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From Postpartum Haemorrhage Guideline to Local Protocol: 
A Study of Protocol Quality

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Abstract  Objective Postpartum hemorrhage (PPH) has a continuously rising incidence worldwide, suggesting sub-optimal care. An important step in optimizing care is the translation of evidence-based guidelines into comprehensive hospital protocols. However, knowledge about the quality of these protocols is lacking. The objective of this study was to evaluate the quality of PPH-protocols on structure and content in the Netherlands. Methods We performed an observational multicenter study. Eighteen PPH-protocols from 3 University Hospitals (UH), 8 Teaching Hospitals (TH) and 7 Non-Teaching hospitals (NTH) throughout the Netherlands were acquired. The structure of the PPH-protocols was assessed using the Appraisal of Guidelines for Research and Evaluation (AGREE-II) Instrument. The content was appraised using previously developed quality indicators, based on international guidelines and Advance-Trauma-Life-Support (ATLS)-based course instructions. Results The quality of the protocols for postpartum hemorrhage for both structure and content varied widely between different hospitals, but all of them showed room for improvement. The protocols scored mainly below average on the different items of the AGREE-II instrument (8 of the 10 items scored <4 on a 1–7 scale). Regarding the content, adoption of guideline recommendations in protocols was 46%. In addition, a timely indication of ‘when to perform’ a recommendation was lacking in three-fourths of the items. Conclusion This study shows that the quality of the PPH-protocols for both structure and content in the Netherlands is suboptimal. This makes adherence to the guideline and ATLS-based course instructions difficult.

Keywords Health care quality access and evaluation · Guideline adherence · Postpartum hemorrhage · Clinical protocols
Significance

Postpartum hemorrhage (PPH) remains a major problem in high resource countries, regardless of the development and dissemination of evidence-based clinical guidelines including the instructions on Advance Trauma Life Support (ATLS)-based courses for obstetric emergencies. Putting evidence-based PPH recommendations into practice begins with the translation of evidence-based guidelines into high quality local protocols. For many care providers these protocols often are the only guide in the prevention and management of PPH in the actual care. However a recent study (Bialit et al. AJOG 2015) showed that merely the presence of PPH-protocols does not indicate a better outcome. Variation in the quality of these protocols could be a possible explanation. This quality and its variation both regarding structure and content is yet unknown. This manuscript gives insight in an underexposed but in our opinion very important component of PPH-care and shows room for improvement. This quality and its variation, both regarding structure and content, is yet unknown. This manuscript not only concerns obstetricians but any professional in any country working with such guidelines. Therefore we think this manuscript fits perfectly in the scope of the Maternal and Child Health Journal.

Introduction

Postpartum Hemorrhage (PPH) is the number one cause of worldwide maternal death [21]. It does not only have its origin in low resource countries, but developed countries also contribute [13, 9, 22, 32]. A high proportion (72–90 %) of the morbidity of obstetric hemorrhage is considered to be preventable if adequately managed through early recognition, adequate interventions in early stages and proper choices of therapies [8, 12, 5]. Actually, PPH-care consists of a prevention phase and a treatment phase, where different actions must be taken by different professionals, consecutively or simultaneously, in a limited time-frame, for PPH can develop into an urgent life-threatening situation that requires an immediate response [20].

Evidence-based guidelines can assist professionals in standardizing adequate management and support the clinical evidence-based decision making [17]. Advanced Trauma Life Support (ATLS) courses educate the professionals in using a highly structured multidisciplinary approach of obstetric emergencies such as PPH [20]. Streamlining day-to-day PPH-care for every professional on the basis of evidence-based PPH-guidelines and ATLS-based course instructions is a challenge [17]. Several national societies of maternal-fetal-medicine [18, 15] strongly recommend the use of protocols as a way to streamline PPH-care, because compliance of guidelines improves if a protocol is present [11, 24, 26]. In fact, for the majority of the professionals, such as nurses, midwives and residents, these protocols are the main guide in the prevention and management of PPH. However, a recent study showed that merely the presence of PPH-protocols does not mean a better outcome [4]. Variation in the quality of these protocols could be a possible explanation. This quality and its variation, both regarding structure and content, is yet unknown. Therefore, we aimed to evaluate the quality of PPH-protocols, both on structure and content, in the Netherlands.

Materials and Methods

Design, Setting and Study Population

We performed an observational multicenter study. The study was established within the Dutch Consortium for Healthcare Evaluation in Obstetrics and Gynecology. This Consortium aims at extending evidence-based medicine in obstetrics and improving the quality of the Dutch obstetric care. Nowadays all ten Dutch Perinatology Centers participate in this Consortium, together with 70 Dutch general hospitals. A viable selection of 1:5 of the Dutch hospitals was made and a total of eighteen (23 %) PPH-protocols from these Dutch hospitals that provide acute obstetric care were collected from February 2011 through February 2012. The selection of hospitals was based on the different types of hospitals [University Hospitals (UH), Teaching Hospitals (TH) and Non-Teaching Hospitals (NTH)], with a similar distribution by type across the country (3 UH, 8 TH, 7 NTH). The obstetrician of these hospitals was contacted through e-mail or telephone with the question to send us a copy of their most recent local PPH protocol, and all the hospitals willingly provided us with a copy.

Assessment of Protocol Quality

To evaluate the quality of the included protocols on structure and form, we used the Appraisal of Guidelines for Research & Evaluation (AGREE-II) instrument [2]. This instrument offers a systematic framework for assessing the most important aspects of quality of guidelines. We selected the following 10 from 23 scoring items for assessing form and structure of the protocols: objective, title with health questions and patient population (domain Scope and Purpose), publication date, revision date, externally reviewed yes/no and references (domain Rigor of Development), authors and target group (domain...
Stakeholder Involvement) and use of appendices/tools (domain Applicability). The remaining 13 items of the AGREE-II instrument were rated as unsuitable for assessing the protocols because they particularly relate to the process used to gather and synthesize evidence, cost implications and editorial independence. The AGREE-II items were scored on a 7-point scale from “totally disagree” to “totally agree” (score 1–7).

To evaluate the quality of the included protocols on content according to PPH-guidelines and the ATLS-based course, we used guideline-based quality indicators for prevention (n = 2), management (n = 15) and organization (n = 5) of PPH (Table 1) [30]. These indicators were previously developed according to the RAND-modified Delphi method to measure guideline adherence in the actual care, and are based on different international PPH-guidelines, including the guidelines from the World Health Organization (WHO), international literature and ATLS-based courses [20, 15, 3, 28, 31]. The indicators for management of PPH were classified into three subsequent stages of seriousness of PPH, in terms of the amount of blood loss or vital signs, namely: 1. >500 mL blood loss and/or signs of shock, namely: 2. >1000 mL or >500 mL with signs of shock, and 3. >2000 mL. This set can be used to measure the actual performances and whether the performances are carried out in the right stages of blood loss.

Twenty (from 22) indicators were relevant to assess the content of protocols and we transformed them into 92 measurable items. All protocols were scored on the presence or absence of these items. In addition, items regarding ‘actions in the management of PPH’ were evaluated on whether they were accompanied by a description of ‘when’ (in terms of the amount of blood loss or vital signs) these actions would have to be taken. For example; it is recommended to place a second drip in the event of more than 1000 mL blood loss.

Two independent researchers performed all measurements.

Statistical Analysis

With regard to the structure of the protocols we calculated median scores per AGREE-II domain, for all the hospitals together and per type of hospital. The results regarding content were analyzed descriptively. At first a total score was calculated, meaning the sum of all present items (Y) in the 18 hospital protocols divided by the maximum amount of items (Y/92 X 18). Subsequently, frequencies per item per type of hospital were assessed. Cohen’s kappa was calculated to measure conformity between the two assessors (HvV and FM) and totaled 0.9 for both structure and content measurements. All measurements were analyzed using SPSS 20.0.

Results

The quality of the analyzed protocols differed substantially for both structure and content.

Regarding the structure of the protocols the length of the total protocol varied, for example from half a page to five pages, and the presence of headlines and paragraphs varied, as well as the presence or absence of a flowchart. The presence of appendices/tools in the domain “Applicability” had a median score of 3 [ranging from 2 (TH and NTH) to 3 (UH)] (Table 2).

With respect to the domain “Scope and Purpose” a clear title with health question was found in all protocols (median score of 7), unlike the item ‘patient population’, which was predominantly absent (median score of 2). Items in the domains “Stakeholder Involvement” and “Rigor of Development” did not score well in almost all protocols, in particular those from the TH. From all these items, the item ‘publication date’ scored best [median score of 5, ranging from 3 (TH) to 7 (NT)].

Overall, the scores on the different items on the AGREE-II instrument were mostly below average, e.g. eight of the total of ten items scored below four on a scale of one to seven.

Regarding the content of protocols about half (46 %) of the total number of 92 items could be found in 18 protocols ranging from 20 % in a NTH to 68 % in a UH (Table 3). Below we present the main results for the different stages of PPH-care.

Prevention of PPH

Recommendations concerning identification of high-risk patients during labor were found in 33 % [ranging from 29 % (NTH) to 38 % (TH)] of the protocols. Active management of the third stage recommendation was included in 22 % of the protocols [ranging from 0 % (TH) to 43 % (NTH)].

Management of PPH

Recommendations for continuous monitoring the vital parameters, e.g. pulse, O2-saturation and blood pressure, were included respectively in 6 % [ranging from 0 % (UH and TH) to 14 % (NTH)], 11 % [ranging from 0 % (UH) to 14 % (NTH)] and 28 % [ranging from 13 % (TH) to 43 % (NTH)] of the total protocols. In all protocols was stipulated that cross-match blood has to be taken and in almost all protocols, except for one TH, that packed cells should be ordered. However, 11 % of the protocols mentioned to in a serious situation give O-negative blood in the absence of cross-match blood, with a range of 0 % in the UH to
Table 1  Guideline-based quality indicators for prevention, management and organization of PPH-care

| Performance indicators for prevention of PPH |  |
|---|---|
| **Prevention** | To identify patients at high risk of PPH during pregnancy at the out-clinic and during labor, determine or adapt a policy for parturition and document it |
| | To ensure IV access during labor, provide an active management of the third stage of labor and objectively measure blood loss |

**Performance indicators for management of PPH:** In case of a patient with PPH the clinician should…

*Time*

| Communication documentation |  |
|---|---|
| >500 mL | Inform the gynecologist (in training) |
| >1000 mL | Call for the obstetrician on ward (if the clinician is not a gynecologist), the anesthetist and surgery personnel, and transport patient to the operating room if the bleeding persists |
| >2000 mL | Allocate one member of the team to record vital signs, events, fluids, and drugs |

| Monitoring and prevention of shock |  |
|---|---|
| >500 mL | Monitor vital functions appropriately, take blood samples and replace fluid |
| >1000 mL | Continuously monitor pulse and oxygen saturation and BP (5–10 min) |
| >2000 mL | Take blood samples: FBC and cross match screen |
| | Give 10–15 L/min oxygen through face mask regardless of her oxygen saturation |
| | Continuously monitor pulse and oxygen saturation and BP (5–10 min) |
| >2000 mL | Call for anesthetic assistance if the airway is compromised |

| Blood products |  |
|---|---|
| >1000 mL | Urgently order units of blood and fresh frozen plasma, check and correct clothing status |
| >2000 mL | Follow hospital-wide mass transfusion protocol |
| | Transfuse uncrossed matched O negative blood if hemorrhage is life threatening, correct clothing status including platelets >50 or when surgery is planned >80 |

**Therapy**

| >500 mL | Treat uterine atony |
|---|---|
| | Continuous uterus massage, bladder catheterization and uterotonic medication in steps |
| | In case of retained placenta: perform controlled cord traction followed by placenta removal in the operating room |
| >1000 mL | Treat PPH as an atony till proven otherwise, use prostaglandins IV if other uterotonic treatment fails |
| >2000 mL | Perform or consider following interventions |
| | (Perform) empty uterus, repair genital tract injury (vaginal, cervical uterine rupture) |
| | (Consider) selective arterial embolization as alternative or in addition to surgical intervention, if not successful |
| | (Consider) internal iliac artery balloon |
| | (Consider) Brace suture, arterial ligation and hysterectomy |
| | In an emergency situation to temporarily stop bleeding and catch up resuscitation, organize the next intervention or transport patient to a tertiary centre: - perform: bimanual compression of the uterus, aorta compression and place Bakri balloon or uterine tamponade through packing (also therapeutically) |

**Organizational indicators for PPH:** In every hospital system…

| Protocols and agreements |  |
|---|---|
| The following local protocols and agreement should be available |
| Protocol PPH according to the national guideline |
| Local mass transfusion protocol |
| Protocol for women refusing blood products |
| A written agreement between the related disciplines (anesthesia, hematology, radiology) for a multidisciplinary approach in the treatment of PPH |
Table 1 continued

Accessibility

It must be clear how to rapidly reach the following staff/departments at any moment
1. Gynecologist; 2. Anesthesiologist; 3. Hematologist; 4. Intensive care specialist; 5. Surgery team; 6. Blood bank; and 7. Resuscitation team

There should be clear prior agreements about the time interval between the call and availability of the following staff (gynecologist, anesthesiologist and surgery team)

Audit and feedback

PPH cases should be

Discussed during morning team-gathering in a structured and detailed way, according to local PPH-protocol/guideline

Monitored by multidisciplinary audit and/or confidential enquiries on a regular basis with the associated caregivers, to identify problems that need reorganization and or training

Documentation and registration

The practitioner must ensure proper documentation for each PPH case, in particular concerning the time course

All cases of PPH (>1000 cc) must be registered

Published in Woiski et al. [30]: Guideline-based development of quality indicators for prevention and management of postpartum hemorrhage

Table 2 Quality of the protocols on structure using the AGREE-II instrument

| AGREE-II domain | Form and structure | Total (Median) (range 1–7) n = 18 | UH (Median) (range 1–7) n = 3 | TH (Median) (range 1–7) n = 8 | NTH (Median) (range 1–7) n = 7 |
|-----------------|--------------------|-----------------------------------|-----------------------------|------------------------------|------------------------------|
| Scope and purpose | Objective | 1 | 7 | 1 | 7 |
|                  | Title with health question | 7 | 7 | 7 | 7 |
|                  | Patient population | 2 | 2 | 2 | 2 |
| Rigor of development | Publication date | 5 | 5 | 3 | 7 |
|                  | Revision date | 1 | 1 | 1 | 1 |
|                  | Externally reviewed | 1 | 1 | 1 | 1 |
| Stakeholder | References | 1 | 4 | 1 | 1 |
|                | Authors | 2 | 2 | 1 | 7 |
| Involvement | Target group | 2 | 3 | 2 | 1 |
| Applicability | Appendices/tools | 3 | 3 | 2 | 2 |

UH University Hospitals, TH Teaching Hospitals, NTH Non Teaching Hospitals

14 % in the NTH. Half of the protocols suggest to consider a B-Lynch suture (33 % UH, 43 % NTH and 63 % TH), however, to consider a timely hysterectomy was found in only one protocol [6 % (UH)].

Time Factor

Of 92 items, 61 indicated at what stage (expressed in the amount of blood loss or shock signs) action should be taken. Of the items that should be performed at the stage of 500–1000 mL blood loss, only 24 % gave an indication of when or under which circumstances these had to be undertaken (Fig. 1). Unfortunately, 76 % of these items were either mentioned with an incorrect time indication (too much blood loss) or without any time indication, or were not mentioned in protocols at all. This also counts for the next stages (1000–2000 mL and >2000 mL blood loss), where 63 and 76 % of the items had an incorrect time indication, no time indication, or could not be found in the protocols at all.

Discussion

This study shows a large variation between hospitals in the quality of protocols for postpartum hemorrhage as regards both structure and content. The protocols scored mostly below average on the different items of the AGREE-II domains [8 out of 10 items scored below 4 (1–7 scale)]; protocols of the TH in particular scored lower (9 out of 10
Regarding the content, less than half (46 %) of the total number of 92 items were found in the 18 PPH-protocols. The content of the protocols of the NTH was the least in accordance with the guideline and ATLS-based course instructions (33 % NTH, 48 % TH, 55 % UH). Furthermore, as regards items that needed a time indication on ‘when to perform’, about three-fourths of these items were mentioned with either an incorrect time indication (too much blood loss), no time indication at all, or were simply not present in the protocols. So, the overall quality of protocols showed much room for improvement.

Table 3 Quality of local protocols on content

| Items                                                                 | Total (n = 18) | UH (n = 3) | TH (n = 8) | NTH (n = 7) |
|----------------------------------------------------------------------|---------------|------------|------------|-------------|
| Overall mean score of the items in the protocols (range)            | %             | %          | %          | %           |
| Prevention of PPH                                                   | 46 (20–65)    | 55 (50–65) | 48 (35–64) | 39 (20–54)  |
| Identification and determining policy of patients at high-risk for PPH|               |            |            |             |
| At outpatient clinic                                                | 11            | 0          | 25         | 0           |
| During labor                                                        | 33            | 33         | 38         | 29          |
| Active management of the third stage of labor                       | 22            | 33         | 0          | 43          |
| Objective (weigh) blood loss of high-risk patients                  | 67            | 33         | 63         | 86          |
| Management PPH >500 mL                                              |               |            |            |             |
| Call for the gynaecologist on ward                                 | 72            | 67         | 88         | 57          |
| Continuously monitor heart rate                                    | 6             | 0          | 0          | 14          |
| Continuously monitor oxygen saturation                             | 11            | 0          | 13         | 14          |
| Measure blood pressure (5–10 min)                                  | 28            | 33         | 13         | 43          |
| Ensure drip                                                        | 94            | 100        | 100        | 86          |
| Assess cross match blood                                            | 100           | 100        | 100        | 100         |
| Assess hemoglobin                                                  | 94            | 100        | 88         | 100         |
| Continuous uterus massage                                          | 78            | 100        | 63         | 86          |
| Bladder catheterization                                            | 100           | 100        | 100        | 100         |
| To give uterotonic medication in steps                             | 94            | 100        | 88         | 71          |
| Medication plan in steps present in protocol                       | 88            | 100        | 88         | 86          |
| If retained placenta, remove placenta in operating room            | 72            | 100        | 75         | 57          |
| >1000 mL                                                           |               |            |            |             |
| Give 10–15 l of oxygen through face mask                           | 56            | 67         | 75         | 29          |
| Order packed cells                                                 | 94            | 100        | 100        | 86          |
| Provide a second drip                                              | 88            | 100        | 100        | 71          |
| Monitor urine production                                           | 56            | 100        | 75         | 14          |
| Control and correct blood clotting                                 | 78            | 100        | 75         | 71          |
| Allocate one member of the team to record events                   | 17            | 33         | 13         | 14          |
| Call for the anaesthesiologist on ward                             | 6             | 33         | 0          | 0           |
| Call for the operating team on ward                                | 11            | 33         | 13         | 0           |
| Replace volume by using pressure bags                              | 33            | 67         | 25         | 29          |
| >2000 mL                                                           |               |            |            |             |
| Transfuse uncrossed matched O negative blood if PPH is life threatening | 11            | 0          | 13         | 14          |
| Follow the local shock protocol                                     | 6             | 0          | 13         | 0           |
| Call for a second gynecologist/perinatologist                      | 17            | 33         | 13         | 14          |
| Consider embolization [if embolization possibility is present in the hospital (n = 17)] | 70 | 100 | 88 | 33 |
| Consider brace suture                                               | 50            | 33         | 63         | 43          |
| Consider a timely hysterectomy                                     | 6             | 33         | 0          | 0           |

UH university hospitals, TH teaching hospitals, NTH Non teaching hospitals
A limitation of this study is, that we did not relate the quality of the protocols to the compliance with the guidelines in the actual care. It is possible that the current care is more in accordance with the guidelines than we now assume based on the protocols. It is possible that the variation in quality found could explain the findings of Bailit et al. [4] that the presence of protocols does not improve care as a rule. Therefore, to measure the current care will be the next step. A second limitation is that we used the Agree-II instrument which is meant to be used for Guidelines. However, a quality instrument for local protocols does not exist, and because local protocols are based on guidelines, the Agree-II instrument is the best instrument which met this purpose.

The strength of our study, however, is that we investigated the quality of local PPH-protocols, including both structure and content. Until now, the few studies that were performed regarding protocols only concerned the presence or absence of protocols, not the quality thereof (see below).

Specific omission of highly relevant clinical items could lead to a delayed recognition and treatment of PPH by the immediate care providers using the protocols. In our study, highly relevant clinical items in the prevention of PPH, such as identifying a high-risk patient, active management of the third stage and monitoring blood loss in high-risk patients, were only present in respectively 11, 22 and 67 % of the protocols. Furthermore, in the management of PPH, to monitor vital signs in case of a PPH was only found in less than one-third of the protocols. Delay and denial are key contributors to poor outcome in PPH while prevention and early recognition of PPH provide better results [8, 12, 5, 18, 6, 25]. A risk assessment of the outpatient-clinic patients, which helps identify high-risk patients, will increase vigilance of the staff and the taking of extra precautions when necessary. An active management of the third stage, as is strongly supported by evidence, diminishes blood loss [6, 27]. Moreover, proper management of PPH includes analyzing maternal status for early recognition through accurate estimation of blood loss, vital signs monitoring and prompt intervention in the early stages using a rapid and adequate multifaceted approach [12, 18]. Different international guidelines highlight the evaluation of vital signs and recommend more accurate management for PPH if blood loss causes changes in vital signs [15, 28, 7]. Omission of these items in protocols may be a factor for improper management of PPH; in our study only one out of 18 protocols suggested to monitor the pulse rate continuously if a PPH occurs. Certainly, it is arguable that these factors are a part of common knowledge and practice, but, the direct care providers in the PPH-care and therefore the ones who are responsible for the prevention and early recognition of PPH are usually the ones with the least experience, especially in the TH. Besides, midwives and nurses who are the professionals primarily responsible for ensuring patient safety, work mainly protocol based and use these protocols as their written source of knowledge and guidance in the daily care [26]. Therefore, it has to be clear for the direct care providers dealing with PPH, which acts must be performed at what amount of blood loss and at what condition the patient in. Unfortunately, only one-third of the items with a time indication were correctly described in the protocols.

In literature little is found about the incorporation of guideline-recommendations in protocols. Cromwell et al. [14] shows that only 20 % of all protocols in Great-Britain took over all recommendations of the national guideline “Group B Streptococcus”. In our study, we see a similar trend. Lack of familiarity with a guideline’s content, with the relevant research literature, disagreement with the guideline’s interpretation of the literature, but also the
ways in which recommendations are formulated are reported factors for not adopting guideline-recommendations [17, 16]. Cameron et al. [10] investigated current Australian practice in the development of a local policy with regard to prevention, early recognition and management of PPH. They found time and staffing issues to be significant barriers to local policy development from guidelines, especially the deficiency of skills and experience needed to develop written protocols.

It is known that not only the content is important for delivering proper care, but the protocol must be feasible and have a clear structure for the direct caregivers as well [19]. Improved compliance with protocols is found if there are comprehensive protocols, especially if nurses are involved in the development of these protocols [1]. In our study the structure of the studied protocols differed greatly whereas the TH scored lower than the other two types of hospitals.

In order to improve adoption of guideline-recommendations and not to ‘keep reinventing the wheel’, guidelines should come up with a template or model protocol with a clear format, better structuring and with all the important guideline-recommendations that can easily be adapted to the local situation [10, 19]. This template could be accompanied by additional materials such as a summary document, flowcharts educational tools, patient leaflets, or computer support for improving compliance with the protocols and therefore the guideline. It is known that the WHO has presented the recommendation as a list to be followed in case of a PPH and the FIGO has prepared a prevention and management protocol for PPH [29, 23]. Despite the fact that these two guidelines mainly focus on low resource countries, they could be adopted by other countries as well.

Conclusion

This study shows that the quality of the local PPH-protocols for both structure and content is suboptimal, especially the adoption of guideline-recommendations in protocols. This makes adherence to the guideline and ATLS-based course instructions difficult. It is possible, however, that the current care is more in accordance with the guideline than we now assume based on the protocols. Therefore, to measure the current care will be the next step. In the future more attention and assistance is needed to ensure the quality of protocols, for example by adding a standard protocol template, flowcharts and checklists to PPH-guidelines.

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