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A postpartum haemorrhage package with condom uterine balloon tamponade: a prospective multi-centre case series in Kenya, Sierra Leone, Senegal, and Nepal

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Objective To evaluate the effectiveness and safety of an ultra-low-cost uterine balloon tamponade package (ESM-UBTTM) for facility-based management of uncontrolled postpartum haemorrhage (PPH) in Kenya, Sierra Leone, Senegal, and Nepal.

Design Prospective multi-centre case series.

Setting Facilities in resource-scarce areas of Kenya, Sierra Leone, Nepal, and Senegal.

Population Women with uncontrolled postpartum haemorrhage in 307 facilities across the four countries.

Methods A standardised ESM-UBT package was implemented in 307 facilities over 29 months (1 September 2012 to 1 February 2015). Data were collected via a multi-pronged approach including data card completion, chart reviews, and provider interviews. Beginning in August 2014, women who had previously undergone UBT placement were sought and queried regarding potential complications associated with UBT use.

Main outcome measures All-cause survival, survival from PPH, and post-UBT use complications (surgery, hospitalisation, antibiotics for pelvic infection) associated with UBT use.

Results 201 UBTs were placed for uncontrolled vaginal haemorrhage refractory to all other interventions. In all, 38% (71/188) of women were either unconscious or confused at the time of UBT insertion. All-cause survival was 95% (190/201). However, 98% (160/163) of women survived uncontrolled PPH if delivery occurred at an ESM-UBT online facility. One (1/151) potential UBT-associated complication (postpartum endometritis) was identified and two improvised UBTs were placed in women with a ruptured uterus.

Conclusions These pilot data suggest that the ESM-UBT package is a clinically promising and safe method to arrest uncontrolled postpartum haemorrhage and save women's lives. The UBT was successfully placed by all levels of facility-based providers. Future studies are needed to further evaluate the effectiveness of ESM-UBT in low-resource settings.

Keywords Maternal mortality, postpartum haemorrhage, uterine balloon tamponade.

Tweetable abstract Evidence for ESM-UBT as a clinically promising and safe method to arrest uncontrolled PPH and save women's lives.

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Introduction

Uncontrolled postpartum haemorrhage (PPH) is the most common cause of maternal mortality and morbidity in low- and middle-income countries, annually accounting for approximately 130 000 deaths and 2.6 million disabled women worldwide.[1–3]

Options for arresting uncontrolled PPH are limited in resource-scarce settings; well-resourced settings allow mul-

tiple uterotonic medications, expensive proprietary balloon tamponade, arterial embolisation, and surgical treatments such as bilateral uterine artery ligation, B-Lynch sutures, and emergency hysterectomy. In resource-limited settings, new, effective treatments are needed that can be applied in lower-level, non-surgical facilities, where the great majority of births take place. Surgical interventions are risky and only accessible at higher levels of care, and are generally not available to haemorrhaging women in time to prevent death or injury. Single-dose vials of oxytocin, anti-shock garments, and other similar interventions are being researched, but these also present the challenge of creating an effective supply chain in settings where supply-chain management is a significant challenge.[1,2,4–6]

Over the past 5 years our team has designed, developed, implemented, and refined a best-evidence postpartum haemorrhage (PPH) package with an embedded ultra-low cost (less than US$5) condom uterine balloon tamponade kit called Every Second Matters for Mothers and Babies™–UBT (ESM-UBT). During this time, UBT was recognised by the WHO and others as a method that may alleviate maternal haemorrhage; however, it is widely agreed that robust data are lacking.[1–3,7–9]

Based on our promising case series data from South Sudan, we designed a prospective multi-centre trial in Kenya, Sierra Leone, Senegal, and Nepal evaluating the effectiveness, safety, and uptake of ESM-UBT for the management of uncontrolled PPH. This paper reports preliminary findings from this four-country trial. We hypothesise that the ESM-UBT package can effectively arrest uncontrolled PPH and save women's lives.[10]

Methods

Facility selection

Study sites were selected with the assistance of the ministries of health and local health organisations, and all met the following criteria: well-established health facility with regular delivery services; a PPH protocol that did not previously include use of UBT; leadership with an interest in the use of UBT for PPH; an individual who was identified as the facility UBT champion, who then was responsible for continued training, documentation, and quality assurance; located in a resource-scarce area of Kenya, Sierra Leone, Nepal or Senegal.

UBT implementation and training

The ESM-UBT kit consists of the following: a size 24 urinary catheter, condoms, cotton strings, Luer-lock one-way valve, illustrated checklist, and data collection card. The condom is rolled out and tied to the end of the catheter using the strings. Care must be taken to ensure that the balloon is placed inside the uterus. The balloon is filled with clean water until the bleeding stops. This usually requires 300–500 ml of water, although this may vary (Figure 1).

To help ensure the safe, effective, and standardised implementation of the condom UBT package, a 3-hour PPH training curriculum that included best-evidence PPH management along with detailed instruction in the ESM-UBT kit was developed, piloted, and refined. This was accomplished in close collaboration with the Ministries of Health of Kenya and Sierra Leone, PATH, UNICEF (Kenya office), the Kisumu Medical and Education Trust (KMET, an NGO in Kenya), Centre de Formation et de Recherche en Santé de la Reproduction (CEFOREP, an NGO in Senegal), and One-Heart Worldwide (an NGO in Nepal). The ESM-UBT training curriculum incorporated current standards from WHO and FIGO for PPH management, including UBT.[10–12] The training and curriculum materials included a PPH-UBT job-aid checklist, a wall poster PPH clinical pathway, a trainer's flipchart, and a learner's booklet. Using a training-of-trainers model, the training programme was a participatory, skills-based training that used hands-on PPH scenarios and simple maternal uterine models made of local components (e.g. a pillow surrounding a plastic water bottle, which represented a uterus within an abdomen).

Figure 1. The ESM-UBT kit contents: a size 24 urinary catheter, condoms, cotton strings, Luer-lock one-way valve, illustrated checklist, and data collection card. Source: Division of Global Health & Human Rights, Department of Emergency Medicine, Massachusetts General Hospital, Boston, MA, USA.

Trainees were instructed to use the UBT within the context of the established national protocol for PPH, which first included active management of the third stage of labour: uterine massage, emptying the bladder, breastfeeding (if feasible), identifying and treating perineal or cervical tears, administering prophylactic oxytocin and/or misoprostol (or other uterotonics if available), and manual removal of the placenta and blood clots (Box 1). All these interventions, along with repeat doses of uterotonics and other resuscitation measures, should occur prior to placement of the uterine balloon. Placement of the uterine balloon should occur if these interventions fail and haemorrhage continues uncontrolled (i.e. the UBT as a rescue device). Data collectors were trained to identify all cases of ESM-UBT kit use; these uses, whether according to protocol or not, were included in the final analysis. All uses of the ESM-UBT kit were tracked and providers contacted for the details. Providers were instructed to leave the uterine balloon in place for 6–24 hours after placement. A dose of a broad-spectrum prophylactic antibiotic was recommended. After the mother was stable, the balloon removal protocol was instituted—a slow deflation of the balloon with simultaneous monitoring for resumption of bleeding.

ESM-UBT was implemented in facilities at all levels of the health care system where deliveries regularly take place; however, there was a greater focus was on community level facilities. Trainees were representative maternal health providers from each facility and were brought to a regional location for initial training. These providers then returned to their facilities and trained their staff with the target of ensuring that at least 85% of maternity providers in each facility achieved competence in UBT placement (defined as 'online' status). All facilities received one wall chart checklist per delivery room, two manuals for PPH management and UBT use, and an adequate number of pre-packaged ESM-UBT kits (i.e. device and checklist). Supplies were replenished free of charge.

Data collection

Given the anticipated challenges with gaining accurate and complete data, a multi-pronged approach to data collection was implemented. The encouraged data collection pathway was triggered when a provider called the toll-free hotline telephone number (to the study coordinators) upon placing a UBT. In the ideal scenario, the data card was fully completed by the UBT provider and then sent to the study coordinators. The study coordinators then would visit the site in the ensuing weeks to verify the data, formally interview the UBT provider and facility champion (this often included focus groups), and compare collected data with the patient's chart. Alternative data collection methods included completion by the study coordinator of data cards (subsequent to research team-initiated monthly facility calls identifying UBT uses), as well as UBT cases discovered during intermittent visits to the facilities. The data collection cards documented the kit tracking number, facility name, delivery date and time, steps in the PPH protocol taken before UBT placement, patient's mental status at the time of UBT placement, effectiveness of haemorrhage control, steps taken after UBT placement, need for maternal resuscitation or transfusion, hysterectomy, and death. Additional space was provided for UBT provider comments. UBT kits and data cards were marked with the same number and were catalogued in a central registry for tracking purposes. Periodic visits were made to each facility to supervise, assist with, and assure adequate training, to confirm proper availability and storage of program resources, and to identify any additional uses of the uterine balloon.

Box 1 Steps before UBT placement
- Empty bladder
- Administer uterotonics
- Massage fundus
- Empty uterus
- Repair lacerations
- Bimanual massage
- Breastfeed

In August 2014, the field data collection team began seeking mothers who had undergone UBT insertion, and their UBT providers, in order to conduct formal follow-up interviews focused on uncovering any and all potential complications associated with UBT use.

Data analysis

Collected data underwent descriptive analysis (utilising Microsoft EXCEL 2007, Seattle, WA, USA) evaluating outcomes associated with ESM-UBT introduction.[13] The analysis focused especially on PPH/UBT-related survival, inadvertent UBT expulsion, complications potentially associated with the UBT and detailed review of all deaths. Qualitative research methods included consensus theme analysis to analyse semi-structured interviews, focus group discussions, and provider-initiated UBT-card comments.[11]

It was anticipated that, in spite of best attempts, data points might at times be missing from the data cards and medical records, and UBT providers would be unreachable (e.g. might have changed jobs and moved elsewhere). Therefore, when data were missing, and/or inconsistencies between the verbal interview and chart review could not be reconciled, these specific data points were not included in the analysis. Hence, the denominator used in calculations varied in order to assure the best possible accuracy. Relevant sensitivity analyses were performed.

Health provider designations in each country were grouped to allow for analysis across the four countries. Sierra Leone uses the following descriptors: maternal child

health aide (MCHA), state enrolled community health nurse (SECHN), state registered nurse (SRN), midwife, clinical health officer (CHO), and medical doctor. Kenya uses the following: community health worker (CHW), nurse, clinical officer (CO), and medical officer (MO). All MOs in Kenya are medical doctors. Based on the definitions of each type of provider, we grouped MCHAs with CHWs; SECHNs, SRNs, and midwives with nurses; and CHOs with COs.

Results

Facilities and training of healthcare providers

A pilot introduction of ESM-UBT was conducted in 12 targeted facilities in Kenya between 1 September 2012 and 30 June 2013. The subsequent scaling up of UBT in additional facilities began in July 2013 in collaboration with the Kenya Division of Reproductive Health (which incorporated UBT into its national reproductive health policy as standard care for PPH). As of February 2015, a total of 307 facilities had been brought online (defined as at least 85% of facility providers trained plus the presence of ESM-UBT wall charts, manuals, and kits)—179 in Kenya, 106 in Sierra Leone, 14 in Senegal, and eight in Nepal. In Kenya the facilities participating were a mix of rural health clinics and lower- and mid-level community health facilities. In Senegal, all participating facilities were referral hospitals in the capital city of Dakar. In Sierra Leone, one facility (the Princess Christian Maternity Hospital) was a referral centre and the remaining 105 facilities were at the community level in the capital city of Freetown. Finally, in Nepal, all of the online facilities were remote rural health clinics.

Patient presentations, management, and outcomes

Both active and passive surveillance of UBT kit uses identified placement of UBTs in 201 women: 143 in Kenya, 40 in Sierra Leone, 13 in Senegal, and five in Nepal (Table 1). Six women were treated with UBT for uncontrolled haemorrhage post-abortion at home, one with an intentional vaginal inflation in order to apply direct pressure (tamponade) to a large cervical tear, and 195 for PPH.

For more than half (103, or 53%) of 193 UBT uses for which provider level was available, placements were performed by SECHNs, nurses or midwives; 52 (27%) were placed by medical doctors. Of the 179 cases for which there were data, the mean time between delivery and UBT placement was 2.42 hours. Of the 174 cases for which there were data, the UBT remained in the patient for an average of 14.15 hours.

Seventy-one of 187 (38%) women were either unconscious or confused at the time of UBT insertion (Table 1); no women were excluded based on clinical severity.

Of the 143 cases in Kenya, 23 were actually from facilities other than the 179 designated as online. These 23 cases were discovered incidentally by word-of-mouth and the data were subsequently pursued by our research team. Each of these 23 cases utilised improvised UBT kits, did not have the contextual benefit of wall charts or institution-wide training, and the providers had generally undergone varying levels of UBT instruction. Thirteen of the 23 (57%) improvised UBT patients were either confused or unconscious prior to UBT placement, two of the 23 presented with a ruptured uterus and in addition to UBT placement underwent hysterectomy (both survived), and 19 (83%) of these 23 survived.

Eleven of the 201 women who underwent UBT placement due to uncontrolled PPH, died. Three of the deaths were determined to be caused by alternative aetiologies: sepsis, malaria, and pulmonary embolus. Of the eight remaining deaths, five were from facilities that were not online (did not have complete training or manuals, wall charts or pre-packaged equipment). Two of the PPH-related deaths were home deliveries and one of the PPH-related deaths was in a woman who had advanced untreated HIV and had been severely beaten 2 days prior to delivery. In the entire case series, in women with uncontrolled PPH who delivered in one of the 307 facilities 'online' with ESM-UBT, there were only three deaths, no placements in a ruptured uterus, and only one postpartum infection. Fourteen UBTs became unintentionally displaced at some point, 10 of those were replaced, and the other four did not require replacement clinically.

There was one complication (0.7%) potentially due to UBT placement in the 151 women able to be followed up for safety (Table 2). One provider reported re-admission of a woman for abdominal pain who had undergone UBT placement, 1 week postpartum. The woman received ampicillin, gentamycin and clindamycin, and recovered.

Of note, there was great enthusiasm for the ESM-UBT package in Sierra Leone during and after it was implemented in the winter and spring of 2014. In September 2014, following the onset of the Ebola epidemic, the use of UBT slowed considerably due to strict government policies that only allowed uteronics to be used in uncontrolled PPH. In Nepal, besides the initial use and survival details gained from an in-country visit by a US-based research coordinator, no data from the remote clinics were available.

Overall, with respect to missing data, it is very likely that the mechanism of the missing data was random. Our sensitivity analysis on the course of treatment statistics assigned the worst-case scenario where all the missing cases would have fallen into a one-course of treatment category, and we noted no change in the 'rankings' of the categories. The same strategy was applied to the other categories selected, and the result remained consistent with the completer only-based frequency distribution.

Table 1. PPH-UBT management (demographics

	Kenya	Sierra Leone	Senegal	Nepal	Total
Total patients*	143	40	13	5	201
Age of patient, mean (range)	26.9 (16–44)	25.7 (16–37)	28.3 (16–37.0)	34 (22–46)	26.93 (16–46)
Prior pregnancies, median (range)	2.00 (0–11)	2.00 (0–5)	2.00 (0–8)	2 (0–6)	2.00 (0–11)
Prior deliveries, median (range)	2.00 (0–11)	2.00 (0–5)	1.00 (0–7)	2 (0–6)	2.00 (0–11)
Living children, median (range)	2.00 (0–10)	1.00 (0–5)	2.00 (0–7)	N/A	2.00 (0–10)
Location of delivery					
Home	14/133	0/38	0/13	0/5	14/189
Facility	119/133	38/38	13/13	5/5	175/189
Level of provider placing UBT**, *n* (%)**					
Total	135	40	13	5	193
MO/doctor	35 (26)	4 (10)	13 (100)	0 (0)	52 (27)
MO & RN	7(5)	0 (0)	0 (0)	0 (0)	7 (4)
CO/CHO	12 (9)	4 (10)	0 (0)	0 (0)	16 (8)
CO/CHO & RN	2 (1)	0 (0)	0 (0)	0 (0)	2 (1)
RN/SECHN/Midwife	79 (59)	19 (48)	0 (0)	5 (100)	103 (53)
CHW/MCHA	0(0)	13 (32)	0 (0)	0 (0)	13 (7)
Time between delivery and UBT placement,					
mean hours:minutes (range)	2:22 (0:05–16:00)	2:25 (0:05–13:37)	2:29 (0:20–6:58)	N/A	2:25 (0:05–16:00)
Patient's mental status at time of UBT placement (%):					
Normal	90/136 (66)	21/39 (54)	6/13 (46)	N/A	117/188 (62)
Confused	36/136 (27)	16/39 (41)	3/13 (23)	N/A	55/188 (29)
Unconscious	10/136 (7)	2/39 (5)	4/13 (31)	N/A	16/188 (9)
Interventions before UBT use (%)					
Uterotonic	127/137 (93)	37/39 (95)	12/13 (92)	N/A	176/189 (93)
Fundal massage	115/137 (84)	38/39 (97)	9/13 (69)	N/A	162/189 (86)
Empty the uterus	34/137 (25)	11/39 (28)	2/13 (15)	N/A	47/189 (25)
Treat lacerations	37/137 (27)	6/39 (15)	5/13 (38)	N/A	48/189 (25)
Bimanual massage	51/137 (37)	17/39 (44)	2/13 (15)	N/A	70/189 (37)

*When data were missing and/or inconsistencies between the verbal interview and chart review could not be reconciled, these specific data points were not included in the analysis.
**Sierra Leone designations: doctor, clinical health officer (CHO), midwife, state enrolled community health nurse (SECHN), maternal child health aide (MCHA). Kenya designations: medical officer (MO), clinical officer (CO), nurse (RN), community health worker (CHW).

Table 2. PPH-UBT course of treatment statistics and follow up*

	Kenya	Sierra Leone	Senegal	Nepal	Total
Facility level where UBT placed, *n* (%)	140	40	13	5	198
Low level	61 (44)	29 (73)	0 (0)	1 (20)	91 (46)
High level	79 (56)	11 (27)	13 (100)	4 (80)	107 (54)
Management after UBT placement (%)					
UBT displacement	8/138 (6)	5/38 (13)	1/13 (8)	N/A	14/189 (7)
IV fluids	121/138 (88)	27/38 (71)	12/13 (92)	N/A	160/189 (85)
Blood transfusion	41/138 (30)	5/38 (13)	3/13 (23)	N/A	49/189 (26)
Antibiotics	118/138 (86)	22/38 (58)	12/13 (92)	N/A	152/189 (80)
Hysterectomy**	2/138 (1)	0/38 (0)	0/13 (0)	N/A	2/189 (1)
Referral	10/138 (7)	12/38 (32)	0/13 (0)	N/A	22/189 (12)
Any recurrence	18/138 (13)	3/38 (8)	0/13 (0)	N/A	21/189 (11)
Duration of UBT in place, mean hours:minutes (range)	15:51 (0:00–44:00)	8:30 (0:20–24:00)	14:55 (6:00–42:50)	N/A	14:09 (0:00–44:00)
Survival	135/143	37/40	13/13	5/5	190/201
Follow-up data* **	101	37	13	N/A	151
In the 6 weeks following delivery and UBT placement, did you have any of the following: antibiotics for pelvic infection, surgery or any hospitalisation?	100/101 reported none	37/37 reported none	13/13 reported none	N/A	150/151 reported none

*When data were missing and/or inconsistencies could not be reconciled between the verbal interview and chart review, these specific data points were not included in the analysis.
**These two women presented with a ruptured uterus to a non-online facility and had improvised UBTs placed. Both of the women survived.
***Available data excluding deaths, patient-reported.

Discussion

Main findings

This is the first-ever large-scale implementation and evaluation of a PPH intervention that included an ultra-low-cost UBT device, a best-evidence training curriculum on PPH management, and provider job aids—the ESM-UBT package—implemented at all levels of health facilities. Despite uncontrolled haemorrhage and the critical health status of most of these mothers (38% had altered mental status from their haemorrhage), placement of UBTs contributed to 95% all-cause survival and supported 98% survival from PPH if delivery occurred at 'online' facilities. There was one case of postpartum endometritis in a women undergoing UBT placement at an 'online' facility.

Maternal health workers continued, and may have improved, their adherence to best evidence PPH clinical pathways after training in the ESM-UBT package. Despite strong recommendations to the contrary, most women who had UBTs placed were not transferred to higher level facilities – an emergent finding that suggests that the UBT may have especially great therapeutic advantages for remote settings. The results support assertions that placement of a UBT may indeed often be an end intervention.[14]

Six of the reported UBT uses were for women suffering severe post-abortion haemorrhage and one was intentionally placed vaginally to temporise successfully a large cervical tear. Neither of these indications were taught during the ESM-UBT training; however, as all six women did well, it certainly speaks to the innovative actions of these maternal health providers.

Strengths and limitations

This study has several major strengths. First, this is the first and largest case series of its kind, and the evidence spans our experience from four countries on two continents—providing aggregated findings across a diverse range of clinical settings. Secondly, this study provides prospective follow-up

data related to safety and complications of the intervention. As a mixed-methods evaluation, the study provides critical quantitative data related to patient outcomes and supplemental qualitative findings in the narratives describing each of the 11 deaths in the sample.

There are several limitations to the current study. The study was designed as a prospective, interventional case series rather than a randomised controlled trial, making it difficult to form definitive associations or draw cause-and-effect conclusions of the impact of the ESM-UBT package. However, based on the existing evidence for the potential life-saving impact of UBT in cases of uncontrolled PPH, the authors considered it unethical to withhold UBT from a study arm.

The study almost certainly did not capture all cases of UBT use from improvised kits in facilities not 'online', nor can we confidently state that all of the facilities designated as online completely met all of the online criteria at the time of UBT placement. In light of these limitations, the authors felt that it was most responsible to include all of the UBT cases that were discovered, as they represented a study ripple effect and, thus, a more accurate picture of the true impact of the package. Whether an ESM-UBT kit was readily available and used, or a UBT was hastily improvised, was a clear binary data point that was felt important to analyse on its own. The remainder of the indicators were felt to be best left commingled, as such analysis was seen to best reflect on-the-ground reality. It is notable that the 23 cases of improvised UBT placement that we did capture were sicker, had a higher mortality rate, and in two cases were in women with a ruptured uterus. The true ripple effect of ESM-UBT on facilities that are not online, and thus UBTs improvised and placed by untrained providers, is not known from this study.

Although the ESM-UBT clinical pathway specifically directed placement of the UBT as a rescue device only after all other interventions had failed, the authors recognise that what occurred in actual practice included cases where the UBT may have been placed earlier than recommended or in moribund women. Given that a considerable proportion of the overall study population was in advanced stages of shock, and in some cases the UBT was placed moments prior to death, it is possible that the ESM-UBT device appeared associated with failures that instead should more accurately have been ascribed to alternative reasons (e.g. other system failures). The authors felt that to best capture actual on-the-ground impact, every uncovered case of UBT use should have been reported, regardless of timing of UBT placement or other variables.

Despite the redundant data collection management system, considerable data points were missing. However, we were meticulous in capturing the most accurate denominator for each data point. Our data from Nepal were limited, beyond learning of each case in narrative form and being assured of a successful outcome. Furthermore, active safety data collection was only begun 2 years after study launch and thus many women and/or health providers that used UBTs early in the study could not be found. With this considerable delay in harvesting follow-up data, the safety data for these cases was vulnerable to recall bias. Additionally, several of the women who underwent UBT placement were from nomadic tribes along the Kenya–Somalia border. Follow up of these women was extremely challenging.

Given that the hemorrhaging women were not randomised, it is possible that other components of the package (e.g. improved use of pharmacologic treatments) contributed to the patient outcomes. However, in keeping with the ESM-UBT clinical pathway, the UBTs were almost always deployed only after failure of all other non-surgical modalities.

Finally, the time to UBT placement was recorded, starting from the time of delivery. While it would have been more accurate to begin recording from the time of haemorrhage onset, the precise time of haemorrhage onset is difficult to record. The time from birth to haemorrhage varied and contributed to the broad range of birth to UBT placement values, as can be seen in Table 1.

Interpretation

This initial set of data from the implementation of ESM-UBT across the 307 facilities in Kenya, Sierra Leone, Senegal, and Nepal are remarkably encouraging. Critical analysis of each case clearly demonstrates that no single intervention alone saves women's lives; however, proper training and skills, equipment (e.g. the ESM-UBT kit), and adherence to best practice together improved the chance for survival. The findings strongly support the imperative that quality care of emergent conditions is heavily dependent on a health system ensuring that a portfolio of best evidence interventions is reliably and immediately available, when and where they are needed. Each of the 11 deaths in this series of 201 women was associated with one or more of the following: failure of delivery in a trained and equipped facility, delay of recognition of the emergent condition, or delay in care provision (Appendix S1).

Conclusions

These pilot data suggest that the ESM-UBT package is a clinically promising and safe method to arrest uncontrolled postpartum haemorrhage and save women's lives. The UBT was successfully placed by all levels of facility-based providers. Future studies are needed to further evaluate the effectiveness of ESM-UBT in low-resource settings.

Although this multi-country trial suggests that the ESM-UBT package can likely reduce the number of global maternal deaths attributable to PPH, several questions remain unanswered. Additional research is needed to better understand the following: precise balloon/uterus physiology, optimal timing of balloon placement and removal, ideal device design, especially regarding undesired displacement, role in combination with other modalities such as tranexamic acid and the non-pneumatic anti-shock garment, provider uptake, cost effectiveness, necessity of concomitant use of antibiotics, training optimisation, and sustainable local commercialisation and distribution. More detailed data are also needed on the potential impact of UBT on reducing maternal morbidity, such as averted hysterectomies and transfusions. There remains a continued need to search carefully for any potential harm of the UBT device, although this appears to be limited in this and previous series. As evidence-based data on the effectiveness of UBT for preventing PPH-related maternal deaths emerge, updated optimal practice guidelines must be expeditiously incorporated into the policy agendas at the local, national, and international levels.

Disclosure of interests

None declared. Completed disclosure of interests form available to view online as supporting information.

Contribution to authorship

TFB, RA, ME, and BN conceived the study, designed the study and obtained research funding. ME, JK, MO, LD, EA, BA, AN, JM, SK, KA, and MN undertook recruitment of participating centres and patients and managed the data, including quality control. TFB, RA, ME, KT, ZA, and ED provided statistical advice on study design and analysed the data. ME, RA, TFB, RH, ZA, KT, and ED drafted the article and TFB, RA, BN, RH, JK, MO, LD, EA, BA, AN, JM, AK, ZA, KT, ED, MN, KA, and ME contributed substantially to its revision. TFB takes responsibility for the paper as a whole.

Details of ethics approval

Ethical approval for this study was obtained from the Partners Human Research Committee (Massachusetts General Hospital, Boston, MA, USA; IRB Approval date 14 January 2013;

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Direct quote interview narratives and chart details of the women who received a UBT and died. ■

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