

**USE OF THE NON-PNEUMATIC ANTI-SHOCK GARMENT (NASG) FOR
LIFE-THREATENING OBSTETRIC HEMORRHAGE: A COST-
EFFECTIVENESS ANALYSIS IN EGYPT AND NIGERIA**

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ABSTRACT

USE OF THE NON-PNEUMATIC ANTI-SHOCK GARMENT (NASG) FOR LIFE-THREATENING OBSTETRIC HEMORRHAGE: A COST-EFFECTIVENESS ANALYSIS IN EGYPT AND NIGERIA

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Objective: To assess the cost-effectiveness of a non-pneumatic anti-shock garment (NASG) for obstetric hemorrhage in tertiary hospitals in Egypt and Nigeria.

Methods: We combined published data from pre-intervention/NASG-intervention clinical trials with costs from study sites. For each country, we used observed proportions of initial shock level (mild: mean arterial pressure [MAP] > 60mmHg; severe: MAP ≤ 60mmHg) to define a standard population of 1,000 women presenting in shock. We examined three intervention scenarios: no women in shock receive the NASG, only women in severe shock receive the NASG, and all women in shock receive the NASG. Clinical data included frequencies of adverse health outcomes (mortality, severe morbidity, severe anemia), and interventions to manage bleeding (uterotonics, blood transfusions, hysterectomies). Costs (in 2010 international dollars) included the NASG, training, and clinical interventions. We compared costs and disability-adjusted life years (DALYs) across the intervention scenarios.

Results: For 1000 women presenting in shock, providing the NASG to those in severe shock results in decreased mortality and morbidity, which averts 357 DALYs in Egypt and 2,063 DALYs in Nigeria. Differences in use of interventions result in net savings of \$9,489 in Egypt (primarily due to reduced transfusions) and net costs of \$6,460 in Nigeria, with a cost per DALY averted of \$3.13. Results of providing the NASG for women in mild shock has smaller and uncertain effects due to few clinical events in this data set.

Conclusion: Using the NASG for women in severe shock resulted in markedly improved health outcomes (2-2.9 DALYs averted per woman, primarily due to reduced mortality), with net savings or extremely low cost per DALY averted. This suggests that in resource-limited settings, the NASG is a very cost-effective intervention for women in severe hypovolemic shock. The effects of the NASG for mild shock are less certain.

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I. INTRODUCTION

The global health agenda has prioritized reduction of maternal mortality for the last two decades. Despite a worldwide decline of 35% from 1990 to 2008,[1] many countries will not meet Millennium Development Goal Five (MDG 5) of reducing maternal mortality by 75% before 2015. [2] The majority of maternal deaths occur in resource-limited settings, despite recent improved access to skilled attendance at delivery, maternity homes in rural areas, emergency obstetric care, mobile clinics, and preconception care.[3][4][5]

Obstetric hemorrhage is the most significant contributor to maternal mortality.[6][7] Delays in identifying hemorrhage, reaching tertiary care facilities, and receiving definitive care such as blood transfusions and surgeries are factors that lead to maternal deaths in limited-resource settings. The non-pneumatic anti-shock garment (NASG) is a low-technology device that offers a potential solution to counteract the effect of these delays. Trials of the NASG in Egypt and Nigeria have demonstrated a 46% decrease in blood loss, 45% decrease in mortality and 81% decrease in severe morbidity in women presenting with obstetric hemorrhage of all etiologies.[8]

Implementation of evidence-based maternal mortality interventions is limited by availability of resources and often depends on the strength of the health system.[9] Strategies that target women with intrapartum complications that can be managed with basic emergency obstetric care have been shown to be effective in reducing maternal

mortality.[10] Interventions that can be used broadly within the health system have the most potential for making a large-scale impact. For example, use of misoprostol for community-based treatment of postpartum hemorrhage (PPH) is considered highly cost-effective, with an incremental cost per disability adjusted life year (DALY) of \$6.[11]

However, no analysis has examined the cost-effectiveness of the NASG. Application of cost-effectiveness analyses is often limited by use of simulated data. If possible, clinical results are preferred in order to capture unexpected costs.[12] We conducted a cost-effectiveness analysis of the NASG using results from trials in several tertiary facilities in Egypt and Nigeria.

II. MATERIALS

Overview: We assessed the cost-effectiveness of adding the NASG to standard hypovolemic shock management. We used clinical data from two published intervention trials, in Egypt and Nigeria, on the effects of the NASG added to standard care on maternal morbidity and mortality at tertiary facilities.[8] The analysis focused on a standardized group of 1,000 women presenting in shock, with the proportions of severe (mean arterial pressure [MAP] ≤ 60 mmHg) and mild (MAP > 60 mmHg) shock specified by country to reflect patient characteristics in the clinical trials. We then examined three intervention scenarios: (a) no use of the NASG (i.e., standard care, as the reference case) for any woman in shock; (b) women in severe shock receive the NASG and women in mild shock receive standard care; and (c) all women in shock receive the NASG, regardless of initial shock status. Each scenario was compared incrementally to the reference group (No NASG for any woman in shock). Clinical outcomes (mortality and morbidities) were translated into disability adjusted life years (DALYs), and compared incrementally across scenarios. Costs for the NASG (materials, training, personnel) were collected from project records, and treatments for maternal hemorrhage (e.g., emergency hysterectomy, blood transfusion, and uterotonics) were obtained from local investigators and published sources. All costs were converted into 2010 international dollars. Net cost (or savings) for the NASG was calculated considering the sum of costs for NASG and for clinical management of maternal hemorrhage. Cost-effectiveness was calculated as the cost per DALY averted, which represents the cost for each unit of “disease burden” that

the intervention prevents. We conducted a one-way sensitivity analysis. Methods are further described below and in the Technical Appendix.

Clinical data: We obtained clinical information from two studies that used a two-phase design (pre-intervention (standard care) and NASG intervention plus standard care), conducted in four sites in Nigeria and two sites in Egypt. Funding for these studies came from The John D. and Catherine T. MacArthur Foundation. The pre-intervention phase employed standard care including etiology identification, fluid resuscitation, and uterotonic administration for those with uterine atony.[13] The intervention phase added the NASG. A total of 1,442 patients with obstetric hemorrhage of any etiology (ranging from ectopic pregnancy to ruptured uterus) were studied. The six participating facilities logged over 100,000 deliveries during the study period, with a severe hemorrhage rate of 1.4%. Women with $MAP \leq 60$ had a significantly greater risk of morbidity and mortality and required additional care.[8] Severe morbidity was defined by the Mantel criteria as end-stage organ dysfunction.[14] Additional information is available in the original study manuscripts.[8,15,16]

The NASG (Zoex Corporation, Colma, CA) resembles the bottom half of a neoprene wetsuit with an abdominal foam compression ball and Velcro closures that allow perineal and abdominal access; circumferential pressure reduces blood flow to the pelvis and lower extremities and increases cardiac and cerebral perfusion (Image 1). During the pre-intervention phase, women with hypovolemic shock secondary to obstetric hemorrhage from any etiology were treated with a standardized shock/hemorrhage protocol.[16]

Their outcomes were compared to outcomes for similar women treated with the same protocol and the NASG during the intervention phase.

Variables selected for this analysis were in two categories: treatments and outcomes (Table 1). **Treatment variables** included mean uterotonic doses, mean units transfused blood, emergency hysterectomies for women with a primary diagnosis of uterine atony and hysterectomies for women with any obstetric hemorrhage etiology. **Outcome variables** included mean measured blood loss after drape placement, mean discharge hemoglobin and total number of women with severe anemia or hemoglobin < 7.0g/dl on discharge (approximated from hematocrit by dividing by a factor of 2.95, rounded to 3, for Nigeria[17]), severe morbidity and mortality. We omitted variables that did not differ significantly in the trials by NASG status including other surgeries and procedures.

Deaths were translated to DALYs using a value of 24 DALYs per death in Egypt and 22 per death in Nigeria. This was based on the difference between median age at maternal death, 28 and 30 and life expectancy at age 70 and 64 for Egypt and Nigeria respectively.[18] DALYs per other adverse event ranged from 0.09 for transient severe anemia to 2.5 for infertility secondary to emergency hysterectomy and 9 for long-term motor deficit (which occurred once, in Nigeria). Details on DALYs are provided in the Technical Appendix.

Costs: We included treatment costs in both clinical study phases, as well as program costs in the intervention phase. The following equations were used to calculate costs:

(1) Cost of standard of care

$$= [\text{Uterotonics}] + [\text{Blood transfusions}] + [\text{Emergency hysterectomy}]$$

(2) Cost of NASG intervention

$$= [\text{Uterotonics}] + [\text{Blood transfusions}] + [\text{Emergency hysterectomy}] + [\text{Training}] \\ + [\text{NASG}]$$

Cost categories included clinical material (disposable and reusable), facility, provider, and laboratory. Unit cost data were collected from local investigators at El Galaa Maternity Hospital in Cairo, Egypt, Assiut University Women's Health Center in Assiut, Egypt, University College Hospital in Ibadan, Nigeria and Katsina General Hospital in Katsina, Nigeria (Table 2). Respondents reported using internal cost accounting systems and hospital charges to patients in order to estimate costs. Due to wide (30-fold) differences in uterotonic unit costs across the Nigerian hospitals, we used a conservative market price.[19] We examined uncertainty in unit costs in the sensitivity analyses.

Cost-effectiveness: We developed a cost-effectiveness model in Microsoft Excel 2004 to calculate net costs and DALYs from adding the NASG to a standard protocol for obstetric hemorrhage and hypovolemic shock. Calculations were performed for 1,000 women experiencing life-threatening obstetric hemorrhage, using standard economic methods, and reflecting the country-specific observed proportions of women in mild and severe shock [20]. Net costs (or savings) were calculated across intervention scenarios

(no NASG for women in shock, NASG for severe shock only, and NASG for all women in shock), for each country. Cost-effectiveness was calculated as net cost per DALY averted, or reported as “dominant” for intervention scenarios with lower costs and better health outcomes.

Training costs to treat 1,000 women were annualized assuming that training effects would last 10 years. Training components (venues, trainee per diems, and trainer salaries) and prices were estimated based on the experience in the Nigerian and Egyptian studies.

Intractable uterine atony is the only hemorrhage etiology for which emergency hysterectomy can be directly reduced by the NASG, because pelvic vascular compression can control blood loss until uterine contraction occurs. However, women who present with shock secondary to other obstetric hemorrhage etiologies (e.g., abruption placenta, ruptured uterus) and are stabilized with the NASG may then survive long enough to have the chance to receive the needed hysterectomy. For this reason, costs were examined in two ways: for hysterectomies secondary to primary uterine atony and for hysterectomies of all etiologies. Results were similar for both approaches, so we present results using the narrower scope and can provide the broader analysis on request.

All costs were converted from Egyptian Pounds and Nigerian Naira to 2010 international dollars using the most recently available conversion factors.[21]

We conducted sensitivity analyses to take into account possible variation in our baseline values. A one-way sensitivity analysis adjusted input parameters by 50% above or below the base case or used published ranges if available from prior NASG trials[8,22] (Table 5 and technical appendix). We also examined different approaches to assigning unit costs in Nigeria due to the very different costs between Northern and Southern Nigeria.

There was no direct funding for this cost effectiveness analysis. There are no known conflicts of interest of any of the authors.

III. RESULTS

Clinical outcomes: The published trial data, adjusted to standard cohorts of 1,000 women, are displayed in Table 3 by country and intervention scenario; no NASG for women in shock, NASG for women in severe shock only, and NASG for all women in shock. The clinical effect of the NASG was most significant for women presenting with severe shock. Use of the NASG in this group reduced overall cohort mortality by 52% in both groups (13-91 per 1000 women in shock), and severe morbidities by 50-100% (24-34 per 1000 women in shock). Units of blood transfused decreased by 7% in Egypt and 4% in Nigeria. The number of units of uterotonics administered was roughly 9% lower in Egypt and 25% lower in Nigeria.

When all women received the NASG in Egypt, there were directionally similar but much smaller magnitude and statistically non-significant benefits. In Nigeria, blood transfusions increased by 8.3%, and there were small and statistically non-significant increases in mortality and severe morbidity.

In Egypt, the number of hysterectomies among women with uterine atony was 59% lower if women in severe shock receive the NASG. In Nigeria, there were very few hysterectomies performed; all were in the NASG phase and most were not associated with uterine atony. The reported number of women in severe shock with severe anemia ($Hb < 7.0$) on discharge was lower for women using the NASG, in both Egypt and Nigeria.

These clinical findings translate into 357 DALYs averted by NASG use for women in severe shock in Egypt and 2063 in Nigeria (Table 4). Reduced mortality accounts for most (82-96%) of the DALYs averted in this cohort (not in table) . If women in mild shock also received the NASG, the estimates of incremental changes in DALYs (+27 to -37) are much smaller and unstable due to few clinical events and thus statistical uncertainty in the original studies among women in mild shock.

Costs: The categories of cost include emergency hysterectomies, blood transfusions, uterotonics, and provider training for use of the NASG, and the NASG itself.

In Egypt, per 1,000 women, providing the NASG to women in severe shock resulted in net savings of Intl\$ 9,489. Major savings were derived from reduced blood transfusions (\$9,572). The primary added cost in this group was for the NASG and associated training. In Nigeria, using the NASG for severe shock resulted in incremental net costs of Intl \$6,460. The NASG saved \$3,543in blood transfusions. However, the savings were more than offset by higher costs of more hysterectomies, as well as the costs of the NASG and training. Providing the NASG for all women in shock resulted in further savings in Egypt and further costs in Nigeria, though again with uncertainty due to precision issues.

Cost-effectiveness: Providing the NASG to women in severe shock is cost-saving for Egypt and cost-effective for Nigeria. Cost-effectiveness ratios for women experiencing shock from maternal hemorrhage are summarized in the final columns of Table 4.

In Egypt, providing the NASG for women presenting with severe shock was “dominant,” saving \$9,489 and averting 357 DALYs per 1,000 women. (No cost-effectiveness ratio is needed with lower costs and better outcomes.) The benefits for treating all women with the NASG were lower (37 averted DALYs with \$21,253 in incremental savings), and uncertain due to unstable estimates of clinical outcomes and thus DALYs, as noted above.

In Nigeria, with only women with severe shock receiving the NASG, the NASG had a net cost of \$6,460 and averted 2,063 DALYs, for an incremental cost-effectiveness ratio (ICER) of Intl\$ 3.13 per DALY averted. Unfavorable incremental results occur when women in mild shock also received the NASG: \$9,777 in increased costs and 27 additional DALYs. As with the small gains in Egypt, these results are uncertain due to unstable estimates of clinical outcomes and thus DALYs.

In settings where the intermediate intervention scenario (NASG only for women in severe shock) is considered infeasible, it is appropriate to compare the more extreme scenarios. In Egypt, “NASG for all” option dominates “No NASG”. In Nigeria, this comparison has a cost-effectiveness ratio of \$4.13 per DALY averted.

Sensitivity analyses: One-way cost-effectiveness analyses for the uterine atony-only hysterectomy scenario with women in severe shock only receiving the NASG are presented in Table 5. Per standard protocol, costs were varied +/- 50% unless market

cost ranges were available (i.e. NASG \$1.36-11.06 in Egypt; \$3.90-11.70 in Nigeria; single use). As the cost of blood transfusion increases, the NASG becomes more cost saving in Egypt. Varying the cost of blood by +/- 50%, we found overall cost savings in Egypt ranged from \$4,703-14,275, while in Nigeria the net cost ranged from \$4,688-8,231. Even when the number of units of blood was removed from the equation, the NASG remained cost saving and cost-effective in Egypt and Nigeria, respectively. Removing uterotonics from the equation had a minor effect on the cost-effectiveness.

Although the clinical trials used garments purchased at \$170 USD, the current (higher) market value of \$295 was used in this analysis. When we increased the cost of the NASG at baseline by 50% to \$11.06 (\$11.70 in Nigeria) per use in the severe shock group, the cost savings in Egypt fell by roughly 7% . When we set the price of the NASG at the lowest available market cost of \$53.76 plus cleaning, or \$1.36 per use in Egypt and \$3.90 in Nigeria, savings in Egypt increased by 10% and costs in Nigeria decreased by 43%.

The DALYs health effect estimates for women in severe shock receiving the NASG (+/- 20% for morbidity and mortality; +/- 50% for severe anemia and infertility) are most sensitive to mortality parameters. As the NASG increases its efficacy in saving lives, more DALYs are averted. For example, when the NASG is 20% more effective at mortality reduction, women in severe shock gain an additional 49 DALYs in Egypt and 291 DALYs in Nigeria. Altering the effect of severe morbidity, severe anemia and infertility have less significant impact on total DALYs.

IV. DISCUSSION

For women in severe shock, the NASG intervention, even with conservative assumptions (highest price), is an economically attractive option for health systems aiming to reduce maternal mortality from hemorrhage and shock. It is cost-saving in Egypt, when compared to standard care only. In Nigeria, it is highly cost-effective, \$3 per DALY averted, far below the WHO standard for “very cost-effective” defined as the annual gross domestic product (GDP) per capita.[23] In comparison, a highly favorable maternal mortality intervention in urban India focused on improved intrapartum care had costs of \$150-350 per DALY averted.[24]

Importantly, the NASG provides a very high health benefit for women in severe shock. For each woman in severe shock receiving the garment, the average expected benefit is 2.0 – 2.9 DALYs averted, i.e., between 2 and 3 added years of life. Few interventions provide this magnitude of health gain. The results with mild shock are of far lower magnitude, and uncertain in direction due to small numbers of events (especially deaths) and thus statistical uncertainty in the clinical trials.

The financial benefit of the NASG is that it allows providers to use fewer medical care resources. In some low-income settings, safe units of blood are scarce and often sold on the black market for high prices. In Nigeria, like other developing countries, patients may die because of deficiencies in blood banking or lack of supply.[25] The cost of blood in our analysis is roughly 60 international dollars per unit. In Egypt, patients with the NASG

use, on average, 0.8 fewer units of blood than those without. In Nigeria, blood supply is highly variable: from the authors' clinical experience, patients often receive blood only if a family member donates it, and thus its use may be more contingent on availability than clinical need. Yet the average number of units of blood was slightly lower with the NASG for women in severe shock.

Likewise, women in severe shock who were put in the NASG used an average of one fewer dose of an uterotonic, in both Egypt and Nigeria. While the cost of a dose of uterotonics is significantly less than a unit of blood, each provide an example of how the use of the NASG can conserve resources. Additional research is needed to determine the contexts within and to the degree to which the NASG is effective in reducing use of blood, uterotonics, and number of surgeries.

In this analysis, emergency hysterectomies served as an indicator for the severity of a woman's hemorrhage; if the hemorrhage was uncontrolled, or appeared uncontrollable, by medical or more conservative surgeries, a hysterectomy might be performed as an extreme effort to save the woman's life. In previous trials,[15,16] the efficacy of the NASG was most definitive for women with a diagnosis of uterine atony. Often for women with other diagnoses, such as placental abruption, an emergency hysterectomy still may be required despite the efficacy of the NASG in controlling bleeding; indeed, the NASG may stabilize women enough to permit life-saving hysterectomies. For women in severe shock, hysterectomies decreased with the NASG for both uterine atony and all etiologies in Egypt, thus saving resources. In Nigeria, the rate of hysterectomies overall

was very low (2%), and in the trial only one hysterectomy was performed for a woman with uterine atony who received the NASG. Hysterectomies for other etiologies rose with NASG. Additional studies are needed to determine the efficacy of the NASG in conserving surgical resources across various settings, and if the increase in surgeries was due to the increased chance of a woman surviving long enough to receive the surgery if she had the NASG compared to those who did not.

If the savings due to the averted use of medical resources is excluded, the “crude” ICER for the NASG material costs and training is Intl\$ 6.37 in Egypt and 3.95 in Nigeria (for the analysis including hysterectomies for uterine atony only). This means that use of the NASG appears very cost-effective even in a clinical setting where blood, uterotonics, and surgery are unavailable. Additional studies are needed to determine the cost-effectiveness of the NASG in a variety of clinical settings to set priorities for implementation.

This analysis was stratified by shock level because resource allocation and protocol for shock management is often dependent on severity of shock. The NASG is very favorable for women with severe shock, but has far smaller and, in this study, inconsistent results for those with mild shock. In Egypt, there was only one death in the entire study (N=619) for those in mild shock. As mortality accounts for a majority of DALYs averted in the severe shock phase, the mild shock results are markedly different, with a high proportion of DALYs contributed by the infertility associated with hysterectomies.

In Nigeria, the number of women in the trial's mild shock group (N=127 total pre- and with NASG) was markedly smaller than for the other groups. Nigerian women in these studies had less access to care compared to women in the Egyptian study sites, and were more likely to come to the facility already bleeding and in severe shock. Thus, the standardized cohort size of 1000 exaggerated the number of key clinical events. There were 4 deaths out of 66 without the NASG, and 4 deaths out of 61 with the NASG, suggesting a statistically insignificantly higher mortality in the NASG group. Also, there was only one hysterectomy. Therefore, DALY calculations are highly uncertain. The number of units of blood and doses of uterotonics also increased, for unclear reasons. Perhaps these changes were due to temporal changes associated with better adherence to protocol, or may reflect changes due to availability of resources. More research is needed to determine the cost-effectiveness of the NASG for women presenting in mild shock.

NASG use resulted in reductions in severe morbidity, ranging from 81-100% for women presenting with severe shock. Cost estimates are conservative and exclude cost offsets from a decline in anemia. The NASG reduced the number of women with severe anemia (by 39% in Egypt and 18% in Nigeria). Although we could not measure the effect of anemia on the study participants' postpartum productivity, anemia has been associated with decreased postpartum economic productivity (Galloway 2003[26]).

The range of trial results by site and country indicate that the NASG will have varied effects on clinical practice, morbidity, and mortality, dependent on pre-existing resources and patient condition on arrival. A large-scale, randomized cluster trial currently being

conducted in Zambia and Zimbabwe may shed more light on the effect of the NASG in the context of different health systems.

A limitation of this analysis is the variability in cost collection methods from local investigators. Some sites were only able to report hospital fees for emergency hysterectomy because they had no access to complete cost data. The collected costs were compared to costs detailed in the CHOICE series,[23] which were lower than costs at UCH and El Galaa and similar to the other two sites. A sensitivity analysis was performed in order to more accurately represent health system costs.

Scaling up the NASG by distributing a larger number to each health system region may provide opportunities for greater efficiency. An identical NASG prototype has been developed and tested for \$53.76 per garment as opposed to the current price of \$295[27] per garment, and can be purchased in a minimum order of 1,000 garments (Blue Fuzion, Hong Kong[28]). Additional manufacturers are being added in Asia. The NGO organization PATH has recommended establishment of regional distributors, and of exclusive garment rights, if necessary to protect from excessively high prices.[28] Additionally, if training on the NASG were included in the standard emergency obstetric care curriculum for medical, midwifery and nursing students, programmatic training costs would be reduced.

We found that the NASG is cost saving or highly cost-effective for women in severe hypovolemic shock when administered in a tertiary care setting. It may become even less

costly to implement if sales prices continue to decrease, and it becomes part of pre-service training. Future research is needed to validate the cost-effectiveness and efficacy of the NASG in other settings. The Zambia and Zimbabwe trial noted above compares effect on outcomes of earlier application of the NASG at the community level before transport to tertiary facilities. Once those results are published, we will conduct a CEA of NASG use to determine level of care at which the NASG will be most cost-effective.

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LIST OF FIGURES

Figure 1: Image of nurse applying non-pneumatic shock garment (NASG) to study patient in Nigeria[1]

[1] Both the provider and patient have given informed consent to publication of their photograph.



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Table 1. Clinical trial results for women with shock from maternal hemorrhage, by country, shock severity, and use or non-use of the non-pneumatic anti-shock garment (NASG).

		Egypt		Nigeria	
		No NASG	NASG	No NASG	NASG
1. Number of women in study trials, unstandardized	All	432	558	175	277
	Severe Shock	72	106	109	215
2. Mean units of blood transfused per patient[1]	All	2.30	1.61	1.81	1.96
	Severe Shock	3.30	2.38	2.06	1.96
3. Emergency hysterectomy, rate per 1,000 [2]	All	34.01	32.26	0	3.62
	Severe Shock	180.56	56.60	0	4.65
4. Mean units of uterotonics given per patient (all)[3]	All	2.01	1.71	2.59	1.58
	Severe Shock	2.70	1.65	2.65	1.68
5. Proportion of women with discharge Hb<7.0g/dl	All	4.5%	4.9%	69.1%	61.5%
	Severe Shock	20.0%	12.2%	80.4%	66.2%
6. Severe morbidity, %	All	4.1%	0.9%	2.7%	0.4%
	Severe Shock	16.7%	3.1%	4.7%	0.0%
7. Mortality, %	All	2.3%	1.1%	16.0%	8.7%
	Severe Shock	12.5%	5.7%	22.0%	9.3%

[1]. 450 mls per unit [2]. Uterine atony only [3]. Oxytocin and Ergometrine

Table 2. Unit costs by study site, 2010 (Int\$)[1]

Costs	Egypt			Nigeria		
	El Galaa	Assiut	Average	UCH	Katsina	Average
1. Hysterectomy[2]	514.72	51.47	283.09	831.03	75.40	453.21
2. 500ml Blood transfusion	77.21	51.47	64.34	83.10	32.78	57.94
3. 10iu Oxytocin	1.12	1.16	1.14	1.11[3]	0.41	0.76
4. 0.2mg Ergometrol	1.02	1.02	1.02	4.16	0.27	2.21
5. Training cost per patient[4]	5.27	5.27	5.27	3.57	3.57	3.57
6. NASG per use[5]	7.39	7.38	7.38	7.79	7.79	7.79

[1]. Costs were adjusted from local currency to international dollar with most recently available purchasing power parity (PPP) factors of 2 for Egypt and 78 for Nigeria.²¹ Refer to Technical Appendix for a detailed explanation.

[2]. Differences in hysterectomy cost were investigated and confirmed with local investigators.

[3]. Oxytocin cost from PATH report²⁸ for price per dose of \$0.55 USD for an occasional purchase, medium volume.

[4]. Training costs were standardized across project sites and include provider time during the training.

[5]. Cost includes purchase price of \$295 USD based on 40 uses.

Table 3. Treatments and outcomes for standardized cohorts of 1,000 women with shock from maternal hemorrhage, by NASG intervention scenario[1,2]

	Egypt			Nigeria		
Intervention scenario:	No NASG	NASG only if MAP<60	NASG for all	No NASG	NASG only if MAP<60	NASG for all
1. Projected total blood transfusion for 1,000 women, mls	1,045,821	971,435	722,024	843,555	812,981	880,606
2. Emergency hysterectomies						
Emergency hysterectomy-uterine atony dx only, n	37	15	32	0	3	3
All emergency hysterectomies	95	68	54	0	17	21
3. Uterotonic (any)						
Oxytocin, total 10iu doses	1,433	1,303	1,226	2,401	1,793	1,499
Ergometrine, total .2mg doses	578	520	488	191	99	80
4. Total number of women with discharge Hb<7.0g/dl	59	45	53	739	637	626
5. Severe morbidity, n	48	24	9	34	0	5
6. Mortality, n	25	12	10	175	84	85

[1]. Proportion of cohort with severe shock (MAP<60) is 18% for Egypt and 72% for Nigeria. This is derived from clinical trial data^{15,16}, combining pre and post trial periods.

[2]. Top 3 definitive diagnoses by country and study phase: Egypt: [Pre (N=432): Uterine atony (34%), Ectopic pregnancy (19%), Placental abruption (14%)] [Post (N=558): Uterine atony (44%), Abortion complications (14%), Ectopic pregnancy (13%)] Nigeria [Pre (N=175): Retained placenta (30%), Uterine atony (25%), Placental abruption (11%)] [Post (N=277): (Uterine atony (26%), Retained placenta (23%), Placental abruption (17%)]

Table 4. Calculated mortality, morbidity, disability-adjusted life years, cost, and cost-effectiveness for 1,000 women with severe or mild shock[1] from maternal hemorrhage, by intervention scenario.

Intervention scenario	Mortality		Morbidity		Total DALYs		Cost		ICER (\$ per DALY averted)[3]	
	# per 1000	Difference[2]	# per 1000	Difference	# per 1000	Difference	\$ per 1000	Difference	Incremental	vs. No NASG
Egypt										
No NASG	24.7		48		730		147,248			
NASG only if MAP < 60	12.4	-49.79%	24	-50.59%	372	-357	137,760	-9,489	Dominant	
NASG for all[4]	10.2	-17.93%	9	-159.39%	335	-37	116,507	-21,253	Dominant	Dominant
Nigeria										
No NASG	175.0		34		3960		100,003			
NASG only if MAP < 60	83.8	-52.09%	0	-100.00%	1896	-2063	106,463	6,460	\$3.13	
NASG for all[4]	85.2	1.68%	5	N/A	1923	27	116,240	9,777	Dominated	\$7.97

1. Proportion of cohort with severe shock (MAP<60) is 18% for Egypt¹⁶ and 72%¹⁵ for Nigeria (from clinical trial, combining pre and post trial periods).
2. "Difference" is versus prior row (scenario). Negative values in "difference" columns are desirable -- disease burden or cost averted.
3. "Dominant" means cheaper and better health outcomes than previous intervention scenario. "Dominated" means more costly and worse outcomes than previous scenario.
4. Results for "NASG only if MAP <60" are more stable than for the incremental effect of "NASG for all", due to the small number of clinical events for mild shock group in original trials; see text.

Table 5: One-way sensitivity analysis on cost and health differences between two intervention scenarios: NASG for severe shock and No NASG

	Egypt			Nigeria		
	Input values		Results: Difference between NASG for severe shock and No NASG	Input values		Results: Difference between NASG for severe shock and No NASG
Input	Base case	Lower and upper bound		Base case	Lower and upper bound	
Costs			Net \$ per 1000 women with shock			Net \$ per 1000 women with shock
Base case result			-\$9,489			\$6,460
1. NASG (per use)	\$7.38	1.36[1], 11.06	-10,572, -8,828	\$7.79	3.9[1], 11.7	3,671, 9,262
2. Uterotonics	\$1.14	0.57, 1.71	-9,388, -9,603	\$0.76	0.38, 1.14	6,327, 6,858
3. Blood transfusion	\$64.34	32.17, 96.51	-4,703, -14,275	\$58	29, 87	8,231, 4,688
4. Emerg. Hyst	\$283.09	141.55, 424.64	-6,334, -12,643	\$453	227, 680	5,704, 7,215
Health			Change in DALYs per 1000 women with shock			Change in DALYs per 1000 women with shock
Base case result			-357			-2,063
1. Mortality effect[2]	1.00	0.80, 1.2	-406, -309	1.00	0.80, 1.2	-2,354, -1,772
2. Morbidity effect	1.00	0.80, 1.2	-364, -351	1.00	0.80, 1.2	-2,074, -2,053
3. Severe anemia effect	1.00	0.50, 1.5	-358, -356	1.00	0.50, 1.5	-2,085, -2,041
4. Infertility	1.00	0.50, 1.5	-371, -344	1.00	0.50, 1.5	-2,068, -2059

[1] Price based on cost provided by Blue Fuzion based in Hong Kong.

[2]. Health effect indicates risk of event compared with the base case, i.e., effect = 0.80 means 20% lower risk of mortality or morbidity for the "NASG for severe shock" scenario than assumed in the main analysis.

Appendix I. Cost-effectiveness calculations

Analysis overview: Calculations were performed in Excel 2004. The analysis was stratified by country, study phase and mean arterial pressure (MAP) on study admission. MAP was calculated by: $((2 \times \text{diastolic blood pressure}) + \text{systolic blood pressure}) / 3$. For each country, we used observed proportions of initial shock level (mild: mean arterial pressure [MAP] > 60mmHg; severe: MAP ≤ 60mmHg) to define a standard population of 1,000 women presenting in shock. We examined three intervention scenarios: no women in shock receive the NASG, only women in severe shock receive the NASG, and all women in shock receive the NASG.

Costs: The costs of uterotonics, misoprostol (200ug), ergometrine (0.2mg) and oxytocin (10iu), and one liter of bleach for NASG disinfecting were estimated by using the pharmacy nearest to the hospital as a reference. In Nigeria, the cost of oxytocin obtained from one hospital, UCH, was almost 40x greater than the other facility and all estimates in the literature; in absence of a reliable confirmation of this cost, we used a standardized value from the literature.[1] In Egypt, we used a weighted average of the costs for ergometrine and oxytocin to estimate total costs for uterotonics. For blood transfusion, providers were asked to report the unit price of a 500ml blood transfusion, in addition to any transaction costs and laboratory fees such as, cross-matching and cost of testing for communicable diseases (human immunodeficiency virus (HIV), Hepatitis B & C). Emergency hysterectomy costs included a facility fee, provider fee, materials (disposable and non-disposable) and medications, if applicable.

Training costs for obstetric care providers (nurses, nurse-midwives and physicians) at study sites were calculated by the project manager at the University of California, San Francisco (UCSF) with receipts from the original training sessions and included cost of local trainer salary, national travel for the trainer, local transport, refreshments and room and equipment rental. The model also considered the number of staff that had to be trained, annual deliveries, and the number of training sessions per day with a maximum number of twenty individuals trained per session. Clinically, providers were trained to apply the garment, monitor vital signs, level of consciousness, urine output, blood loss, apply standard protocols for vaginal procedures and/or hemostatic surgeries, and correct NASG removal. Providers, public health personnel, were paid their normal salary during the hour-long training, but may have missed income from elective procedures or private practice income. The collective physician time spent was assumed to be 20 hours at a wage of \$15.44 per hour. [2] Although each provider only needs to be trained once over the course of a lifetime, we assumed in this analysis that the training was valid for ten years.

The manufacturer price and the cost associated with cleaning the NASG with bleach between uses was collected. Cost of the NASG was determined by dividing the manufacturer's suggested retail price by a standard number of forty uses determined by prior pilot studies and addition of cleaning costs.[3] The bleach dilution factor for garment disinfection is a 0.05% bleach solution, with 50ml bleach in 4,950ml water and a total of 2L bleach required over the NASG lifetime. To account for inaccurate dilution, theft or missing

bleach bottles, the amount of bleach was doubled in calculations. Investigators were asked to provide daily wages for cleaning staff, which ranged from \$0.13-\$1.52 per eight hour shift. With only one or two garments used per day at the highest volume facilities, the labor cost of cleaning the garment were estimated to be less than \$0.01/ day and was not included in this analysis.

Collected costs were compared to WHO CHOICE regional estimates. For example, the CHOICE estimate for hysterectomy, one of the most significant analysis costs, was expected to be lower than study estimates because it was calculated in 2000 I\$. The CHOICE regional estimates were similar to costs provided at Assuit and Katsina Hospital, but were significantly lower than costs at the university hospitals, El Galaa and UCH. We were unable to collect costs for two sites in northern Nigeria because the study had closed these sites prior to this analysis. As a result, we made estimates using costs from proximate hospitals that had similar provider and resource access profiles. One hospital, MMSH, was a government hospital and had similar resource availability to Katsina General Hospital, while the other, AKTH, was a teaching hospital, with a cost and resource profile more similar to UCH.

Cost-effectiveness calculations: To calculate baseline values, disability-adjusted life years (DALYs) were calculated as the sum of the total years of life lost due to mortality (YLL) and years of life lost due to disability (YLD) (Table 4; YLD/YLL not shown). YLL was calculated by discounting the difference of the average age of maternal death in our study and the age-adjusted female life expectancy.[4] YLD included anemia, infertility secondary to hysterectomy and severe morbidities (heart failure, renal failure, cerebral impairment and motor deficits).[5] YLD for severe anemia, heart failure, acute renal failure and acute respiratory distress was calculated with a standard disability weights from the literature assuming durations less than a year because no discharge follow-up information was available to assess the sequelae, if any, of these peripartum injuries.[6] Infertility's disability weight was discounted at 3% over average national reproductive spans available in the literature from the hysterectomy cases indicated for a primary uterine atony diagnosis. The weights for cerebral impairment and motor deficits were discounted for 3% over the average woman's lifetime due to the poor or non-existent rehabilitation options.

The incremental cost-effectiveness ratio (ICER), the change in costs divided by the change in DALYs, was calculated to compare the NASG intervention with standard care. In the text, "Dominant" means cheaper and better health outcomes than previous intervention scenario, while "Dominated" means more costly and worse outcomes than previous scenario. In the two incremental Egyptian scenarios, there were net-savings and DALYs averted which resulted in negative ICERs, which were not reported because they have no intrinsic meaning.[7] These intervention scenarios were labeled "Dominant" scenarios. In Nigeria, providing the NASG incrementally for all women as opposed to women in severe shock only resulted in a "Dominated" scenario. However, when the NASG was provided for all women and compared to the "No NASG" scenario, there was an ICER of \$7.97. As explained in the text, ICERs are presented in Table 4 for the severe shock group in Nigeria.

Sensitivity analysis: All sensitivity analyses were performed from the perspective of the

uterine atony-only hysterectomy group comparing the health costs and outcomes of “No NASG” standard care for all women in shock vs. the NASG for women in severe shock only. For the one-way sensitivity analysis, we used an interval for the variables that was wide enough for the assumptions of the model to be credible. Cost outcomes were assessed assuming 50% variance, with the exception of the NASG low value, \$53.76.[3] Health outcomes, such as morbidity, mortality, emergency hysterectomy and severe anemia were also assessed using 20% variance for the rare outcomes of mortality and severe morbidity and assuming 50% variance for severe anemia and infertility. The variance, or health effect, indicates the risk of the event (i.e. mortality) compared to the base case. Therefore, an effect of 0.80 on mortality indicates a 20% decrease in mortality risk in the “NASG for severe shock only” scenario. After a high or low value had been calculated for each variable, the value (or the scale factor multiplied by the base value) was substituted in each original cost or DALY cell, and the change in package cost or change in DALY from intervention to standard care analysis was documented and corresponding ICERs were calculated. The outputs of the sensitivity analysis for cost and DALY values were then compared to baseline values.

Differences in study sites: While patients in both countries were low income and using the public health care system, the health system contexts, health care infrastructures, and human and capital resources differed. For example, Egypt’s life expectancy for a female was 70 years in 2010 while Nigeria’s was 52.[4] Further, Egypt’s MMR is 43/100,000 compared to Nigeria’s MMR of 608/100,000 births.[8] In fact, while Egypt is one of the only countries that met MDG5, Nigeria is one of six countries that contributed to 50% of all maternal deaths.[8]

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