

# Factors Affecting Peripartum Blood Transfusion in Women Undergoing Cesarean Section

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## Abstract

**Background:** Postpartum hemorrhage is the most common cause of maternal death in developing countries. Since no known risk factors are observed in a number of women who experience postpartum hemorrhage and blood transfusion, this study was conducted with the aim of determining risk factors of blood transfusion in women who underwent cesarean. **Methods:** This cross-sectional study was conducted in 2022 and 2023 in two hospitals in Tehran. Demographic characteristics of mother and newborn, and information about pregnancy and cesarean of 54 women who underwent cesarean and received blood during the peripartum period and 108 women who did not receive blood were recorded and compared to determine risk factors of needing blood transfusion in the peripartum period in women who underwent cesarean. **Results:** The results showed that the two groups in terms of mother's age ( $P < 0.001$ ), gestational age ( $P = 0.001$ ), number of previous births ( $p = 0.015$ ), mother's body mass index ( $P = 0.019$ ), sufficient number of visits during pregnancy ( $P < 0.0001$ ), weight of the newborn ( $P = 0.045$ ), frequency of cesareans that lasted more than 60 minutes, the cesareans that were completed during the night shift ( $P < 0.001$ ) were significantly different. Also, these groups had significantly difference in terms of emergency cesarean ( $P = 0.005$ ), cesarean in the active phase ( $P = 0.007$ ), uterine atony ( $P < 0.001$ ), preoperative hemoglobin and hematocrit level and women with hemoglobin less than 9 g/dL ( $P < 0.001$ ). **Conclusion:** The results of this study showed that some factors increase the probability of peripartum hemorrhage and some of these factors can be corrected. Probably, paying attention to these risk factors will reduce the amount and better management of peripartum hemorrhage in women who undergo cesarean.

**Keywords:** Cesarean Section, Peripartum, Blood transfusion, Postpartum hemorrhage.

## Introduction

Postpartum hemorrhage (PPH) is the most common cause of maternal mortality and is responsible for about 30% or more of maternal deaths in all countries of the world and in developing countries [1,2]. This complication occurs in about 2.5 to 12% of births [1,3,4]. Causes of PPH include uterine atony, abnormal placentation, genital tract trauma, and coagulopathy. Transfusion of blood and blood products is an important part of PPH management, especially in patients with critical condition [5].

It is estimated that on average, 1.3% to 1.6% of obstetric cases require the injection of blood products [3,6], although this rate varies in different regions and ranges from 0.16 to 6% [6]. The most common causes are PPH, placental causes, and anemia [6,7]. The most important risk factors of blood transfusion are maternal anemia, increasing maternal age, increasing maternal parity, multiple births, trial of labor, placenta previa, abruptio placenta, abnormal adhesion of the placenta, induction and augmentation, preterm labor, history of cesarean, vascular disease, history of PPH, preeclampsia, HELLP syndrome and coagulation disorders [3,6]. We realize that there are a

number of risk factors for PPH in some mothers who come for delivery, and on the other hand, PPH may occur in persons who do not have any known risk factors for it. And this issue makes it difficult to predict it [1,8]. Therefore, conducting studies to identify individual risk factors and the existence of protocols for prevention (in cases that can be modified and adjusted) and management of PPH is necessary and helpful. In addition, determining risk factors for transfusion of blood and blood products in obstetrics cases, can improve the ability to manage bleeding complications and the possibility of preparing products. It also makes the limited resources of medical centers to be used well and provides the possibility of referring patients to more equipped centers. Since cesarean is one of the known risk factors of PPH [5], this study was conducted with the aim of determining risk factors of blood transfusion in cesarean patients.

## Methods

After obtaining the code of ethics from the ethics committee of Shahid Beheshti University of Medical Sciences (IR.SBMU.RETECH.REC.1402.145) this cross-sectional study was

conducted in the year 2002 and 2003. The study was performed on 162 women aged 18 years and older with 26 weeks or more gestational age who underwent cesarean in two university hospitals of Taleghani and Akbarabadi. After the start of the work, all the women who received blood in peripartum period were included in the study until the sample was completed (54 women). For each woman in the blood receiving group, two women who had a cesarean after her and did not receive blood (108 women) entered the control group. Exclusion criteria were the presence of known malignancy and bone marrow failure and non-Iranian and Afghan patients.

In this study, peripartum transfusion meant the injection of blood transfusion in the 48 hours before cesarean, during cesarean, or the first 24 hours after cesarean. Hemoglobin, hematocrit, and platelet levels before cesarean meant the patient's last level of hemoglobin, hematocrit, and platelets before cesarean, which was usually performed at a short distance from cesarean.

In this study, women with symptomatic anemia or women with a hemoglobin level equal to or less than 8 g/dL (regardless of having or not having symptoms) had blood transfusion. In these centers, in a person with active bleeding, 2 units of packed RBC were first transfused, and if the bleeding continued, two more units of packed RBC and 2 units of fresh frozen plasma (FFP) were injected. In case of need for more blood transfusion, massive transfusion protocol (MTP) was used, i.e., injection of 1 unit of FFP for every 1.4 unit of packed RBC. Also, in women with obstetric hemorrhage, the platelet level was kept above 50,000/ $\mu$ L by platelet injection. Also, in case of fibrinogen level < 200 mg/dL or prolongation of PT or PTT, FFP injection at the rate of 10 to 15 mL/Kg or cryoprecipitate was performed.

After selecting the patient and giving an oral explanation and obtaining informed consent, an information form was completed for her. This form included mother's age in years, mother's pre-pregnancy BMI in kg/m<sup>2</sup>, gestational age in days, mother's education level (illiterate, under diploma or diploma and above diploma), whether the mother is Iranian or Afghan, being employed or housewife, number of prenatal visits during recent pregnancy, number of deliveries, cesareans and abortions, use of assisted reproductive technology, the reason for cesarean, elective or emergency (latent phase or active phase of labor or being out of labor), cesarean, use of oxytocin before cesarean, presence of diabetes (overt or gestational), hypertensive disorders (gestational, severe and non-severe preeclampsia, eclampsia, chronic), HELLP syndrome, presence of other underlying diseases, history of previous surgery except cesarean, abruptio placenta, placenta previa, abnormal placentation (was defined as placenta accreta, increta or percreta), multiple pregnancy, bleeding disorders, meconium, atony, abnormal liver function tests before cesarean, polyhydramnios, cesarean hysterectomy, use of anticoagulants during pregnancy, history of PPH or blood transfusions in previous pregnancies, history of blood transfusions in recent pregnancies, platelet, hemoglobin, and hematocrit levels before cesarean, hospitalization of the mother in ICU before or after cesarean, The duration of the operation in minutes, performing cesarean on a working day or holiday, the time of completion of the operation (in the morning, evening, or night shift), performing other surgery at the time of cesarean, sex and weight of the newborn, and still birth.

SPSS 16.0 for windows was used for statistical analysis. Numerical data was expressed in the form of mean and standard deviation, while categorical data were given as frequency and percentage. The Kolmogorov-Smirnov test was used to assess whether non-categorical data follows the normal distribution or not. Comparison of data abiding by normal distribution was done by using the student t test. But comparison of data not abiding with normal distribution was performed by using the Mann-Whitney U test. Comparison of categorical data in the groups used the chi-square test. P<0.05 was considered significant in all comparisons.

## Results

The results of the study showed that the average unit of blood injected in 54 women was  $1.61 \pm 1.04$  units, with a minimum of 1 and a maximum of 7 units. Three women received 5 units of platelets each. Six patients (11.1%) received FFP, 2 patients 1 unit, 2 patients 2 units, 1 patient 3 units, and 1 patient 4 units. Fibrinogen was also injected for 1 person.

In both groups, no person had platelets below 50,000/ $\mu$ L. 3 subjects in the infusion group had platelets below 100,000/ $\mu$ L, but none in the non-infusion group had platelets below 100,000/mL. In total, 7 women (4.3%) had hemoglobin below 9 g/dL, all of them were in the injection group, and in this regard, there was a significant difference between the two groups. (P<0.001) Also, 14 women in the group without injection and 4 women in the group with injection had hemoglobin below 10 g/dL, and from this point there was a significant difference between the two groups (P<0.001).

As seen in Tables 1 and 2, the results of the study showed that the two groups have significant difference in terms of maternal age (P<0.001), gestational age (P=0.001), number of previous births (P=0.015), maternal body mass index (P=0.019), sufficient number of visits during pregnancy (P<0.0001), newborn weight (P=0.045), and frequency of cesareans that lasted more than 60 minutes. Also, these groups have significantly difference in terms of cesareans that ended in the night shift and cesareans that were completed between midnight and 4 am (p<0.001) and emergency cesarean (p=0.005) and cesarean in the active phase (p=0.007), uterine atony, and preoperative hemoglobin and hematocrit levels (p<0.001).

Also, the results showed that one, zero, and one person in the group without blood transfusion, respectively, had received blood in the recent pregnancy, had bleeding disorders, and had abnormal liver tests before cesarean. This number was zero, one and three in the blood transfusion group, respectively.

There was one case of still birth in each group. In the group without injection for 5 women and in the group with injection for 3 women, another surgery was performed at the same time as cesarean. Also, in the group without injection, there was no case of cesarean hysterectomy and abnormal placental adhesion, but there was one case of each in the other group. Also, in the group without injection, there was one case with polyhydramnios, but there was no case in the other group.

12 women in the group that received blood were admitted to the ICU, but no person in the group without blood transfusion was admitted to the ICU, and the two groups had a significant difference in this respect as expected (P<0.001).

**Table 1: Comparison of maternal characteristics in two groups with and without blood transfusion in 162 women who underwent cesarean section.**

Variable	Group with blood transfusion n: 54	Group without blood transfusion n: 108	P-value
maternal age(year)*	31.98 $\pm$ 6.68	28.07 $\pm$ 6.35	<0.001
gestational age (day)*	258.2 $\pm$ 23.2	268.9 $\pm$ 13.03	0.001
Parity*	1.41 $\pm$ 1.58	0.69 $\pm$ 0.84	0.015
number of abortion(s)*	0.48 $\pm$ 0.84	0.29 $\pm$ 0.6	0.136
number of previous cesarean sections*	0.61 $\pm$ 0.94	0.43 $\pm$ 0.64	0.483
history of previous surgery (except cesarean section) **	7 (13)	26 (24.1)	0.098

history of previous abdominal surgery (except cesarean section) **	2 (3.7)	14 (13)	0.173
Blood transfusion during previous pregnancy**	1 (1.9)	4 (3.7)	0.539
maternal BMI (kg/m <sup>2</sup> ) **			0.019
<18.5	2 (3.7)	2 (1.9)	
18.5- 24.9	27 (50)	27 (25)	
25- 29.9	17 (31.5)	52 (48.1)	
30-34.9	6 (11.1)	18 (16.7)	
35- 39.9	1 (1.9)	6 (5.6)	
>40	1 (1.9)	3 (2.8)	
maternal education**			0.124
illiterate	14(25.9)	17 (15.7)	
under diploma or diploma	34 (63)	65 (60.2)	
above diploma	6 (11.1)	26 (24.1)	
maternal Employment status**			0.693
house wife	52 (96.3)	101 (93.5)	
employed	2 (3.7)	7 (6.5)	
Nationality**			0.361
Iranian	37 (68.5)	78 (72.2)	
Afghan	17 (31.5)	30 (27.8)	
Adequate prenatal visits**	23 (42.6)	90 (83.3)	<0.0001
Having diabetes during pregnancy**			0.476
absence	44 (81.5)	86 (79.6)	
Gestational diabet	10 (18.5)	21 (19.5)	
Overt diabet	0 (0)	1 (0.9)	
Having hypertensive disorders during pregnancy**			0.109
absence	48 (88.9)	102 (94.4)	
Hypertensive disorders during pregnancy	4 (7.4)	6 (5.6)	
HELLP syndrome	2 (3.7)	0 (0)	
presence of other underlying diseases**	13 (24.1)	22 (20.4)	0.589
use of assisted reproductive technology **	3 (5.6)	11 (10.2)	0.552
use of anticoagulants during pregnancy**	3 (5.6)	7 (6.5)	0.559
Fetus sex (female)**	23 (40.35)	50 (46.30)	0.742
neonatal weight**			0.045
< 2500	13 (24.1)	10 (9.3)	
2500-4000	37 (68.5)	91 (84.3)	
>4000	4 (7.4)	7 (6.5)	
Duration of surgery more than 60 minutes**	23 (42.6)	25 (23.1)	<0.001
Time of completion of surgery**			<0.001
morning shift	9 (16.7)	52 (48.1)	
evening shift	15 (27.8)	28 (25.9)	
night shift	30 (55.6)	23 (21.3)	
performing cesarean**			0.105
on a working day	40 (74.1)	98 (90.7)	
on holiday	14 (25.9)	10 (9.3)	
Time of completion of surgery**			<0.001
Between midnight and 4 am	14 (25.9)	4 (3.7)	
Between 4 am and midnight	40 (74.1)	104 (96.3)	

\*mean  $\pm$  SD; \*\* n (%); BMI: body mass index

**Table 2: Comparison of surgical characteristics in two groups with and without blood transfusion in 162 women who underwent cesarean section.**

Variable	Group with blood transfusion n: 54	Group without blood transfusion n:108	P-value
Cesarean section due**			0.075
Repeat C/S	18 (33.3)	43 (39.8)	
Twin pregnancy	3 (5.6)	5 (4.6)	
meconium	4 (7.4)	10 (9.3)	
Fetal distress	6 (11.1)	22 (21.4)	
Abnormal presentation	3 (5.6)	6 (5.6)	
Intra uterine growth restriction (IUGR)	0 (0)		
failure to progress	10 (18.5)	6 (5.6)	
placenta previa	4 (7.4)	2 (1.9)	
maternal request	2 (3.7)	4 (3.7)	
other	3 (5.6)	7 (6.4)	
Emergency cesarean section**	33 (61.1)	68 (63)	0.005
Cesarean section in**			0.007
Active phase	10 (18.5)	10 (9.3)	
Latent phase	37 (68.5)	59 (54.6)	
Out of labor	7 (13)	39 (36.1)	

pre C/S hemoglobin*	10.88 ± 1.71	12.27 ± 1.11	<0.001
pre C/S hematocrit*	32.46 ± 3.36	36.79 ± 3.19	<0.001
pre C/S platelet*	203.2 ± 64.44	219.4 ± 63.39	0.072
Placenta previa*	4 (7.4)	2 (1.9)	0.105
meconium*	4 (7.4)	10 (9.3)	0.805
abruptio placenta*	1 (1.9)	2 (1.9)	0.988
uterine atony*	8 (14.8)	1 (0.9)	<0.001
twin pregnancy*	3 (5.6)	5 (4.6)	0.719
use of oxytocin before cesarean section*	9 (16.7)	11 (10.2)	0.308

\*mean ± SD; \*\* n (%)

## Discussion

The results of the recent study showed that the average packed RBC injected in 54 women who underwent cesarean was 1.61 units, the average injected platelet was 0.28 units and the average injected FFP was 0.24 units. These values were found in Sushil's study, which reported blood product transfusion values in 32 women who gave birth in India: 2.46 units of RBC, 2.06 units of FFP, and 0.46 units of platelet concentrate [6] and in Salik's study, which was conducted in Turkey on 156 women who gave birth, it was 2.12, 1.13, 0.14 units respectively [3]. It is possible that the reason for the lower values in our study is that most of the patients in the current study were visited in sufficient numbers during pregnancy and were treated in the prenatal period in case of anemia. On the other hand, our study included patients who underwent cesarean, but Sushil's study included patients who had vaginal delivery, cesarean, and even abortion. Salik's study included patients with cesarean and vaginal delivery, and although the amount of blood loss is higher in cesarean patients, but perhaps more accurate control of these patients will allow PPH to be recognized and treated in the early stages.

In the present study, it was shown that the level of hemoglobin and hematocrit before cesarean and the frequency of women who had hemoglobin less than 10 g/dL were significantly higher in patients who received blood after the operation than in the other group (P<0.001). Like this study, in Wang's study, which is very similar in design to our study, 71 women who received blood after cesarean and 170 who did not receive blood had a significant difference in terms of hemoglobin (P=0.006) and hematocrit (P<0.001) before the operation [9]. This issue has also been shown in the studies of Davis, Ehrenthal, Rottenstreich [10,11,12]. Therefore, women should be checked for anemia before giving birth and treated if diagnosed. Also, if someone has low hemoglobin at the time of delivery, the necessary measures should be taken to prevent bleeding and prepare blood products. In our study, as in the studies of Salik & Wang, the mean platelet count before delivery was not significantly different in two groups with blood transfusion and without blood transfusion [3,9]. However, it should be noted that in our study, only two women had platelets less than 100,000/μL, and in order to investigate the relationship between the preoperative platelet count and the need to inject blood products, a study should be conducted on a sufficient number of women with low platelet counts.

In the present study, there was a significant difference between the two groups in terms of maternal age (P<0.001). Thus, the average age of mothers in the group that received blood was higher than the other group. This issue has been shown in other studies [2,9,12,13]. Maybe the reason is that maternal comorbidities are more in these women and maybe their referral for prenatal care is less.

In the present study, the two groups had a significant difference in terms of the mother's BMI (P=0.019), so that the frequency of women with a BMI greater than 24.9 in the group without blood transfusion was about 2 times that of the other group. This issue may be due to greater blood volume in individuals with a higher BMI. Also, in the present study, two groups had a significant difference in terms of gestational age.

Thus, the average gestational age in the group that received blood was lower than the other group. This issue has been shown in other studies [2,9]. The reason for the difference may be that premature births occur both spontaneously or iatrogenic and secondary to factors that increase the need for blood transfusions.

In the present study, there was no significant difference between the two groups in terms of gestational diabetes. This result has been shown in other studies [3,11]. Probably the reason is that today gestational diabetes is carefully screened and treated and usually does not have many complications.

Of course, this issue may not be true for diabetes mellitus, as Ouh's study in Korea showed that the two groups requiring and not requiring blood transfusion in the peripartum period were significantly different in terms of FBS and FBS ≥ 126 before pregnancy (P< 0.001, P<0.001) [2]. Although some studies have not shown that preeclampsia is a risk factor for PPH [2], but preeclampsia is associated with increased systemic vascular resistance and decreased cardiac output and hypovolemia, and therefore these women are more prone to hypodynamic instability following blood loss. Also, in these women, the decrease in the number of platelets and the increase in blood pressure cause the blood loss to increase and the need for blood transfusion [9]. And for this reason, a large number of studies have shown that the incidence of pregnancy hypertensive disorders was different in two groups requiring and not requiring blood transfusions [12,13,14]. But in the present study, this difference was not shown.

Several studies showed a significant difference between the two groups requiring blood transfusion and those not requiring blood transfusion in terms of incidence of abruptio placenta [2,3,14] and placenta previa [2,9,13,14]. But in the present study, these differences were not significant. Probably the reason is that most of these studies included vaginal delivery and cesarean cases together, but our study included only cesareans. It is obvious that in cesarean cases, especially elective cesareans, women are carefully prepared for the operation and necessary measures are taken to prevent bleeding during the operation.

In the present study, it has been shown that there is a significant difference between the two groups in terms of the rate of emergency cesarean, cesarean in the active phase, completion of cesarean in the night shift, and completion of cesarean between midnight and 4 am. In other studies, the difference in the rate of emergency cesarean [3,14,16] has been shown in the two groups. Probably, the reason for these differences is that in emergency cesareans, there are more factors that lead to an increase in blood loss during and after delivery, for example the unavailability of blood products and no time to correct anemia. And probably in cesareans that are performed in the night and around midnight, access to human resources (such as help from colleagues, especially more experienced colleagues) and quick access to blood products decreases. Also, mortality and complications are more in night surgery [16,17]. As expected, in the present study, as in Rottenstreich's study, it was shown that the duration of surgery in the group requiring blood transfusion is longer than in the group that does not require blood transfusion [12]. It is probably because the length of the operation is longer for complicated patients such as women with a lot of intra-abdominal adhesions and patients who are operated by

less skilled surgeons. In Salik's study, the need for blood transfusion was more in women with first cesarean than in women with repeat cesarean [3] which was probably due to the fact that most of the previous cesareans were performed electively, but in the present study, the number of cesareans in the two groups was not significantly different. The amount of medical induction of labor was not significantly different in the two groups requiring and not requiring blood transfusion in the present study, as in Wang & Mhyre's studies [9,13]. Since uterine blood flow reaches 600 cc/min during labor, the lack of proper uterine contractions can cause PPH that requires blood transfusion, so as expected, in the present study, the amount of uterine atony was different in the two groups. In Gulucu's study, it was also shown that among 213 women who needed blood transfusions in the peripartum period, 50.7% had atony and this factor was at the top of the reasons for needing blood transfusions [7]. Also, the present study, like some other studies, showed that the two groups did not have a significant difference in terms of indications for cesarean [3].

As expected, in the present study, the two groups were significantly different in terms of duration of surgery. In Rottenstreich's study, in which 170 women who needed blood transfusion and 340 women who did not need blood transfusion were compared, it was also shown that the two groups differed in terms of operation time (OR=1.03, CI 1.02-1.04, (P<0.001) [12]. This issue is probably due to the fact that in patients with more complex conditions such as severe adhesions and placental disorders and those with less skilled and experienced surgeons, both the duration of the operation and the possibility of bleeding are higher.

The present study showed that the two groups were significantly different in terms of the number of previous births. Salik's study on 318 women with PPH also showed that parity and PPH blood transfusion are related (aOR=0.258, P<0.001) [3]. Also, the studies of Ouh and Rottenstreich have also shown this difference [2,12]. Maybe the reason is that nulliparous women have more prenatal care. On the other hand, studies such as Uzundere in Turkey on women with PPH hemorrhage who were admitted to the ICU showed that the two groups receiving blood (205 women) and those not needing blood (169 women) did not differ significantly in terms of parity (p= 0.480) [14]. The present study, like Rottenstreich's study, which was conducted on 170 women who needed blood transfusion after cesarean and 340 women who did not need it, showed that the presence of maternal comorbidities is associated with an increase in the need for blood transfusion (OR: 4.16 CI 95% 1.88-9.1, P<0.001) [12].

Uzandere's study has shown a similar result [14]. Although Salik's study showed that women who did not need blood transfusions after delivery had more maternal comorbidities compared to the group that needed blood transfusions [3]. This issue can be due to the fact that in that study, only maternal complications were considered, but in the present study, we have separated this group of mothers.

Similar to the present study, a study conducted in the Netherlands showed that comparing 95 women who received heparin during pregnancy with 524 who did not receive heparin, the rate of PPH hemorrhage was 18% and 22%, respectively (RR: 0.8) and the rate of severe bleeding after delivery in both groups (RR=1.2) was 6% and there was no significant difference between the two groups [18]. Considering that prophylactic doses of anticoagulant drugs are often used in pregnant women and these drugs are stopped near delivery, these results are justified.

In the present study like Ouh's study in Korea, neonatal weight below 2.5 kg (OR: 1.64; 95% CI: 1.56–1.72) or above 4.0 kg (OR: 1.40; 95% CI: 1.33-1.48) were independently associated with peripartum blood transfusion [2]. It is probably because macrosomia increases the possibility of atony due to overdistension of the uterus. On the other hand, low fetal weight may be associated with other factors such as premature delivery, preeclampsia and abruptio

placenta [2]. Also, the cause may be a defect in blood supply to the uterus and placenta.

There was a significant difference in fetal weight in two groups. Regarding the gender of the fetus in the present study, like the Salik study, the two groups did not differ significantly [3].

As expected, there was a significant difference in the number of pregnant women who had adequate prenatal visits in the two groups. It seems that adequate visits during pregnancy lead to timely diagnosis and management of a number of peripartum hemorrhage risk factors, and on the other hand, the physician will be able to properly prepare blood products, necessary tools, and ask for help from colleagues.

One of the strengths of the recent study was that it was prospective and had a detailed protocol for blood transfusion and the selection of two centers with different geographic locations and socio-economic status of the clients. Also, in this study, only women who underwent cesarean were included, and although this reduces the possibility of generalizing the study to women who give vaginal birth, it increases the specificity of the studied population. It is recommended that the study be done with matched groups in the future to reduce the effect of confounding factors. It is also recommended that future studies be done with more samples and in more centers. In this way, the possibility of accurate multivariable regression models will be provided.

## Conclusion

This study suggests that peripartum hemorrhage during and after cesarean can be predicted to some degree. Additionally, certain risk factors, like anemia, can be addressed preemptively. Even when these factors are uncorrectable, proactive measures can be taken to manage hemorrhage. These measures include preparing blood products, coordinating with colleagues, or transferring high-risk patients to better-equipped facilities.

However, it's important to acknowledge the limitations of prediction. Therefore, all healthcare providers, regardless of facility size, should undergo training in peripartum hemorrhage management. Implementing such programs ensures a prepared response in all delivery settings.

## Declaration of interest

## Ethical approval

Not applicable.

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## Conflicts of Interest

There are no conflicts of interest.

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