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Cost-effectiveness of condom uterine balloon tamponade to control severe postpartum hemorrhage in Kenya

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Keywords: Condom uterine balloon tamponade; Cost-effectiveness; Disability-adjusted life year; Economic evaluation; Kenya; Low-resource settings; Maternal hemorrhage; Postpartum hemorrhage

Synopsis: Condom uterine balloon tamponade was a cost-effective device for controlling severe postpartum hemorrhage among women in Kenya.

ABSTRACT

Objective: To evaluate the cost-effectiveness of condom uterine balloon tamponade (UBT) for control of severe postpartum hemorrhage (PPH) due to uterine atony versus standard PPH care in Kenya.

Methods: A cross-sectional analysis was conducted using cost data collected from 30 facilities in Western Kenya from April 15 to July 16, 2015. Effectiveness data were derived from the published literature. The modeling analysis was performed from the health-system perspective for a cohort of women who gave birth in 2015. Sensitivity analyses tested the robustness of model estimates. Costs were in 2015 US dollars.

Results: Compared with standard care with no uterine packing, condom UBT could prevent 1255 hospital transfers, 430 hysterectomies, and 44 maternal deaths. At $5 or

$15 per UBT device, the incremental cost per disability-adjusted life year (DALY) averted was $26 or $40, respectively. If uterine packing was assumed to be done with standard care, the cost per DALY averted was $164 when the UBT price was $5 and $199 when the price was $15.

Conclusion: Condom UBT was a highly cost-effective intervention for controlling severe PPH. This finding remained robust even when key model inputs were varied by wide margins.

1 INTRODUCTION

Postpartum hemorrhage (PPH) is the main cause of maternal mortality worldwide, with estimates suggesting that 115 000 deaths are caused by this condition every year [1]. The overwhelming majority of these deaths occur in low-income and middle-income countries (LMICs) [1], where challenges such as inadequate staff training, shortage of essential medical supplies, and weak referral systems for patients are frequently encountered. Although global efforts have managed to decrease the maternal mortality ratio in the past 25 years, much still remains to be done to reach the United Nations Sustainable Development Goals target of reducing the maternal mortality ratio to less than 70 per 100 000 live births worldwide [2].

The leading cause of PPH is uterine atony, which manifests as failure of the uterus to contract after delivery. Global recommendations for the treatment of uterine atony include interventions such as uterotonic drugs and mechanical interventions, and surgery when all other recommended interventions have failed [3]. Women who experience persistent uncontrollable hemorrhage despite standard interventions are at high risk of death unless they can undergo rapid treatment at a health facility equipped for advanced obstetric surgical care [4,5]. Emergency transportation and obstetric surgical capabilities are often limited in low-resource settings, which highlights the need for simple, yet effective, treatments at the point of care.

Use of uterine balloon tamponade (UBT) can potentially overcome barriers to managing PPH [6–8]. Although various permutations are available, the condom UBT approach was developed specifically for use in low-resource settings. Various studies have shown that UBT, including the condom method, is safe, easy to use, and effective at treating PPH due to uterine atony [8–12]. Nonetheless, UBT is either unavailable or else widely underused in most LMICs.

Massachusetts General Hospital in Boston, MA, USA, has worked closely with key stakeholders to introduce a condom UBT device into several resource-limited countries, including Kenya, Sierra Leone, Senegal, and Nepal [9]. The components that make up this device—known as “Every Second Matters for Mothers and Babies-UBT” (ESM-UBT)—are assembled locally at a registered social enterprise in Kenya.

Several studies have evaluated the cost-effectiveness of uterotonic drugs (e.g. misoprostol and oxytocin) to manage non-severe cases of PPH [13–16]. By contrast, as far as we are aware, only one study conducted to date has modeled the cost-effectiveness of interventions for controlling severe PPH [17]. The objective of the present study was, therefore, to evaluate the cost-effectiveness of ESM-UBT versus standard of care without UBT for the management of severe PPH due to uterine atony among women in Kenya.

2 MATERIALS AND METHODS

The analysis was conducted using cross-sectional cost data combined with impact data from the published literature to model the cost-effectiveness of interventions for managing PPH in a cohort of Kenyan women who gave birth during a 1-year period. The cost data were collected from the head nurses at 30 facilities in Western Kenya between April 15 and July 16, 2015. The costing study was approved by the regional ethics review committee of Maseno University, Maseno, Kenya. Informed consent was not required because the head nurses were providing information about their health facility rather than personal opinions.

The cost-effectiveness analysis was conducted from the health-system perspective and did not consider costs borne by the women or their households. The analysis was performed using Excel 2013 (Microsoft, Redmond, WA, USA). The standard of care without UBT was compared with an approach that incorporated ESM-UBT to treat uncontrolled PPH caused by uterine atony. The analysis assumed that ESM-UBT was available only in health centers and hospitals with trained providers and not for home deliveries. However, deliveries in health centers were modeled separately to account for the costs of hospital transfer.

Alternative interventions for the treatment of severe PPH are outlined in Figures S1–S3. Figures S1 and S3 each represent a standard-of-care scenario without the inclusion of ESM-UBT. For scenario 1 (Figure S1), it was assumed that some of the women would be transferred from a health center to a hospital, without further intervention at the health facility if uterotonic drugs and mechanical interventions failed to arrest PPH. In scenario 2 (Figure S3), it was assumed that some of the women who delivered at a health center would be transferred to a hospital, with uterine packing performed before transfer if uterotonic drugs and mechanical interventions failed to arrest the PPH. When treatment included ESM-UBT (Figure S2), it was assumed that the initial clinical pathway was identical to that of scenarios 1 and 2, and that ESM-UBT was used only after uterotonic drugs and mechanical interventions had failed to arrest PPH. In this approach, it was assumed that only those women who continued to experience PPH would be transferred to hospital.

A micro-costing approach [18] was used to collect resource use and unit price data specific to PPH care. Purposive (selective) sampling was used to identify 24 government-owned health centers and six hospitals in Western Kenya. Resource use data were collected through structured interviews with the head nurse at each facility to determine the types and quantities of resources used for treating women with PPH. These resources included medications, supplies, laboratory tests, and time spent managing the patient. Unit prices for these resources are standard across all government-owned facilities in Kenya and so were collected from the records of one hospital. Unit prices were multiplied by the quantities of resources used to estimate the cost per resource per woman; the total resource costs were then aggregated. Costs of transferring women with uncontrolled PPH to hospital were obtained from each facility based on the fees charged for these services. All costs were calculated in 2015 US dollars, with an exchange rate of 94 Kenyan shillings per $1. These data were used to estimate the cost per woman for the three treatment pathways modeled and also used as inputs for the cost-effectiveness analysis (Table 1).

The ESM-UBT device was not commercially available at the time of the present study; hence, an assumed price of $5 was used in the analysis. This price was based on the cost of materials needed to assemble the device (a condom, string, catheter, and syringe). Modeling at a price assumption of $15 was also undertaken.

Costs for training healthcare providers on the use of ESM-UBT (Table 1) were estimated using expenditure data from PATH. These costs included transport, venue and equipment rentals, meals, printing, and office supplies for a 1-day training session, with 20 trainees per session. The assumed number of trainees was intended to reflect the number that would require training if ESM-UBT was available across all health facilities in Kenya, with an assumption of two providers trained per facility. Training costs were amortized over a 2-year period.

Several data sources were used to inform the input values used to estimate the impact of standard care and ESM-UBT, including the published literature, online databases, and assumptions (Table S1). Data on effectiveness of the condom UBT were obtained from the original ESM-UBT trial [9]. No published data were found regarding the effectiveness of uterine packing without UBT or on the availability of uterotonic drugs at Kenyan health facilities. Consequently, the values for these assumptions were derived from an online model of PPH care in LMICs [19,20].

The baseline number of deaths in the absence of UBT was calibrated to align with the number of maternal deaths due to PPH reported by the Institute for Health Metrics and Evaluation, which estimated approximately 500 such deaths in Kenya during 2013 [21].

The number of PPH cases was estimated using Kenyan population data on the number of deliveries during a 1-year period [22], the proportion of deliveries that would occur in each setting (home, health center, or hospital) [20,23], and the percentage of deliveries with PPH [20]. The epidemiological inputs and assumptions depicted in Table S1 were used to estimate key outcomes for the clinical pathways modeled. The numbers of hospital transfers, hysterectomies, deaths, and disability-adjusted life years (DALYs) were estimated as the main outcomes or measures of effectiveness. DALYs represent the sum of years of life lost owing to premature death plus years lived with disability. Years of life lost were calculated by multiplying the number of deaths due to PPH estimated in the present model by the corresponding WHO Global Burden of Disease 2010 loss-of-function estimates for females based on the assumed age of death [24]. Years lived with disability were estimated by multiplying the number of cases of PPH for each age group, the disability weight, and the average duration of disability. The disability weight for anemia (0.16) was used because this condition is the principal source of disability associated with PPH. The duration of anemia associated with PPH was assumed to be 1 month [14]. Tables 1 and S1 show the minimum and maximum values specified for each input that were used for the sensitivity analyses.

Incremental cost-effectiveness ratios (ICERs) were obtained by calculating the difference between the costs for controlling PPH with ESM-UBT versus standard care (scenarios 1 and 2 separately) and dividing this value by the difference in DALYs. Thresholds from WHO were used to determine whether the intervention was cost-effective [25]. An intervention is considered to be very cost-effective if the ICER is less than the gross domestic product (GDP) per capita. If the ICER is between one and three times the GDP per capita, the intervention was considered to be cost-effective. However, the intervention is considered not to be cost-effective if the ICER was greater than three times the GDP per capita. Kenya's GDP per capita was $1358 in 2014 [26].

Sensitivity analyses were conducted using @Risk version 7 (Palisades, Ithaca, NY, USA) to explore the impact of modifying the key input values on the cost-effectiveness estimates.

3 RESULTS

Approximately 1.5 million deliveries occurred in Kenya during 2015. The number of women with PPH due to uterine atony was estimated at 110 000, of which approximately 10 230 (10%) cases would be classified as severe.

Table 2 illustrates the results of the cost-effectiveness analysis for this cohort. With no uterine packing (scenario 1), there would have been 1390 transfers from health centers to hospitals, 462 hysterectomies to treat severe PPH, and 412 deaths, with approximately 80% of deaths occurring after home births. Use of ESM-UBT would have averted 430 hysterectomies and 44 deaths. The estimated costs for scenario 1 were $453,884, including the costs for initial attempts to halt PPH, as well as fees for transfers, hospitalizations, and surgeries. At an assumed price of $5 per ESM-UBT device, the estimated costs were $518,225 and the incremental cost per DALY averted was $26. If the ESM-UBT device was priced at $15, the incremental cost per DALY averted was estimated at $40. These data suggested that ESM-UBT was highly cost effective when compared to scenario 1.

With the assumption that standard of care plus uterine packing (scenario 2) would be 60% effective at stopping uncontrolled PPH (the baseline assumption), the use of ESM-UBT would have averted 116 hysterectomies and 18 deaths. The incremental cost per DALY averted was estimated be $164 or $199 if the price per ESM-UBT device was $5 or $15, respectively. Therefore, ESM-UBT remained highly cost-effective even when uterine packing was taken into account.

Figures 1 and S4 depict the findings of the sensitivity analysis with an assumed price of $5 per ESM-UBT device. For both scenarios, ESM-UBT remained highly cost-effective even after varying input values. Without uterine packing (scenario 1), the variables with the largest impact were the percentages of women referred from health centers to hospitals, given oxytocin, and needing surgery. For scenario 2, the variable with largest impact was the effectiveness of uterine packing. A sensitivity analysis was also conducted at an assumed price of $15 per ESM-UBT device. This analysis found similar drivers to the previous analysis, with ESM-UBT still highly cost-effective despite the increased per unit price.

4 DISCUSSION

To the best of our knowledge, the present study was the first cost-effectiveness analysis that used local data to evaluate both the cost and impact of using a condom UBT to treat severe PPH arising from uterine atony. When compared with the standard of care without UBT, all the various assumptions and scenarios used in the present study demonstrated that ESM-UBT was a highly cost-effective intervention for controlling this condition. Therefore, the addition of ESM-UBT to the package of interventions already available for managing severe PPH could substantially decrease the number of hospital transfers and hysterectomies required. These findings were greatest for the scenario in which no uterine packing at health centers was assumed. However, even if uterine packing was the standard of care and was effective in stopping up to 70% of PPH (the upper range in the sensitivity analysis), ESM-UBT would still be highly cost-effective.

The use of ESM-UBT represented an effective and affordable measure to manage PPH, with the largest impact seen at lower levels of the health system. The present analysis assumed that 50% of all women who needed to be transferred to hospital would be transferred. However, in Kenya, as in other resource-limited countries, most health centers do not have an ambulance on site. Therefore, using the standard of care without UBT pathway, women with uncontrolled PPH at health centers would experience a potentially life-threatening delay while waiting for an ambulance. Additionally, some hospitals might not be properly equipped to perform hysterectomies; thus, any intervention that reduces strain on the health system could have an impact on improving maternal health outcomes.

The present study had several limitations. The analysis relied on assumptions for certain key input parameters because robust data were not readily available. For example, data on the effectiveness of the standard of care without ESM-UBT (i.e. the ability of uterine packing to stop PPH) were lacking. Nonetheless, the sensitivity analyses showed that ESM-UBT remained highly cost-effective when key inputs were varied by large margins. Similarly, because the analysis assumed that only women who failed to respond to uterotonic drugs and mechanical interventions (i.e. only women with severe PPH) would be treated with ESM-UBT, this variable became a key driver for cost-effectiveness. Relaxing this assumption and extending ESM-UBT use to non-severe PPH cases rendered ESM-UBT even more cost-effective. The present study did not include the costs associated with potential sepsis arising from the use of ESM-UBT or any potential PPH sequelae such as anemia. Additionally, the analysis was conducted from the health-system perspective and, therefore, did not include the impact of PPH on household productivity and wages for affected women and their families. However, ESM-UBT was still found to be highly cost-effective even when focusing primarily on the health system. If a broadened societal perspective was considered, the overall value of the ESM-UBT could be even greater than that reported here. The present study used cost and impact data from one region in Kenya and applied this information to the entire country—an approach that did not take into account potential differences in costs of care across the various regions. Finally, transfusions were not modeled as a part of the management of PPH. As a result, the impact of ESM-UBT might have been underestimated because UBT use would have reduced the need for transfusion.

In conclusion, the present study provided evidence that ESM-UBT is a cost-effective intervention to reduce hospital transfers, surgeries, and maternal deaths attributable to severe PPH. These findings could be used to inform policymaking for the scale-up of this intervention in Kenya and other low-resource settings.

Author contributions

MM, EA-H, EO, and JM were involved in the design of the study. MM, DK, EA-H, EO, JM, and MO were involved in the planning of the study. DK led the costing data collection, with assistance from EO. TH and TB provided data for the impact analysis. MM conducted the analysis. All authors were involved in writing the manuscript.

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Conflict of interest

The authors have no conflicts of interest.

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Figure legend

Figure 1 Sensitivity analysis for the cost-effectiveness of the Every Second Matters for Mothers and Babies-Uterine Balloon Tamponade device versus standard of care without either uterine packing or UBT (scenario 1). When computing the ICER in the sensitivity analyses, @Risk software randomly draws input values for each variable within the range specified for the sensitivity analysis as shown in Table 1 and Table S1. We ran 10 000 simulations and so there were 10 000 random draws of input values. For low input, the ICER was computed using lower values of each variable, and for high input, the ICER was computed using the higher values of the each variable. Abbreviation: ICER, incremental cost-effectiveness ratio.

Supporting information legends

Figure S1 Scenario 1 for the treatment of PPH. This pathway comprised standard of care without either uterine packing or uterine balloon tamponade. Abbreviation: PPH, postpartum hemorrhage.

Figure S2 Addition of the ESM-UBT device to standard care for the treatment of PPH. This pathway comprised standard of care with the inclusion of a condom UBT.

Abbreviations: ESM-UBT, Every Second Matters-Uterine Balloon Tamponade; PPH, postpartum hemorrhage; UBT, uterine balloon tamponade.

Figure S3 Scenario 2 for the treatment of PPH. This pathway comprised standard of care with uterine packing but without uterine balloon tamponade. Abbreviation: PPH, postpartum hemorrhage.

Figure S4 Sensitivity analysis for the cost-effectiveness of ESM-UBT versus standard care with uterine packing but without uterine balloon tamponade (scenario 2). When computing the ICER in the sensitivity analyses, @Risk software randomly draws input values for each variable within the range specified for the sensitivity analysis as shown in Table 1 and Table S1. We ran 10 000 simulations and so there were 10 000 random draws of input values. For low input, the ICER was computed using lower values of each variable, and for high input, the ICER was computed using the higher values of the each variable. Abbreviations: ESM-UBT, Every Second Matters-Uterine Balloon Tamponade; ICER, incremental cost-effectiveness ratio; PPH, postpartum hemorrhage.

Table S1 Assumptions used to estimate the impact and effectiveness of the interventions.

Table 1 Estimated direct medical and training costs associated with the management of PPH.[a]

Type of cost	**Baseline cost**	**Minimum and maximum costs used in the sensitivity analysis** [b]
Direct medical costs per woman		
Preventive interventions, including injectable uterotonic drugs and mechanical interventions	5.24 [c]	3.93; 7.86
Treatment interventions, including intravenous uterotonic drugs and mechanical interventions	13.88 [d]	10.41; 20.28
Transfer from health center to hospital	17.92 [e]	13.44; 26.88
Additional management at health center if PPH stops or the patient is not transferred	14.64 [f]	10.98; 21.96
Additional management at hospital if PPH stops or surgery is not performed	16.99 [f]	12.74; 25.49
Hysterectomy	197.49 [g]	148.12; 296.24
Hospital bed costs per day	6.37	4.28; 9.56
Training costs per provider	30.29 [h]	NA

Abbreviations: PPH, postpartum hemorrhage; NA, not applicable.

[a] All costs are given in 2015 US dollars.

[b] The β distribution (α=2 and β=2) is assumed for all input values included in the sensitivity analysis. The minimum and maximum values correspond to 75% and 150% of the estimated costs, respectively.

[c] Includes costs for laboratory tests, supplies, drugs, and health-worker time.

[d] Includes costs for supplies, drugs, and health-worker time.

[e] Includes a provider-reported fee of $10 per trip plus staff time for the provider who accompanied the patient.

[f] Includes costs for supplies, drugs, and health-worker time.

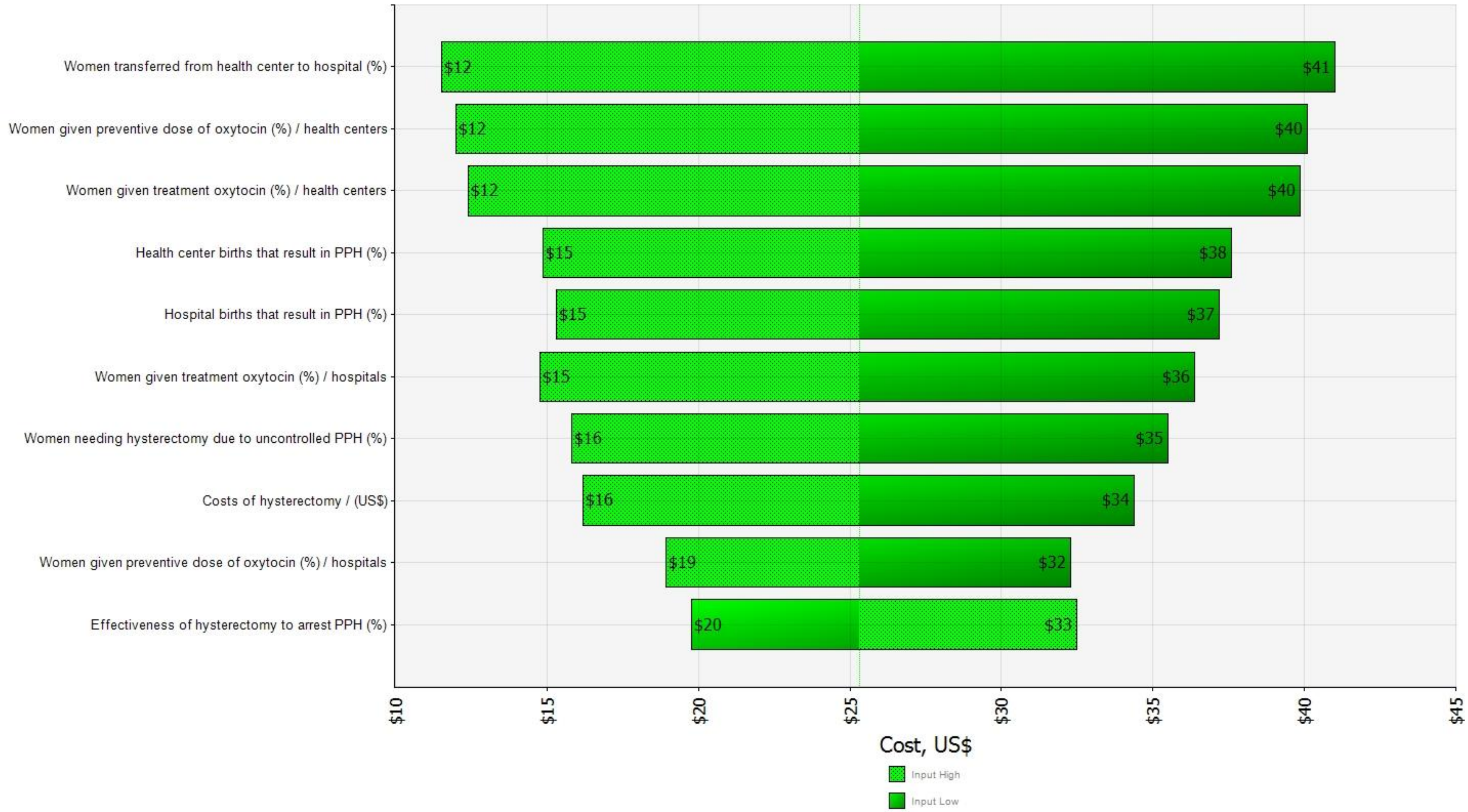
[g] Data from one private facility in Kenya estimated that a hysterectomy costs approximately $300; therefore, a public-sector cost of 50% less is assumed. Drugs and per-day bed costs after hysterectomy are also included in the cost of doing the surgery.

[h] Includes costs for transport, venue and equipment rentals, meals, printing, and office supplies for a 1-day training session.

Table 2 Effectiveness, costs, and cost-effectiveness of various strategies for postpartum hemorrhage management among women in Kenya.[a,b]

Scenario of postpartum hemorrhage management	Transferred to hospital	Underwent hysterectomy to treat postpartum hemorrhage	Deaths	DALYs	ESM-UBT at $5 per device		ESM-UBT at $15 per device	
					Costs	Incremental cost per DALY averted	Costs	Incremental cost per DALY averted
Standard of care without either uterine packing or ESM-UBT (scenario 1)	1390	462	412	23 508	453,884	NA	453,884	NA
With ESM-UBT	135	32	368	20 990	518,225	NA	553,371	NA
Incremental (ESM-UBT minus scenario 1)	–1255	–430	–44	–2518	64,341	26	99,487	40
Standard of care with uterine packing but without ESM-UBT (scenario 2)	1390	148	386	22 013	350,153	NA	350,153	NA
With ESM-UBT	135	32	368	20 990	518,225	NA	553,371	NA
Incremental (ESM-UBT minus scenario 2)	–1255	–116	–18	–1023	168,060	164	203,205	199

Abbreviations: DALY, disability-adjusted life year; ESM-UBT, Every Second Matters-Uterine Balloon Tamponade; NA, not applicable.
[a] Values are given as number, unless otherwise indicated.
[b] Costs are given in 2015 US dollars.



Women transferred from health center to hospital (%)
Women given preventive dose of oxytocin (%) / health centers
Women given treatment oxytocin (%) / health centers
Health center births that result in PPH (%)
Hospital births that result in PPH (%)
Women given treatment oxytocin (%) / hospitals
Women needing hysterectomy due to uncontrolled PPH (%)
Costs of hysterectomy / (US$)
Women given preventive dose of oxytocin (%) / hospitals
Effectiveness of hysterectomy to arrest PPH (%)
$12
$41
$12
$40
$12
$40
$15
$38
$15
$37
$15
$36
$16
$35
$16
$34
$19
$32
$20
$33
$10
$15
$20
$25
$30
$35
$40
$45
Cost, US$
Input High
Input Low