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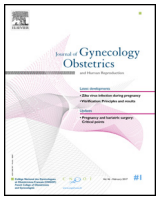

Original Article

A French audit of maternity unit protocols for immediate postpartum hemorrhage: A cross-sectional study (HERA)

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ABSTRACT

Objectives: The principal objective of this work was to assess how well the written protocols of maternity units used for the prevention and management of postpartum hemorrhage (PPH) corresponded to the 2004 French guidelines on this topic. The second objective was to assess whether or not this correspondence with the national guidelines varied according to hospital level (basic, specialized, and subspecialized) and status (teaching, public, and private).
Methods: This observational multicenter cross-sectional study took place in September 2010 and included French perinatal networks that volunteered to participate. We asked 300 French maternity units belonging to these networks to participate by emailing a copy of their department's protocol for PPH to the study team. This team designed and performed a clinical audit of these protocols, defining 16 criteria that incorporated the 2004 French guidelines for prevention and management of PPH. The main outcome measure was the percentage of units reporting protocols meeting these criteria.
Results: Of the 244 maternity units responding, 97.1 % had a written protocol but only 67.0 % had a local protocol. Protocol correspondence with the 2004 French guidelines was good for the criteria involving quantitative assessment of the quantity of blood loss (83.5 %) and secondary management of PPH (>80 %). Correspondence with the guidelines was poor in terms of defining PPH in the protocol (25.3 %) and of requiring the recording of the time of PPH diagnosis (53.2 %) and of the volume of blood loss (55.7 %). These results differed only slightly according to maternity unit status or level.
Conclusion: In all, 67.0 % (159/237) of maternity units had a local protocol for PPH. The contents of these protocols should be improved to be closer to the national guidelines.

Introduction

Postpartum hemorrhage (PPH) remains a major cause of maternal morbidity and mortality worldwide [1–4]. It is the leading cause of maternal deaths in France, responsible for 18 % of those during the decade from 1998 to 2007 [5]. Hemorrhage-related events are among the most preventable causes of maternal death. The prevalence rates of PPH (defined as ≥500 mL blood loss) and severe PPH (≥1000 mL) vary widely throughout the world [6,7]. In a stage of the HERA French cohort study, we found a PPH incidence of 3.36 % [95 % CI 3.25 %–3.47 %] (>500 mL) after vaginal deliveries and 2.83 % [95 % CI: 2.63 %–3.04 %] after cesareans (>1000 mL) [8].

Another part of the HERA study described the policies for the prevention and early management of PPH reported by a medical supervisor of French maternity units, by questionnaire responses, collected in a multicenter survey from January 2010 to April 2011 [10]. We noted differences between the contents of the French 2004 guidelines [9] on this topic and the self-reported policies of the French maternity units we studied [10]. These results, like those of other authors, underlined that simply distributing a policy directive does not suffice to cause the policy to be implemented [11–13]. Almost all French units reported that they had a written protocol for PPH (97.2 %) [10]. Nonetheless, there may well be a gap between the reported policy and the written policy followed in

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each maternity ward, specifically in terms of its quality: does it actually cover the aspects intended, follow the guidelines on which it is based, adapted to local conditions? Should following this policy lead to adherence to national guidelines? It therefore appeared useful to audit the quality of the protocols of the maternity units that participated in the HERA study.

Protocols are intended to cover prevention and, for those PPH that are not preventable (or not prevented), management, because early identification and rapid response may reduce the maternal morbidity and mortality. However, the evidence base supporting decisions about the strategies for guideline dissemination and implementation most likely to modify clinical practices remains imperfect, to say the least [14]. Most authors have studied the impact of multifaceted intervention on the rates of moderate and severe PPH or on practices for the prevention, diagnosis, and management of PPH [15–22], but no compelling evidence has shown that multifaceted interventions are more effective than single-component interventions [23]. We consider that each maternity unit should adapt national guidelines in their own local PPH protocol (tailored to local characteristics and updated regularly in the light of new scientific publications): the resulting additional contact and investment of staff members may reduce substandard care, by making them more familiar with the guidelines, and prevent delay, by making severe blood loss easier to recognize. That is, involvement in drafting a local protocol may help to improve health care quality and practitioners' adherence to the guidelines [24–26]. Only one Dutch study has assessed the quality of the PPH hospital protocols; it stressed that the protocol structure and contents varied widely between different hospitals [27]. However, it included relatively few protocols (n = 18).

The principal objective of this work was to assess how well the written protocols of maternity units used for the prevention and management of postpartum hemorrhage (PPH) corresponded to the 2004 national guidelines on this topic [9] and thereby evaluate their quality. The second objective was to assess whether or not this correspondence with the national guidelines varied according to hospital level (basic, specialized, and subspecialized) and status (teaching, public, and private).

Materials and methods

Participants and settings

This observational multicenter cross-sectional study was supported by the French Federation of Perinatal Network (Fédération Française des Réseaux de Santé en Périnatalité: FFRSP). The role of this federation is to promote and support perinatal networks in their tasks and responsibilities, set by the ministerial circular of July 2015. We invited the 33 regional perinatal French networks (n = 33) and the 11 perinatal networks of the Paris metropolitan area to participate in the study. We excluded French overseas territories (n = 2) and non-perinatal networks (preterm infant networks and non-regional perinatal networks: precarity or abortion networks; n = 23). Finally, 24 coordinators of French perinatal networks agreed to participate in this clinical audit (24/44 eligible perinatal networks). These 24 networks included 300 maternity units. In September 2010, we asked them to email the study team a copy of their department's protocol for PPH prevention and management, or failing that, their perinatal network protocol they used, if any, in their maternity unit (no later than June 2011).

The competent French institutional review board (Comité d'Ethique des Centres d'Investigation Clinique de l'Inter-région Rhônes-Alpes-Auvergne, Grenoble: CECIC) approved this study on November 9, 2009 (IRB 0917).

Construction of the clinical audit rubric

The rubric included 22 criteria including 15 highly recommended by Collège National Des Gynécologues et Obstétriciens Français (CNGOF) in their 2004 clinical practice guideline; they ranged from the definition of PPH to its prevention and its management [9]. A glossary accompanied the rubric to prevent information bias during the audit [see Appendix 1]. The obstetricians and midwives of the HERA study scientific committee validated the clinical audit rubric. This work considers only the 15 most important criteria according to the French guidelines, as well as one more (date of distribution and/or last update). Two research midwives, trained in audit procedures, conducted the audit of the protocols used by the maternity units. Disagreements were resolved by conversation between the midwives and the first author until consensus was reached. The study finally included 244 maternity units, for a participation rate of 81.3 % (244/300). Two email reminders were sent to non-responding units.

The main outcome measure was the correspondence (that is, adherence) of each hospital's protocol and overall for each criterion of the maternity hospital audit grid, that is, the difference between the expected adherence rate according to the 2004 French guidelines for PPH, as a percentage (thus, expected of 100 %) and the observed correspondence rate.

Statistical analysis

The results are expressed as percentages. The maternity units were compared by level (1: basic; 2: specialized; and 3: subspecialized) and status (teaching, public, and private) with a Chi2 statistical test (or Fisher's exact test when appropriate). Significance was set at 0.05. Data collection and analysis were performed with SAS software (version 9.4, SAS Institute, Cary, NC, USA, 2002–2012).

Results

The characteristics of the 244 participating French maternity units (244/300) were compared with those of the units that did not respond to the survey among the perinatal networks that volunteered to participate in the HERA study and with the maternity units belonging to the perinatal networks that did not participate (Table 1). Among the perinatal network participating in the HERA study, the smaller maternity units, which were more often level 1 and private, responded less often than the other maternity units (Table 1). The maternity units outside the Paris metropolitan area (the "province") responded at higher rates than those of Ile of France ($P < 0.01$) (Table1). When we compared the responding maternity units with all units in the non-participating perinatal networks; private maternity units again participated less often ($P = 0.01$), as did the units with the fewest deliveries (<500 births per year; $P = 0.01$).

Of the 244 maternity units that responded, 97.1 % (237/244) had a written protocol. More precisely, 67.0% (159/237) had a local protocol for PPH, while 33.0 % used only the regional perinatal network protocol. Overall, 75.5 % of the protocols had a date of distribution or of last update (Table 2), and only 48.3 % were signed by a medical director. PPH was defined in 25.3 % of protocols and useful contacts were listed in 27.0 %. Active management of the third stage of labor was recommended in 65.8 % and measurement of blood loss in 83.5 % (Table 2). Slightly more than half the protocols (53.2 %) called for noting the time of PPH diagnosis in the records (Table 2). Routine and selective use of carbetocin, not mentioned by the CNGOF, was included in 15 and 11 maternity units, respectively, and factor VIIa use in 35.4 % (84/237). More than

Table 1
Characteristics of French maternity units, comparison of the units belonging to the perinatal networks that volunteered to participate that did and did not respond and of all maternity units in the perinatal networks that did not volunteer for the HERA study.

	Perinatal networks participating in the HERA study			Perinatal networks not participating in the Hera study	
	Respondents n = 244 %	Non-respondents[1,2] n = 46 %	P[3]	Non-participants[2] n = 318 %	P[4]
Total number of deliveries[5]					
< 500	6.6	23.9	0.001	12.6	0.01
500 - 1499	58.6	50.0		47.8	
≥ 1500	34.8	26.1		39.6	
Level of care					
Level 1[6]	43.9	71.7	0.0007	50.6	0.28
Level 2[7]	41.8	28.3		36.8	
Level 3[8]	14.3	0		12.6	
Status of facility[9]					
Academic hospital	10.7	10.9	0.0006	9.1	0.01
General public hospital	61.1	32.6		50.6	
Private hospital	28.3	56.5		40.3	
Region[10]					
Province	85.2	69.6	0.01	80.5	0.14
Paris metropolitan area	14.8	30.4		19.5	

[1] Corresponding to all French maternity units among the perinatal network that did not participate in this study.
[2] Data from the statistics of health facility activities [http://archives.sae-diffusion.santé.gouv.fr/Collecte 2010/].
[3] *P* for maternity units that did and did not respond among the perinatal networks that volunteered to participate.
[4] *P* for responding maternity units among the participating perinatal network versus all maternity units in the non-participating perinatal networks.
[5] Deliveries per year.
[6] Basic: Maternity ward without a pediatrics department.
[7] Specialized: Maternity ward with a neonatology department.
[8] Sub-specialized: Maternity unit with a neonatology department and a NICU.
[9] Academic Hospitals are in France regional hospitals connected with an university; General public hospital for the study are hospitals not connected with an university but with a maternity unit; Private hospitals are those in the private sector, whether for profit or not for profit, with a maternity unit.
[10] Paris metropolitan area includes Ile de France and Paris. Province: all other French regions.

Table 2
Audit results among all respondents for the prevention and diagnosis of PPH, and according to the maternity unit level and status.

Criteria that should be included in the protocols	Total	Maternity unit level			Test	Maternity status			Test
	n = 237 %	1 n = 110 %	2 n = 94 %	3 n = 33 %	P	Public n = 153 %	Private n = 65 %	Academic n = 19 %	P
Date of distribution and/or last update	75.5	74.6	76.6	75.8	0.94	73.9	81.5	68.4	0.36
PPH definition[1]	25.3	24.6	22.3	36.4	0.27	28.1	18.5	26.3	0.32
Useful contacts and telephone numbers[2]	27.0	20.0	31.9	36.4	0.07	26.1	23.1	47.4	0.10
Routine active management of the third stage of labor[3]	65.8	61.8	70.2	66.7	0.45	67.3	60.0	73.7	0.44
Active management of third stage of labor with oxytocin[4]	68.4	70.9	67.0	63.6	0.69	68.6	64.6	79.0	0.49
Time of hemorrhage diagnosis recorded	53.2	42.7	60.6	66.7	0.009	51.6	50.2	73.7	0.19
Manual removal of the placenta indicated after 30 min[5]	43.5	45.5	43.6	36.4	0.65	48.4	30.8	47.4	0.05
Quantitative assessment of blood loss[6]	83.5	80.9	85.1	87.9	0.56	86.3	76.9	84.2	0.23
Volume of blood loss recorded in medical file	55.7	48.2	64.9	54.6	0.06	55.6	50.8	73.7	0.21

[1] The audit defined agreement for postpartum hemorrhage definition by two criteria: the presence of a specific definition, and its adherence to the definition in the French 2004 guidelines (more than 500 mL of blood loss, regardless of mode of delivery). The definition of more than 500 mL for vaginal delivery and more than 1000 mL for cesarean delivery was also considered correct.
[2] The audit defined correspondence for "useful telephone numbers" in case of PPH. The presence of the numbers for the French Blood Agency and/or the hospital blood bank were expected. If embolization was available onsite, the telephone number of the interventional radiology department had to be listed.
[3] The audit defined correspondence by the specification of an active management of the third stage of labour, defined as the early administration of oxytocin, regardless of the time: before or after delivery of the placenta.
[4] The audit defined correspondence for oxytocin as the statement that it was to be used at an intravenous dose of 5 IU on delivery.
[5] The audit considered correspondence was absent when the protocol did not specify manual removal of the placenta after 30 min in the absence of its spontaneous delivery.
[6] Regardless of how blood loss was estimated (collector bag, weighing dressings, etc.).

80 % of protocols specified the first- and second-line technical and pharmacological procedures to be used (Table 3).

These results did not differ by type of maternity unit (Tables 2 and 3), except for reporting the time of PPH diagnosis in the medical file, which was more frequent in Level 2 and 3 facilities; *P* = 0.009). Similarly, they did not differ by maternity unit status (Table 2).

Discussion

Although not all maternity units have a written protocol specific for their maternity ward, our results nonetheless underline the awareness of a large number of obstetric professionals of the need to diagnose PPH and manage PPH as well as possible, as shown by the high percentage of recommendations for quantitative

Table 3
Audit results among all respondents for PPH management, and according to maternity unit level and status.

Criteria that should be included in the protocols	Total	Maternity levels			Test	Maternity status			Test
	% n = 237	1 n = 110 %	2 n = 94 %	3 n = 33 %	*P*	Public n = 153 %	Private n = 65 %	Academic n = 19 %	*P*
Initial management for PPH									
Technical procedures[1]	84.0	82.7	86.2	81.8	0.75	82.4	87.7	84.2	0.63
Pharmacological procedures[2]	80.2	75.5	85.1	81.8	0.22	79.7	80.0	84.2	0.97
Immediate resuscitation[3]	51.1	44.5	54.3	63.6	0.11	53.6	43.1	57.9	0.31
Specific PPH care included in medical file[4]	50.2	42.7	58.5	51.5	0.08	48.4	50.8	63.2	0.49
Management for persistent PPH									
Medical management process described[5]	94.9	94.6	94.7	97.0	1.0	93.5	96.9	100.0	0.56
Surgical management process described[6]	90.7	88.2	90.4	100.0	0.12	90.9	87.7	100.0	0.30
Embolization access described[7]	79.8	80.6	81.8	90.9	0.38	80.4	75.4	89.5	0.38

[1] Technical procedures: bladder voiding, manual exploration of the uterus, careful visual assessment of the lower genital tract. The audit defined lack of correspondence by the absence of at least one of these items from the protocol. [2]Pharmacological procedures: plasma expansion by crystalloids, antibiotic prophylaxis after manual exploration of the uterus, uterotonic agents. The audit defined lack of correspondence by the absence of at least one of these items from the protocol.

[3] Immediate resuscitation of women: noninvasive monitoring (heart rate, blood pressure, pulse, and oximetry), establishment or securing of venous access, oxygen therapy, protection against hypothermia, and coagulation screens). The audit found no correspondence if at least one of these items was missing from the protocol. [4]Relevant information of management and monitoring must be recorded on a specific monitoring sheet in the chart (paper or electronic). [5]The audit defined correspondence as the description of medical management of persistent PPH according to the French 2004 guidelines, as follows: if oxytocin fails to control the bleeding, the administration of sulprostone is to be administered by intravenous infusion (syringe).

[6] The audit defined correspondence as the description of surgical management of persistent PPH according to the French 2004 guidelines as follows: conservative surgery techniques (arterial ligation and/or uterine compression suture) and in case of failure, hysterectomy without salpingectomy).

[7] The audit considered this criterion applicable when the maternity unit was not part of an institution with an onsite interventional radiology unit that could perform vascular embolization because patients could be transferred to another hospital in this case (n = 8 units).

assessment of blood loss in the audited protocols. The second-line technical and pharmacological procedures are fairly well explained in the protocols, but the definition of PPH and the need to note the time of PPH diagnosis were lower than expected. It is highly likely that the 2014 update of the French guidelines led to the update or creation of more protocols in French maternity units since this study was conducted [28].

Because the passive dissemination of clinical practice guidelines has repeatedly been shown to be ineffective in improving practices and multiple interventions to be no more effective than a single one [23], it is important that each hospital unit adapt national guidelines in a local protocol appropriate to their local organization. This adaptation may reduce substandard care and improve practitioners' adherence to national guidelines [24–26]. Batra et al. conducted a before-and-after study to compare PPH cases during the 2 years before protocol implementation in August 2009 and in the 2 years afterward [25]. They stressed that the PPH protocol improved the identification of severe PPH cases and that standardized management guidelines promoted intensive resuscitation when transfusion was indicated [25]. In a similar before-and-after study (retrospective study from January 1 to June 30, 1999, n = 54 women with massive PPH vs. prospective data collection from January 1 to June 30, 2002, n = 15 women with massive PPH), the incidence of massive PPH fell significantly, to 0.45 %, with 100 % adherence to the guidelines and a significant reduction in maternal morbidity [26]. Figueras et al. also showed that the proportion of women with PPH decreased from 12.7 % at baseline to 5% at 1 year after the intervention [24]. It is impossible to know if the results observed in this study are linked to the drafting of local clinical guideline, as the intervention also included training. We have found only one publication assessing the quality of the contents of protocols on PPH as related to national guidelines, in 2011–2012 [27]. The authors stressed that active management of the third stage of labor was included in 22 % of the protocols (vs. more than 65 % in our audit), 70 % of protocols considered embolization (vs. 79.8 % in our audit), and three-quarters of the items did not indicate the time at which the relevant recommendation should be performed, which was not the case in our study [27]. One explanation of the difference between the Dutch study and ours could be that Woiski et al. did not use national guidelines. Their content was appraised by using previously developed quality indicators, based on international guidelines and Advance-Trauma-Life-Support (ATLS)-based course instruction. Finally, the Dutch PPH protocols varied more widely between hospitals than the French protocols in our study.

Involving people in the decision-making process about issues that will affect them may lead to their having more of a sense of ownership and a greater commitment to adhering to the decision reached [29]. However, the delivery of high-quality patient care is a complex process that demands effective and efficient collaboration by health care professionals. Poor collaboration between professionals can aggravate the problems of a woman with PPH. Interprofessional education offers a possible way to improve interprofessional collaboration and patient care [30]. The local protocol is a way to facilitate collaboration and interprofessional education. Moreover, the French GYNERISQ (http://gynerisq.fr/) association, an organization authorized to provide accreditation to physicians practicing obstetrics and gynecology (both classified by statute as specialties at risk), strongly recommends that professionals reporting near-misses adapt national guidelines into local protocols specific to their maternity ward; we strongly agree. However, only 67.0 % (159/237) had a local protocol for PPH.

The first limitation of this study is that we cannot state with any certainty that the written protocol is actually used in clinical practice, for the management of parturients. Its second limitation is that we did not exclude the maternity units that sent us only their regional perinatal network protocol. Our choice was made, nonetheless, because these units knew and really used it locally. The third limitation is that we did not cover all French maternity units. As noted above, private maternity units participated less often ($P = 0.01$), as did the units with the fewest deliveries (<500; $P = 0.01$); these two groups overlapped, since most of the private maternity units in France are small (Table 1). Nonetheless, the participation rate among the perinatal health networks that participated in the study was high: more than 80 % of their maternity units sent us their protocol. Moreover, these 244 participating maternity units represented 43.6 % of all deliveries performed in France in 2010 (361,328/828,108 births). The other strength of our study, however, is that we assessed the quality of PPH protocols used by maternity units, including structure and

content. Until now, to our knowledge, only one study has audited PPH protocols [27].

In conclusion, this study allowed us to observe that 65.1 % of maternity units had a PPH protocol used locally. Nonetheless the national policy, implemented through perinatal networks, should be to encourage strongly the local adaptation of perinatal network PPH protocols. This study also showed that most of these protocols included the guideline recommendations to quantify blood loss (83.5 %) and to management PPH, including first- and second-line technical and pharmacological procedures (>80 %). Fewer protocols adhered to the guidelines by including a definition of PPH (25.3 %), or by recommending inclusion in the medical file of the time of PPH diagnosis (53.2 %) or of the volume of blood loss (55.7 %). This study merits repetition now that the 2014 updating of the French guidelines have been in effect for 6 years [28]. Finally, it would be useful to assess both the correspondence of the policies reported by maternity unit directors to the contents of their protocols used locally, and the incidence of PPH and of non-pharmaceutical curative second line procedures performed for PPH according to the quality of the PPH protocol used by maternity units.

Human and animal rights

Study ethics approval was obtained on November, 2009 (CECIC Rhônes-Alpes-Auvergne, Grenoble, IRB 5044).

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Declaration of Competing Interest

None of the authors has any conflict of interest concerning the topic or contents of this article.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.jogoh.2020.101934.

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