.2 (1.8)	(96.8, 97.6)	95.3 (5.4)	(93.5, 97.1)
Mother's Respiratory rate (breaths per minute, BPM)	23.63 (4.20)	(22.2, 25.0)	21.6 (2.1)	(21.1, 22.5)

and the mean amount of normal saline (Table 2) used to treat patients were higher among women in the active group than in the control group.

### B. ASSESSMENT OF THE USABILITY OF THE MATERNAL PPH WRAP DEVICE FOR CONTROLLING POSTPARTUM HEMORRHAGE

All the twenty midwives responded to questions on the usability of the Maternal PPH Wrap and their attitudes and concerns towards the device are recorded in Table S- I (*see supplementary material*). Most of the midwives, 16 (80%), either agreed or strongly agreed that the device would be easy to

**TABLE 2.** Summary of the amount of oxytocin, misoprostol, and normal saline administered to the participants.

Drugs	Active group (N=5)		Control group (N=5)	
	Mean (SD)	95% CI	Mean (SD)	95% CI
Drug 1 (Oxytocin)	22.00 (9.94)	(18.7, 25.4)	22.0 (7.6)	(19.4, 24.6)
Drug 2 (misoprostol)	640.00 (349.12)	(522.3, 757.3)	800.0 (128.3)	(756.7, 843.3)
Drug 3 liters (Normal saline)	1.67 (0.48)	(1.5, 1.9)	1.6 (0.8)	(1.3, 1.9)

wrap around patients, 14 (70%) either strongly disagreed or disagreed that the device would come off the patients during inflation, 11 (55%), either strongly disagreed or disagreed that it would take a long time to wrap the device on the mothers.

Additionally, most midwives, 13 (65%), either strongly disagreed or disagreed that bleeding would increase upon the device's application on the mothers, 15 (75%) strongly disagreed or disagreed that the device would hurt the mother. Nearly half (55%) of midwives either strongly disagreed or disagreed that the device would not be as tight as expected when applied to the mothers, 12 (60%) strongly disagreed or disagreed that more complications would develop on the mother when using the device. However, 8 (40%) midwives strongly agreed or agreed that blood would stain on the device and would be challenging to clean off, and 16 (80%) expressed concerns that the device would be difficult to disinfect.

The midwives also evaluated the usability of the Maternal PPH Wrap device after using it on either a mother after birth (study-midwives) or study mannequins (non-study-midwives) and their attitudes and concerns recorded in Table S- II (*see supplementary material*). All the study midwives, 5 (100%) and the majority of the non-study midwives, 10 (67%), either strongly disagreed or disagreed that they had problems wrapping the device onto the study subjects. All study-midwives, 5 (100%), and most non-study-midwives, 12 (80%), either strongly disagreed or disagreed that they had issues with straps coming off the study subjects during device inflation.

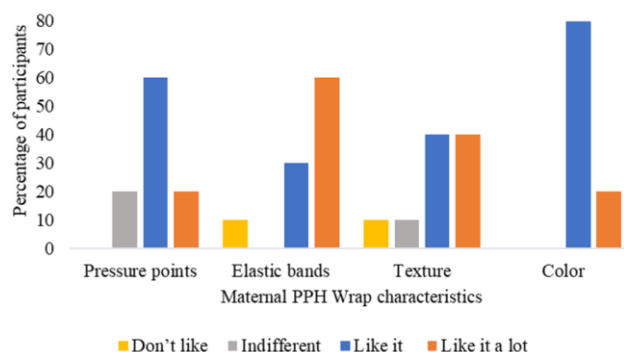
Additionally, all study-midwives, 5 (100%) and non-study-midwives, 10 (67%), either strongly disagreed or disagreed that it took a long time to wrap the device onto the study subjects. All the study midwives, 5 (100%) and most non-study-midwives, 11 (73%), either strongly disagreed or disagreed that the bleeding increased when the device was applied to the study participants. All the study-midwives 5 (100%) and most of the non-study-midwives, 11 (74%), either strongly disagreed or disagreed that the device hurt the study participants when applied to them.

Most of all the health providers 18 (90%) disagreed that the Maternal PPH Wrap was loose when applied to the

participants and mannequins as well as caused more complications when applied to participants.

**C. ASSESSMENT OF THE ACCEPTABILITY OF MATERNAL PPH WRAP FOR CONTROLLING POSTPARTUM HEMORRHAGE**

All the mothers that participated in the pilot study (100%) liked the device’s color; 80% were impressed with its texture, 90% and 80% were fascinated with the device’s elastic bands and pressure points, respectively, as shown in Figure 2 below



**FIGURE 2.** Shows how much the participants liked the Maternal PPH Wrap device (n = 20).

Among the women who had normal bleeding, most of them 7 (70%) disagreed that the Maternal PPH Wrap came off during inflation, 8 (80%) disagreed that it took long to wrap the device around their bodies, and 6 (60%) disagreed that the bleeding reduced when the device was used on them. Additionally, 9 (90%) strongly disagreed or disagreed that there was increased discomfort inside and around their bodies, and 10 (100%) strongly disagreed or disagreed that the device increased pain inside and around their bodies.

Furthermore, 8 (80%) of the mothers reported no skin reaction to the material of the wrap by itching or swelling, 8 (80%) were comfortable with the device around them, 9 (90%) reported no heat around their belly where the wrap was, and 7 (70%) acknowledge that the device never hindered mother’s movement when in place. The majority, 7 (70%) reported normal breathing with the device wrapped around them (Table S- III in the supplementary material).

**D. EVALUATING THE PRELIMINARY PERFORMANCE OF THE MATERNAL PPH WRAP ON WOMEN WITH MILD PPH**

Assessment of the group means and differences of the average blood collected from mothers in both the active and control groups was done and compared using a t-test as seen in Table 3. The average blood volume collected in the active group (mild PPH) increased over time from 552±50.5 ml at enrolment to 737±57.8 ml at 120 minutes, whereas that collected in the control group increased from 510±36.6 ml to 768±64 ml. The average amount of blood collected in the active group was slightly higher than in the control group between enrolment and 60 minutes. However, between 80 and

120 minutes, the average amount of blood collected in the control group increased beyond that collected in the active group indicating an increase in blood loss among mothers in the control group compared to those in the active group. The mean differences in the amount of blood collected between both groups at any time point were not statistically significant ( $p > 0.05$ ).

**TABLE 3.** Group means and standard errors (SE) for blood volume collected from postpartum mothers (ml) over time.

Time (minutes)	Blood volume changes over time (Mean (SE))				
	Active group (N=5)	Control group (N=5)	Differences	t	P-values
0 (enrolment)	552 (50.5)	510 (36.6)	42 (62.4)	0.68	0.740
20	622 (48.5)	602 (30.2)	20 (57.2)	0.35	0.632
40	658 (52.7)	643 (29.7)	15 (60.5)	0.25	0.595
60	686 (57.3)	684 (34.4)	2 (66.9)	0.03	0.512
80	708 (60.8)	725 (49.6)	-17 (78.5)	-0.22	0.417
100	728 (56.5)	760 (65.9)	-32 (86.9)	-0.37	0.361
120	737 (57.8)	768 (64.0)	-41 (93.4)	-0.44	0.336

The change in the average volume of postpartum blood collected from mothers overtime was also assessed using mixed-effects models in STATA. The results are shown in Table S-IV (please see supplementary material). At unadjusted rates, a unit increase in mother’s age, gestational age of the pregnancy, baseline systolic and diastolic blood pressure were associated with a non-significant reduction in the average amount of blood loss by 2.19 (−9.80 5.41), 13.60 (−23.45 −3.74), 2.57 (−4.83 −0.31), and 4.28 (−6.76 −1.79) ml, respectively ( $p > 0.05$ ).

Additionally, a unit increase in mother’s pulse, average systolic blood pressure at follow up, respiratory rate, and amount of oxytocin and misoprostol used to treat PPH were associated with a non-significant reduction in the average volume of blood loss by 0.97 (−4.15 2.21), 1.12 (−2.12 −0.41), 2.82 (−6.67 1.03), 4.54 (−11.13 2.05), 0.03 (−0.22 0.16) ml, respectively ( $p > 0.05$ ). In contrast, a unit increase in number or prior pregnancies, the weight of the baby, and mother’s temperature were associated with a non-significant increase in the average volume of blood loss by 13.89 (−6.92 34.70), 0.01 (−0.02 0.04), and 35.53 (6.33 64.72) ml, respectively ( $p > 0.05$ ).

At adjusted rates, a unit increase in the number of mothers in the control group, amount of time, average blood glucose, and amount of normal saline used to treat PPH was associated with a significant increase in the average amount of blood loss

by 43.86 (37.49 50.22), 2.02 (1.36 2.67), 59.81 (52.83 56.79), and 59.20 (54.08 64.32) ml, respectively ( $p < 0.001$ ). In contrast, a unit increase in the average diastolic blood pressure at follow up and the saturation of oxygen was associated with a significant reduction in the average volume of blood loss by 4.16 (−4.37 −3.95) and 1.32 (−1.60 −1.04) ml, respectively ( $p < 0.001$ ).

#### IV. DISCUSSION

Our results acknowledge that the Maternal PPH Wrap is easy-to-use, it did not loosen after application, straps did not come off during inflation of the device's bladder, it took a short time to wrap the device around the patients and it slightly reduced blood loss from mothers when applied to them and it was safe.

Furthermore, the most significant proportion of midwives noted that the device did not cause any harm to the patients and that no complications arose in patients due to the use of the device. However, there were concerns about the difficulty of cleaning off blood stains and disinfecting the device before and after service on the patients. These concerns need to be addressed such that Maternal PPH Wrap is fit to be used in a clinical setting.

The Maternal PPH Wrap was acceptable to most mothers and the following factors were favorable: the device's color, texture, pressure points, and elastic bands. This demonstrated the device's potential to achieve product satisfaction. In addition, most mothers acknowledged that the device did not come off the waist during inflation; it took a short time to wrap it around their waist; the bleeding did not increase when the device was used on them, and they felt comfortable with the device around their bodies.

Furthermore, a significant portion of mothers noted that the device did not cause any pain inside or around their bodies, the device did not cause any skin burns due to increased temperatures around the wrapped body area, and they could easily move around with the device wrapped onto them. This feedback is vital given the intimate nature of the device's application on the female human body. However, there is a need to note the small proportions of mothers who agreed that their skin reacted to the device by itching or swelling and difficulty breathing with the device wrapped around them. This could have been due to the device being too tight on the mother.

Our results also show that the use of the Maternal PPH Wrap in the treatment of PPH was associated with a non-significant decrease in the average volume of blood loss over time that is, from the onset of PPH at enrolment to 120 minutes compared to the control group, which was subjected to only the standard care of PPH management. Between enrolment and 60 minutes, the average volume of blood loss was higher in the group with Maternal PPH Wrap than the control group. However, it reduced to amounts below that of the control group between  $t = 80$  and 120 minutes, indicating that the Maternal PPH Wrap has the potential to control PPH and to reduce the amount of blood loss from mothers over time as they are being transported to referral

health facilities or while awaiting further treatment interventions at the health facilities.

The study results further show no significant relationship between the mother's social, demographic, and clinical characteristics at unadjusted rates and the average amount of blood loss among mothers after delivery. However, after adjusted analysis, the relationship became significant with a unit increase in the average amount of time, blood glucose, and normal saline used to treat PPH associated with a considerable increase in the average amount of blood loss. At the same time, a unit increase in average diastolic blood pressure at follow-up and oxygen saturation is associated with a significant reduction in the average volume of blood loss. When the relationship becomes significant, as shown after adjusted analysis, it indicates variation between the groups at baseline on those variables. Therefore, randomization could help reduce these variations. It is also important to note that the small sample sizes used in this pilot study make it harder to find statistical significance. However, finding statistical significance indicates that the difference between the groups may be significant and more likely to drive action.

#### V. CONCLUSION AND FUTURE WORK

In conclusion, the Maternal PPH Wrap demonstrated potential for product satisfaction from end-users, as shown by the usability and acceptability study results. The key attributes of the Maternal PPH Wrap were that it was easy and quick to apply to the patients. Additionally, the device was safe as it did not cause any harm or additional complications to the mothers, and minimum training was required to learn how to apply and remove the device from the patients.

The Maternal PPH Wrap was also associated with a decrease in the average volume of blood loss over time when used to manage PPH in combination with the standard management of PPH compared to only using the standard care. Despite the lack of statistical significance, these findings show that the Maternal PPH Wrap has the potential to control PPH as a first-aid device during delays in attaining proper medical care. Another study with a large sample size needs to be done to ascertain the results obtained in this pilot study.

A small sample size mainly limited the pilot study due to restrictions on the number of study participants acceptable by SOMREC and UNCST as the device was to be tested for the first time on mothers at risk of death. Besides, midwives and mothers raised concerns such as difficulty in cleaning and disinfecting the Maternal PPH Wrap, mother's skin reaction to the device by itching or swelling, and difficulty breathing with the device on. These will be addressed in the next phase of clinical evaluation (Phase I of the clinical trial) of the device. In this phase, we will redesign the Maternal PPH Wrap putting into consideration the feedback from the pilot study and then clinically evaluating it on over two hundred mothers experiencing postpartum hemorrhage after birth at

one National Referral Hospital and four Regional Referral Hospitals (north, east, west, and central) in Uganda.

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## REFERENCES

- [1] *Trends in Maternal Mortality 2000 to 2017: Estimates by WHO, UNICEF, UNFPA, World Bank Group, and the United Nations Population Division*. World Health Organization, Geneva, Switzerland, 2019.
- [2] WHO, UNICEF, UNFPA, WBG, & UN. *Trends in Maternal Mortality 2000 to 2017: Estimates by WHO, UNICEF, UNFPA, World Bank Group, and the United Nations Population Division*. World Health Organization, Geneva, Switzerland, 2017. [Online]. Available: <https://apps.who.int/iris/handle/10665>
- [3] Y. Oyelese and C. V. Ananth, "Postpartum hemorrhage: Epidemiology, risk factors, and causes," *Clin. Obstetrics Gynecol.*, vol. 53, no. 1, pp. 147–156, Mar. 2010.
- [4] S. Ononge, F. Mirembe, J. Wandabwa, and O. M. R. Campbell, "Incidence and risk factors for postpartum hemorrhage in Uganda," *Reproductive Health*, vol. 13, no. 1, pp. 1–7, Dec. 2016, doi: [10.1186/s12978-016-0154-8](https://doi.org/10.1186/s12978-016-0154-8).
- [5] L. Say, D. Chou, A. Gemmill, Ö. Tunçalp, and A. B. Moller, "Global causes of maternal death: A WHO systematic analysis," *Lancet Global Health*, vol. 2, no. 6, pp. 323–333, 2014.
- [6] A. Sadaf, Z. P. Brohi, and U. Parveen, "Primary postpartum hemorrhage and maternal health-effects and outcome," *Ann. Punjab Med. College*, vol. 14, no. 4, pp. 345–348, 2020, doi: [10.29054/apmc/2020.989](https://doi.org/10.29054/apmc/2020.989).
- [7] J. P. Vogel, M. Williams, I. Gallos, F. Althabe, and O. T. Oladapo, "WHO recommendations on uterotonics for postpartum haemorrhage prevention: What works, and which one?" *BMJ Global Health*, vol. 4, no. 2, Apr. 2019, Art. no. e001466, doi: [10.1136/bmjgh-2019-001466](https://doi.org/10.1136/bmjgh-2019-001466).
- [8] N. Prata, S. Bell, and K. Weidert, "Prevention of postpartum hemorrhage in low-resource settings: Current perspectives," *Int. J. Women's Health*, vol. 5, pp. 737–752, Nov. 2013, doi: [10.2147/IJWH.S51661](https://doi.org/10.2147/IJWH.S51661).
- [9] Ö. Tunçalp, J. P. Souza, and M. Gülmezoglu, "New WHO recommendations on prevention and treatment of postpartum hemorrhage," *Int. J. Gynecol. Obstetrics*, vol. 123, no. 3, pp. 254–256, Dec. 2013, doi: [10.1016/j.ijgo.2013.06.024](https://doi.org/10.1016/j.ijgo.2013.06.024).
- [10] K. Güngördük, Y. Olgaç, V. Gülseren, and M. Kocaer, "Active management of the third stage of labor: A brief overview of key issues," *J. Turkish Soc. Obstetric Gynecol.*, vol. 15, no. 3, pp. 188–192, Sep. 2018, doi: [10.4274/tjod.39049](https://doi.org/10.4274/tjod.39049).
- [11] N. Mobeen, J. Durocher, N. F. Zuberi, N. Jahan, J. Blum, S. Wasim, G. Walraven, and J. Hatcher, "Administration of misoprostol by trained traditional birth attendants to prevent postpartum haemorrhage in home-births in Pakistan: A randomised placebo-controlled trial," *BJOG, Int. J. Obstetrics Gynaecol.*, vol. 118, no. 3, pp. 353–361, Feb. 2011, doi: [10.1111/j.1471-0528.2010.02807.x](https://doi.org/10.1111/j.1471-0528.2010.02807.x).
- [12] M. Gülmezoglu, J. P. Souza, D. Chou, S. Hill, M. Mathai, and E. Abalos, *WHO Guidelines for the Management of Postpartum Hemorrhage and Retained Placenta*. Piscataway, NJ, USA: IEEE Press, 2009, pp. 1–62. [Online]. Available: [https://apps.who.int/iris/bitstream/handle/10665/44171/9789241598514\\_eng.pdf;jsessionid=35589E36A4C915F2AFF7840C35CA2E1E?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/44171/9789241598514_eng.pdf;jsessionid=35589E36A4C915F2AFF7840C35CA2E1E?sequence=1)
- [13] G. Bekele, G. Terefe, M. Sinaga, and S. Belina, "Utilization of non-pneumatic anti-shock garment and associated factors for postpartum hemorrhage management among health care professionals in public hospitals of Jimma zone, south-west Ethiopia, 2019," *Reproductive Health*, vol. 17, no. 1, pp. 1–10, Dec. 2020, doi: [10.1186/s12978-020-0891-6](https://doi.org/10.1186/s12978-020-0891-6).
- [14] T. Sutherland, J. Downing, S. Miller, D. M. Bishai, E. Butrick, M. M. Fathalla, M. Mourad-Youssif, O. Ojengbede, D. Nsima, and J. G. Kahn, "Use of the non-pneumatic anti-shock garment (NASG) for life-threatening obstetric hemorrhage: A cost-effectiveness analysis in Egypt and Nigeria," *PLoS ONE*, vol. 8, no. 4, Apr. 2013, Art. no. e62282, doi: [10.1371/journal.pone.0062282](https://doi.org/10.1371/journal.pone.0062282).
- [15] M. H. Soltan and R. R. Sadek, "Experience managing postpartum hemorrhage at minia university maternity hospital, Egypt: No mortality using external aortic compression," *J. Obstetrics Gynaecol. Res.*, vol. 37, no. 11, pp. 1557–1563, 2011, doi: [10.1109/JTEHM.2022.3197688](https://doi.org/10.1109/JTEHM.2022.3197688).
- [16] P. R. Koh, D. Di Filippo, A. Bisits, and A. W. Welsh, "Bimanual examination for clot evacuation: A retrospective cohort study of women with postpartum haemorrhage after vaginal delivery," *BMC Pregnancy Childbirth*, vol. 20, no. 1, pp. 1–7, Dec. 2020, doi: [10.1186/s12884-020-02916-w](https://doi.org/10.1186/s12884-020-02916-w).
- [17] USAID. (2011). *Prevention and Treatment of Postpartum Hemorrhage at the Community Level*. [https://www.mchip.net/sites/default/files/PPH Prevention and Treatment at the Community Level Second Edition 2011.pdf](https://www.mchip.net/sites/default/files/PPH%20Prevention%20and%20Treatment%20at%20the%20Community%20Level%20Second%20Edition%202011.pdf)
- [18] Ministry of Health. (2020). *Annual Health Sector Performance Report, Financial Year 2019/20*. Ministry of Health, Uganda. [Online]. Available: <http://library.health.go.ug/publications/performance-management/annual-health-sector-performance-report-financial-year-2019>

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