

## CLINICAL ARTICLE

## Obstetrics

# Every Second Matters - uterine balloon tamponade implementation across ten medical colleges in Maharashtra and Madhya Pradesh in India: A qualitative study

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## Abstract

**Objective:** To understand facilitators, barriers, and perceptions of the Every Second Matters uterine balloon tamponade (ESM-UBT) package implemented across 10 medical colleges in India, 3 years after the program was introduced.

**Methods:** Semi-structured interviews were conducted until thematic saturation in March 2020. Multiple provider cadres, including nurses, Obstetrics/Gynecology residents, professors, and program leads, were eligible. Interviews were transcribed and thematically coded using an inductive method.

**Results:** Sixty-two obstetric providers were interviewed. Facilitators of implementation included recurrent training, improved teamwork and communication, strong program leadership, and involvement of lower-level facilities. Barriers to implementation included administrative hurdles, high staff turnover, language barriers, and resources required to reach and train lower-level facilities. Overall, the majority of clinicians viewed the ESM-UBT package as a useful intervention in aiding efforts to reduce maternal deaths from postpartum hemorrhage.

**Conclusions:** Among 10 medical colleges in India the ESM-UBT package is seen as a beneficial intervention for managing refractory atonic postpartum hemorrhage, and for reducing maternal morbidity and mortality. Identified facilitators of and barriers to implementation of the ESM-UBT package in India should be used to guide future implementation efforts.

## KEYWORDS

India, maternal mortality, postpartum hemorrhage, uterine balloon tamponade

## 1 | INTRODUCTION

India has made tremendous progress in reducing maternal mortality, lowering the maternal mortality ratio by over 50% between 2004–2006 and 2016–2018.<sup>1,2</sup> Postpartum hemorrhage (PPH) is the leading cause of maternal death in India, accounting for between 19.9%

and 38% of maternal deaths annually.<sup>3,4</sup> Many cases of PPH can be effectively managed with low-cost solutions such as active management of the third stage of labor and uterotonic.<sup>5,6</sup> However, in refractory cases, high-resource surgical interventions such as uterine artery ligation, B-lynch sutures, or hysterectomy may be necessary.

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Uterine balloon tamponade (UBT) offers a non-surgical, highly effective option for managing refractory atonic PPH.<sup>7,8</sup> UBT has been shown to improve survival from atonic PPH and is recommended by both FIGO (the International Federation of Gynecology & Obstetrics) and the World Health Organization (WHO) in refractory cases.<sup>6,9</sup> The cost of commercial UBT devices is prohibitive in low- and middle-income countries, where it may be most impactful. The Every Second Matters UBT (ESM-UBT) device and package, developed by the Global Health Innovation Laboratory at Massachusetts General Hospital, is ultra-low cost and was designed to address this challenge. ESM-UBT has been shown to be safe and effective in managing refractory, atonic PPH in multiple low- and middle-income countries.<sup>10-13</sup>

In 2017, a consortium of 10 medical colleges in Maharashtra and Madhya Pradesh states in India implemented the ESM-UBT package for management of severe PPH. These medical colleges serve as referral centers for wide catchment areas, with patients often traveling several hours to reach higher levels of care. The introduction of the ESM-UBT package was studied using a difference-in-difference analysis. Across the 10 facilities and 214 123 consecutive deliveries, there was a significant reduction in the rate of deaths and invasive procedures from PPH, from 21.0%<sup>ccc</sup> to 11.4%<sup>ccc</sup>.<sup>14</sup> The purpose of this study was to understand the facilitators, barriers, and perceptions of the ESM-UBT package across these same implementation facilities 3 years after the program was introduced.

## 2 | MATERIALS AND METHODS

As described in detail previously,<sup>10</sup> the ESM-UBT package includes the device in addition to a 3-h PPH training led by experienced clinicians to ensure safe, effective, and standardized implementation. The ESM-UBT device is ultra-low cost (less than US \$5) and consists of a 24 French urinary catheter, condoms, O-rings, a Leuer-lock one-way valve, an illustrated checklist, and a data collection card. The training incorporates current standards from WHO and FIGO for PPH management, including the use of active management of the

third stage of labor and UBT. Training materials include a PPH-UBT job-aid checklist, a wall poster of PPH clinical pathway, and a learner's booklet. Using a training-of-trainers model, the training program is a participatory, skills-based training that uses hands-on PPH scenarios and maternal uterine models. Trainees are instructed to use the UBT within the context of established protocols for PPH management as outlined by FIGO and WHO. The training emphasizes that first-line interventions, along with repeat doses of uterotonics and other resuscitation measures, should occur before placement of the ESM-UBT. Placement of the ESM-UBT should occur if these interventions fail and hemorrhage continues uncontrolled.

In January 2017, the ESM-UBT package was introduced to 10 medical colleges in Maharashtra and Madhya Pradesh states (Table 1). The 10 medical colleges subsequently cascaded training of the ESM-UBT package across the network of facilities that refer to them. One program lead (typically the head of the Obstetrics/Gynecology department) was identified at each medical college. In April 2018 further training was conducted in which a PPH bundle approach, as supported by WHO and the American College of Obstetricians and Gynecologists,<sup>15,16</sup> was introduced to strengthen overall care delivery. Fifty-five facilities were included in this training, including district hospitals, sub-district hospitals, and primary health centers. Since 2017, there have been no other PPH interventions implemented in the study facilities.

In March 2020, two external researchers (SS and NP) conducted semi-structured interviews of obstetrician/gynecologists, postgraduate doctors, and nurses with experience managing PPH at each of the first 10 medical colleges (see Appendix for interview guide). Purposive sampling was used to obtain perspectives from a variety of provider cadres and experience levels. Interviews continued until thematic saturation. Some interviews were conducted through focus groups because of provider scheduling constraints. Interviews were audio-recorded and transcribed verbatim. SS and NP independently coded the data using an inductive approach to identify themes. A common codebook was then created and used to re-code the data. Data were coded using NVivo (QSR International Pty Ltd.; NVivo,

TABLE 1 Characteristics of study facilities

Facility	Type	Ob/Gyn training program	Annual deliveries 2016	Total facility beds	Total maternity beds	No. of delivery beds
1	Government	Yes	3544	1000	120	10
2	Government	Yes	8861	594	165	8
3	Private	Yes	1739	550	60	6
4	Private	Yes	8423	1275	120	16
5	Government	Yes	4636	1200	286	18
6	Private	Yes	2842	1060	100	7
7	Government	Yes	16817	1177	200	25
8	Private	Yes	2784	1525	70	8
9	Government	Yes	12139	NR	235	8
10	Government	Yes	10617	1734	312	8

Abbreviations: Ob/Gyn, Obstetrics/Gynecology; NR, not recorded.

released in March 2020). Verbal informed consent was obtained before each interview. Ethical approval for this study was obtained from the Partners Human Research Committee (Massachusetts General Hospital; institutional review board approval date February 10, 2020; Protocol #2020P000091) and from the Mahatma Gandhi Institute for Medical Sciences Ethical Review Committee (February 2020).

### 3 | RESULTS

Across the 10 medical colleges, 44 interviews were conducted with 62 obstetrics healthcare providers. Eleven interviews were of focus groups, while 33 were individual interviews. Of those interviewed, 10 (16%) were PPH program leads, 6 (10%) were professors, 11 (18%) were assistant professors, 2 (3%) were lecturers, 17 (27%) were postgraduate trainees in Obstetrics/Gynecology, and 16 (26%) were nurses. In all, 74% of interviewees were female ( $n = 46$ ) and 26% were male ( $n = 16$ ). Excluding postgraduate trainees, interviewees had an average of 14.8 years of experience in obstetrics. Key themes emerged related to PPH management before UBT implementation, facilitators and barriers to implementation, and outcomes after implementation.

#### 3.1 | PPH management before ESM-UBT

All providers noted that options were limited in cases of refractory PPH before ESM-UBT implementation. Patients who did not respond to uterotonics were brought to the operating theater for definitive management. Providers unanimously agreed that, although emergency response protocols for PPH existed, the response was often disorganized.

"It was like, we had only two things in our hand. One is like pitocin, methergine, carboprost, the medical management. And if it is not...controlled with these... we will ship the patient to the OT...that was the only option."

—resident

"[I] used to do uterine artery ligations two or three times per week."

—assistant professor

"Previously before we started with this program, stepwise devascularization was thought to be the first modality of treatment [for refractory PPH]"

—program lead

#### 3.2 | Key facilitators

Obstetric providers from all cadres identified the ESM-UBT device as an alternative, noninvasive option to use during refractory PPH.

This noninvasive option helped to promote enthusiasm for the device. Participants emphasized that the use of the ESM-UBT device allowed for more time to manage PPH in lieu of proceeding directly to the operating theater. Above all, providers felt that acceptance of the ESM-UBT device was largely due to its positive results.

"We have used UBT in more than 80 cases and only of those two people have required surgical interventions...so every case of PPH that is not going to be managed medically, we use the balloon...we have done more than 20 obstetric hysterectomies in the past 2 years, out of which for PPH there were only two."

—resident

"as far as the severe cases are concerned, there aren't many. They are all taken care of by UBT, so hardly any patient has gone to OT."

—nurse

All participants identified continual ESM-UBT training, both within the medical college and in lower-level facilities, as central to adoption of the ESM-UBT package. Each facility described regular PPH training involving all cadres of providers. Many providers noted that effectively training facility staff at lower-level facilities required a significant investment of time and resources. Across all facilities, strong program leadership was cited as crucial to establishing training programs and facilitating implementation.

"Training of the hospital staff who are involved in the labor duty [helps] more. In training we also tell what are the duties of doctors, what are the duties of nurses...so there is no confusion between them and no haphazardness in management."

—resident

"It's almost 38 [peripheral] facilities, where we have gone five times...we had to take a lot of follow-up visits with them and that has changed the mindsets."

—program lead

"The changes are there because ma'am (head of department) has conducted so many outside presentations like to talk in [the city], everywhere, she goes."

—resident

#### 3.3 | Key barriers

Administrative hurdles, high staff turnover, language barriers, and the significant resources involved in training lower-level facilities were all cited as key barriers to ESM-UBT implementation. Medical postgraduates and nurses were identified as cadres with high

turnover, which was cited as a rationale for continual training. Training materials were initially developed in Hindi and English. This proved challenging for some staff at medical colleges and in lower-level facilities, who primarily spoke the local language, Marathi. Training health centers were identified as a major challenge because of geographic distances, staff shortages, and cultural factors.

"We work with a lot of peripheral centers so it was quite difficult to train all the PHCs [peripheral health centers]...I think we should be giving much more time to train them...we will have to take repeated follow ups with them."

—assistant professor

"[The peripheral centers] were not teaching hospitals, and they were having lots of workload, lack of manpower, they were tremendously overloaded."

—program lead

### 3.4 | Outcomes after implementation

Introduction of the ESM-UBT package was credited with increased awareness of and "sensitization" to PPH in the study facilities and their surrounding referral networks. Postgraduate trainees at the medical colleges observed that the ESM-UBT package increased their confidence in managing PPH. Providers identified that increased awareness of PPH was paramount to preventing adverse maternal outcomes.

"Whatever changes have been made over time by introduction of UBT...the sensitization that everyone has now to PPH has led to the decline in the number of cases and moreover now there is better management."

—nurse

"I think if a case of PPH is there in front of me, I can manage that case...until the help comes to me. And I think every resident working here and every doctor working here has more confidence [since ESM-UBT package implementation]."

—resident

Improvements in teamwork and communication were associated with implementation of the ESM-UBT package. Participants noted that established guidelines were now well-known and consistently used. Several facilities created designated obstetric rapid response teams following ESM-UBT implementation, as well as a "PPH corner" with key supplies in the labor room.

"The whole group used to manage [PPH] together. Now we have a leader, we have an assistant, one who

is the supplier, one who is keeping the checklist. Now since we are following the protocol and the checklist, things are not being missed."

—program lead

"The strategic approach, stepwise approach, use of checklist, PPH corner, use of UBT...that is the important cause why these surgeries have declined."

—nurse

Many providers associated changes in referral patterns after ESM-UBT package implementation as a key factor in changing outcomes for women with PPH. Providers noted that patients were now being referred earlier, with more initial management, and with better communication to the medical college. All 10 of the medical colleges created a PPH phone helpline and a WhatsApp referral group that referring providers used to alert the medical college of a transfer.

"Earlier they didn't used to call us, but now we are having the helpline number...and so before they send, we are knowing. As soon as we get the call, we are ready with the PPH kit and everything in casualty."

—resident

"The referral pattern has changed in two ways, like one is that they are writing everything properly and sending the referral sheets...secondly...they thought the patient was bleeding quite a lot, they have put in a UBT and NASG [non-pneumatic anti-shock garment] and shifted. So, the morbidity and the chances of their survival has been better."

—program lead

"[Patients] used to come in a really bad state, like they were having severe hypotension, severe DIC [disseminated intravascular coagulation]...there was not hardly any time left to do anything for the patient... now the patients they are sending, they are giving oxytocin, blood is there. So that has reduced fatal cases."

—assistant professor

## 4 | DISCUSSION

Three years after ESM-UBT package implementation across 10 medical colleges and their networks in Maharashtra and Madhya Pradesh states, obstetric providers from all cadres perceived the package to be beneficial in managing refractory PPH. Our study identified several facilitators of implementation including regular training, strong program leadership, and involvement of lower-level facilities. Participants reported high numbers of severe PPH referrals from lower-level facilities, and as a result the medical colleges

were motivated to include them in ESM-UBT training. Many programs established ongoing relationships with lower-level facilities through referral helplines or WhatsApp groups to streamline referrals. Providers identified these efforts as crucial to reducing transfer time and improving morbidity and mortality. Future ESM-UBT implementation efforts must be multidimensional and involve the entire referral network, including smaller facilities. Participants identified several ongoing challenges with regards to ESM-UBT package implementation. Reaching a large network of lower-level facilities was identified as a key challenge by providers at all interview sites.

Overall, providers associated the concurrent reduction in adverse maternal outcomes<sup>14</sup> with the implementation of the ESM-UBT package. Factors such as raised awareness of PPH, use of the UBT as an alternative to surgery, increased definition of team roles, and changes in referral patterns were all repeatedly cited as contributors to reducing maternal mortality. These assertions underscore that reductions in adverse maternal outcomes were not simply the result of the ESM-UBT device alone, but rather the cumulative result of a holistic implementation package. This is the first study assessing perspectives on the ESM-UBT program 3 years after its introduction. Understanding provider perspectives at this time-point is crucial not only to understand facilitators of initial uptake, but also to identify those that have promoted lasting change. Our findings underscore that the facilitators to implementation identified allowed for durable change past the 1-year quantitative study period.

Our study has several limitations. Purposive sampling was used to ensure that a diverse array of providers was included; however, this may have introduced selection and social desirability bias. To mitigate both of these potential biases, providers were asked about both positive and negative experiences with the ESM-UBT package. As PPH bundle training was conducted during the study period, it is likely that providers' responses reflected changes sparked by both the ESM-UBT package and the PPH bundle training. Although this may have confounded causal assertions, it did not detract from providers' opinions regarding the ESM-UBT package and its efficacy over time. Additionally, this study only includes data from the first 10 medical colleges because this is where implementation was studied in the corresponding quantitative study. In future studies, including smaller referral facilities in the analysis, such as primary health centers, will be crucial to gaining a broader understanding of ESM-UBT implementation.

This study contributes to a larger body of evidence supporting UBT use in a variety of settings. Qualitative studies of ESM-UBT use among providers in Tanzania, Kenya, Senegal, and Sierra Leone demonstrated that the device was widely accepted, easy to use, and helpful in managing refractory PPH and averting emergency hysterectomy.<sup>17-20</sup> Our findings are consistent with previous studies and support implementation of the ESM-UBT package in tertiary referral centers and their networks. Our study contributes several key points to consider with future ESM-UBT implementation in low-resource settings. Frequent training should be provided to all providers involved in PPH care, including those at lower-level health facilities. Open lines of communication with referring providers, such as

phone help lines or WhatsApp referral groups, should be employed to facilitate early referral to care. Identified facilitators and barriers to ESM-UBT implementation should be incorporated into future efforts to optimize the package's impact on maternal morbidity and mortality in low-resource settings.

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## CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

## AUTHOR CONTRIBUTIONS

NP, SS, PVS, and TFB conceptualized the study. NP, SS, and TFB jointly designed the study protocol. PVS arranged in-country logistics and facilitated participant recruitment. NP and SS conducted and transcribed interviews. NP and SS analyzed the data. NP and TFB drafted the manuscript and NP, TFB, SS, and PVS contributed to its revision. All authors take responsibility for the paper as a whole.

## DATA AVAILABILITY STATEMENT

Research data are not shared.

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## APPENDIX A

### Interview guide.

Introduction,  
Background  
information

**Overarching Question:** Please tell us a little bit about yourself without using your name. Please tell us how long you have been working in this role, what your role is in relation to maternal health and if your work pertains to a particular sector of health care.

(Ex: public/private/NGO/rural/urban/government).

**Probing Questions:**

Were you in this facility before UBT program development? (before 2017)

If you were working in a different facility, did that facility have any type of UBT (e.g. Bakri, Ellavi, condom catheter) or a PPH program?

Facility level:  
Information

**Overarching Question:** Please tell us a little bit about this organization or facility. Please also mention if this is a public/private sector facility and if the population is usually of urban or rural setting. What tier or level is your facility?

**Probing Questions:**

About how often does your facility have a case of PPH? How many per day or per week? In the past 6 months (or in the past year), how many cases of PPH have you had to deal with?

Does your facility have a special protocol, guidelines, or a special team to manage PPH?

When were these guidelines established and who determined them? How are they enforced?

Are these guidelines clear, and do providers typically agree with the guidelines?

## APPENDIX A (Continued)

<b>Provider:</b> PPH experience	<p><b>Overarching Question:</b> In an attempt to better understand the provider experience with PPH, could you tell us about your personal experience managing PPH in your career?</p> <p><b>Probing Questions:</b>          How do you define PPH? What are the signs of PPH?          In your opinion, what is the best way for care teams to identify and manage PPH?          What resources are needed to best care for patients with PPH? Staff? Supplies?          If you have been personally involved in providing care to a patient with PPH, please think of your most recent experience:          -Please describe the situation (when or where it occurred, age of the patient, cause of the PPH, interventions used, the basic scenario, was it a referral?)          -What went well during that case?          -What went poorly?          -What interventions did you use (uterotonics, UBT, surgery)? Were these readily available to you? How easy were these interventions to use? In what order were the interventions done?          -What do you think could have been done differently to positively change the outcome?          What do you think are the general attitudes about use of UBT for PPH of your colleagues?</p>
<b>Facility level:</b> Teamwork and Communication	<p><b>Overarching Question:</b> We would like to better understand the role that teamwork and communication play in managing PPH. What do you think is a good example of teamwork and communication? Could you provide some insight on this?</p> <p><b>Probing Questions:</b>          What providers are typically present during an obstetric emergency such as PPH?          Who is in charge during obstetric emergencies?          What are some examples of good communication during an obstetric emergency? Bad communication?          What training, if any, do providers at your facility receive regarding communication during emergencies?          After a PPH emergency is there an opportunity to debrief or learn from this experience? If so, what is the process like? Who moderates the debrief? How often does it occur? Does someone document it?          Do you feel supported during a PPH emergency? Why or why not? Is there anything being done by your facility to make you feel better supported?          Let us say you wanted to make a change in your facility's UBT or PPH program, how would you go about suggesting a change, and how easy do you think this process would be?          How does the hierarchy in medicine and medical professionals affect PPH management?</p>
<b>Facility level:</b> ESM-UBT development [for leadership]	<p><b>Overarching Question:</b> We have been told that you played a key role in the development of the ESM-UBT program at your facility. What was that experience like?</p> <p><b>Probing Questions:</b>          How did you become interested in this program? How did you get involved with its development? Why was PPH something that your facility chose to target for improvement?          Why did you choose to focus on UBT? What other PPH interventions were considered?          Please describe the program in your own words. How did this version of the program come to exist?          What were some of the key challenges you faced in developing this program? What did you do to overcome these?          What existing strengths in your facility helped to implement this program?          Which people were key to the development of this program? What roles did they have and how did they contribute?          Has your facility ever tried to implement an intervention targeting PPH in the past? What was that like? What was involved? What was successful/challenging?          If additional funds were needed, how were you able to obtain those funds for program implementation, including commodity availability?          How would you describe the outcome of the current program? What is working well? What needs improvement?          What is the role of the ESM-UBT in this program? How do you ensure that providers are well trained to use the ESM-UBT?          How do you plan on keeping this program sustainable? What do you expect will be challenging in the long-term?          Who keeps up with quality and monitoring of the program?          What was the process, if any, for getting approval at the government level? At the district, state or national level? Does the government regulate this program or provide support? If so, how does the government offer support and how often?</p>

(Continues)

## APPENDIX A (Continued)

<p><b>Facility level:</b> ESM-UBT program</p>	<p><b>Overarching Question:</b> To better understand the impact of recent changes in PPH management, could you please give us your general impression of what PPH care has been like here in the past year?</p> <p><b>Probing Questions:</b> The number of deaths and surgeries due to PPH has dropped significantly in your facility in the past several years. What do you think explains this? Please describe how your health center currently identifies and manages patients with PPH How does your health center ensure that staff are adequately trained to identify and manage PPH? If a new staff member were to start work tomorrow, what would they learn, and how would they learn this, about how to identify and manage patients with PPH? In your opinion, what is most important to successfully managing PPH in your hospital? What people, processes, or materials are required? What changes have been made in the past year/2 years to improve PPH care? What do you think of these changes? If you were working here before implementation of these changes, what were things like previously with regards to PPH care? What changed the most as a result of recent changes in PPH management? How was implementation of changes received by staff? What was their initial reaction? Was it easy to implement? Difficult? Why? What were the major challenges with regards to implementation of changes? In your opinion, what are the pros and cons of the changes made? Which people at your health center were most important in implementing this program? What did they do to facilitate this? Are these changes sustainable? What do you feel your facility had/did to make this sustainable? Do you think there will be more changes in your facility's PPH management? What changes do you anticipate? Why do you think there would be changes?</p>
<p><b>Training package:</b> Pharmaceuticals &amp; Interventions</p>	<p><b>Overarching Question:</b> We want to understand the current availability and importance of the components of the training package. Could you provide your thoughts on the medications or devices currently used for postpartum hemorrhage management as part of PPH management at your facility?</p> <p><b>Probing Questions:</b> Do you feel that all necessary components (uterotonics, TXA, intravenous fluids, blood, UBT, NASG), are currently available in your facility? Are they readily accessible in the delivery room? If not, what have been some challenges in the procurement of these commodities? What uterotonics are available in your facility? (pitocin, misoprostol, others?) Has there been a change in the number of stock-outs or availability in uterotonics? When did this happen and why? Are there any barriers to obtaining uterotonics? If no, what do you think are the barriers to obtaining uterotonics? Is TXA readily available? If no, why not? If TXA is available, how often is it used in a PPH? What is your experience with UBTs? How is the one you use here different from other UBTs? Have you ever used the ESM-UBT? How did it go the first time you used it? Which balloon did you use? How difficult do you find the ESM-UBT to use? Have you had challenges using it? Is the NASG available at your facility? How often is it used? Can you tell me your experience using the NASG?</p>
<p><b>Facility level:</b> Future directions</p>	<p><b>Overarching Question:</b> Your facility has reduced the number of deaths and surgeries from PPH in the past several years. We'd like to hear your thoughts on how other facilities can do the same, and what it will take to continue this work at your facility. What advice would you give to another health center attempting to reduce PPH deaths?</p> <p><b>Probing Questions:</b> What aspects of the health system are most important for facilities to reduce PPH deaths and surgeries? What people or cadres are most important to reduce PPH deaths and surgeries? What training programs are most important to reduce PPH deaths and surgeries? What interventions (both clinical and non-clinical) are most important to reduce PPH deaths and surgeries? If you had to choose one thing that most contributed to this trend, what would you pick? What is/are the most important changes your health center has implemented to reduce PPH deaths? How do you think that your facility should ensure the longevity of these results? What would you do? What improvements do you think are needed for your program regarding supplies availability, clinical training, and guidelines? Are there any other changes that you think would improve PPH management in this hospital or in India (or Maharashtra state) more broadly? Why? How would you make these changes?</p>

Abbreviations: ESM-UBT, the Every Second Matters uterine balloon tamponade; NASG, non-pneumatic anti-shock garment; NGO, non-governmental organization; PPH, postpartum hemorrhage; TXA, tranexamic acid; UBT, uterine balloon tamponade.