Quality of Postpartum Hemorrhage Care

The need for standardization

Mallory Woiski
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For reasons of consistency within this thesis, some terms have been standardized throughout the text. As a consequence the text may differ from the articles that have been published.

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General introduction
This thesis focuses on the improvement of care for women with postpartum hemorrhage (PPH). In the introduction we begin with a short description of PPH and the changes in incidence in the past ten years. Next, PPH-care for patients and the role of guidelines, Advanced Trauma Life Support (ATLS)-courses and local protocols in the management of these patients will be described. Subsequently, attention will be paid to better implementation of these guidelines, courses and protocols. This chapter concludes with the outline of the thesis.

POSTPARTUM HEMORRAGE

Definition of Postpartum Hemorrhage (PPH)
The world health organization (WHO) has defined PPH as a volume of blood loss of more than 500 ml within 24 hours after birth while severe PPH is defined as a blood loss of more than 1000 ml in the same timeframe. Different definitions apply for different countries, however, for the maternal condition and the accessibility of blood products is of influence on how rapidly PPH becomes life threatening. The Royal College of Obstetricians and Gynecologists of the United Kingdom defines PPH as minor (500 to 1000 ml) or major (>1000 ml), with further subdivisions of major hemorrhage as moderate (1000 to 2000 ml) or severe (>2000 ml)\(^1\). An international expert panel defined PPH as "active bleeding >1000 ml within the 24 hours following birth that continues despite the use of initial measures, including first-line uterotonic agents and uterine massage"\(^2\). In the Dutch setting, the Dutch association of obstetricians and gynecologists (NVOG) defined in its PPH-guideline, PPH as a blood loss of more than 1000 ml in 24 hours after birth, with the observation that for women with pre-existent diseases potential clinical consequences may occur in blood loss of less than 1000 ml. Therefore different recommendations were described for blood loss between 500 and 1000 ml\(^3\).

Incidence of PPH
In the year 2000, government leaders of 189 countries determined 8 millennium goals. One of the millennium goals was lowering worldwide maternal death by three quarters between 1990 and 2015\(^4\). However, in 2015, maternal mortality was down by only 45% and every hour 33 women are still dying\(^5\). Post-partum Hemorrhage (PPH) is the number one cause of worldwide maternal death\(^6\). Although the majority of the mortality occurs in developing countries, several studies report an increasing trend in incidence of PPH in high resource countries such as the US, Canada, Australia, the UK, France and the Netherlands\(^7-14\). In
these countries, PPH is still one of the main causes of maternal death and maternal morbidity. A recent study in the United States estimated PPH to be responsible for almost half of the cases (48%) of severe maternal morbidity\textsuperscript{15}. In the Netherlands PPH is still in the top four of maternal deaths\textsuperscript{16}. In this country the reported incidence of PPH is 7% in secondary care\textsuperscript{14}. In the Lemmon trial (2004-2006), in which a large part of Dutch hospitals participated, all severe maternal morbidity was documented and PPH in an absolute number is the major factor contributing to severe maternal morbidity\textsuperscript{16}. A clarification for PPH increase in high resource countries remains unclear and cannot be fully explained by alteration in high-risk groups regarding maternal age, obesity, induction of labor or cesarean sections\textsuperscript{10,11,17-20}.

Postpartum Hemorrhage-care
A high proportion of the morbidity of obstetric hemorrhage is considered to be preventable if adequately managed. PPH-care consists of two phases, the prevention and treatment phase, where professionals perform routine care followed by emergency care. In these phases different actions must be taken by different professionals, consecutively or simultaneously, in a limited timeframe, for PPH can develop into an urgent life-threatening situation, which requires an immediate response\textsuperscript{21-23}. Streamlining PPH-care for every professional, on the basis of evidence-based PPH-guidelines and ATLS-based course instructions, is necessary to provide high quality PPH-care\textsuperscript{21}.

However, substandard care factors, such as delay of both diagnosis and treatment are frequently reported in literature\textsuperscript{8,16,24-26}. In a study in France, suboptimal care factors were found in 38% of women with PPH > 1500 ml and in 70% of women who died of PPH. In the Netherlands, in 30-80% of the cases substandard care factors were found\textsuperscript{26}. Clark \textit{et al.} performed a retrospective analysis of all reported maternal deaths in the United States from 2000-2006. They found 72% of PPH cases to be preventable mainly due to the lack of adequate interventions in early stages and proper choices of medication, therapies or blood replacements\textsuperscript{22}. Berg \textit{et al.} reported that 93% of maternal deaths due to PPH could have been prevented through improved quality of PPH-care\textsuperscript{25}. Antony \textit{et al.} showed lower incidences of PPH in hospitals with a fetal maternal specialist on staff\textsuperscript{27}. A possible explanation for this could be the presence and implementation of PPH protocols and intensive skills training. Briley \textit{et al.} found deprivation of skills training and education to be a risk factor in progression to severe PPH\textsuperscript{28}.
Furthermore, in emergency situations such as PPH, serious medical errors are often committed through miscommunication and poor cooperation between the several team members. Different health organizations report dysfunctional obstetric teams to increase the risk of maternal and fetal morbidity and mortality and they therefore advocate teamwork and communication as a factor to be addressed in PPH-care.

QUALITY OF CARE
To deliver high quality PPH-care, the following fundamentals are important.

Guidelines
Evidence-based guidelines on prevention and management of PPH have been developed in recent years in several countries to provide recommendations for high quality PPH-care. Evidence based guidelines can assist professionals in standardizing adequate management and support the clinical evidence-based decision-making. These guidelines provide clinicians with information regarding ‘the best available evidence based care’ and aim to increase the effectiveness of care and reduce variation in performance between professionals and hospitals. They are very important in standardizing and optimizing clinical care and influencing outcomes, such as maternal mortality and morbidity.

ATLS-based courses
In the English Advanced Trauma Life Support (ATLS)-training for obstetric emergencies the clinical evaluation by means of the Airway-Breathing-Circulation (ABC)-methodology is fundamental. This ABC-methodology is used to strive after the principle “treat first what kills first” and was found effective in the reduction of the number of preventable deaths. The ATLS-based course for obstetric emergencies was widely introduced in several countries in order to reduce preventable mortality and morbidity in obstetrics. It educates the professionals in using a highly structured multidisciplinary approach of obstetric emergencies by means of the ABC-methodology such as PPH.

The assumption is that substandard care can be overcome by the use of evidence-based guidelines and the introduction of ATLS-based courses, resulting in standardization of care, timely recognition and rapid management.
PPH- protocols
Several national societies of maternal fetal medicine\textsuperscript{1,35,36} but also different international guidelines strongly recommend the use of local protocols as a way to streamline PPH-care, because compliance with guidelines improves if a local protocol is present\textsuperscript{37-39}. In fact, for the majority of professionals such as nurses, midwives and residents, these local protocols are the main or only guideline in the prevention and management of PPH. It is known that a well structured and comprehensive PPH protocol has been related with better use and better outcome\textsuperscript{39-42}. In addition, the content of the protocols should be based on evidence based guidelines and, and in case of PPH, on the ATLS-based course instructions\textsuperscript{37,38}.

Nontechnical-skills
Adoption of communication and teamwork training such as Crew Resource Management (CRM) was recommended to improve the performance of healthcare providers\textsuperscript{43,44}. In these training sessions nontechnical-skills such as leadership, situational awareness, mutual support and communication are central. In the emergency department, it resulted in a significant improvement of the clinical performances, 56% reduction of medical errors and a better attitude towards teamwork\textsuperscript{45,46}. The CRM concepts were introduced in the (obstetric) care in order to reduce the incidence of errors and complications. As a result of improved communication, coordination, plan development and shared mental model, the number of adverse events should decrease. Good teamwork with clear communication was associated with a 23% reduction of adverse events and a 13% reduction in the seriousness of events\textsuperscript{47}, but the effects on clinical outcome remain scarce\textsuperscript{48-52}.

Implementation of guidelines and ATLS-based courses
The World Health Organization (WHO), as did many high resource countries, developed and disseminated evidence-based guidelines for management and prevention of PPH\textsuperscript{1,35,53-55}. In addition, by analogy with the emergency care, many countries adapted the ATLS-based course instructions on the management of massive blood loss, such as the Managing Obstetrics Emergencies Trauma (MOET) course instructions, in their guidelines\textsuperscript{21}. The dissemination of evidence-based PPH-guidelines and introduction of the ATLS-based courses, however, did not lead to a reduction in PPH. The increasing incidences of PPH suggest an incomplete implementation of guidelines and courses\textsuperscript{41,56,57}. This also applies to
the Netherlands, with an increase in PPH incidence despite a newly developed and disseminated evidence-based guideline by the Dutch society of obstetricians and gynecologists (NVOG) and the introduction of the MOET-course for obstetricians working in the delivery rooms in 2003. We assume that this is due to inadequate implementation of the guideline and MOET-instructions. In general, publication and dissemination is not sufficient to maximize the effect on the quality of care,

**IMPLEMENTING INNOVATIONS**

To improve the quality of PPH-care, proper implementation of these guidelines and ATLS-based course instructions is essential and can only be achieved once the causes for not following guidelines and course instructions on different levels have been identified and overcome\(^5^8,^5^9\). A systematic approach is necessary for the implementation of guidelines and the improvement of PPH-care\(^3^3,^6^0\). Literature shows that guideline dissemination without an implementation strategy is often ineffective\(^6^1\). The gap between evidence-based guidelines and clinical practice can only be bridged by a situation specific strategy\(^2^3,^6^2\). Most theories on implementation of evidence in healthcare emphasize assessment of influencing factors first, in order to develop a tailored improvement strategy\(^6^3,^6^4\). A review evaluating implementation within the field of obstetrics concludes that a prospective identification of barriers to change is necessary to improve clinical practice guidelines implementation\(^6^5\). The strategy choice needs to be tailored with the use of the gathered information for best possible results. The model of Grol *et al.* describes six steps to develop, test, and evaluate an innovation (see figure 1)\(^5^8\). We will describe the first four steps for PPH-care below.

**Step 1: Description of optimal PPH-care**

As we mentioned above, optimal PPH-care is described in evidence-based PPH-guidelines and ATLS-based courses. However, the dissemination of these guidelines and introduction of the ATLS-based courses in the Netherlands did not lead to a reduction in PPH. The increasing incidences of PPH suggest an incomplete implementation of guidelines and courses. Quality indicators, which can be defined as evidence or consensus based measurable elements for assessing quality of care, are crucial to define optimal care\(^6^6\). However, valid sets of quality indicators for professional performance and organization are barely available in the field of PPH.
A set of valid quality indicators for assessing the actual care for prevention, management and organization of PPH has first to be developed. An essential recommendation for optimal PPH-care by guidelines, policy makers and societies of specialists is the presence of clear and comprehensive local PPH-protocols. These protocols have to contain guideline and ATLS-based course recommendations and have to be modified to the local situation. An evaluation of the quality of local PPH-protocols is an important step in defining optimal care.
Step 2: Assessing current PPH-care
The next step in the process of effective implementation is to acquire insight into actual practice. By measuring current PPH-care, using the developed quality indicators, it can be assessed to what extent clinical guidelines for PPH are followed in routine care in Dutch hospitals at both professional and hospital level. Furthermore, insight into additional aspects of current PPH-care such as teamwork is important for tailoring the implementation strategy.

Step 3: Identification of influencing factors for delivering high quality care
Every step in a process is influenced by surrounding factors. It is important to explore which experienced obstacles and facilitators concerning delivered care exist among patients and professionals involved in PPH-care. These factors can be quantified and used in the development of a tailored implementation strategy. Several models have shown to be effective in structuring the experienced obstacles and facilitators. These models include features of the guidelines, features of physicians and patients, features of the guideline, and of the social and organizational context.

Step 4: Development of a tailor made improvement strategy
In step 2 and 3, it becomes clear to what extent professionals adhere to the PPH guideline and ATLS-based course instructions and which factors on what level determine the performances of the different care-providers involved in PPH-care. Furthermore, it becomes clear which obstacles PPH-patients experience in the care they receive. Insight into these obstacles and facilitators is of great importance to develop a strategy to improve the implementation of guidelines and ATLS-based course instructions and as such prevent inadequate management of PPH. Many potentially effective strategies for implementing clinical guidelines are available, but none are superior in all aspects. Therefore, improvement strategies have to be developed based on the results of step 2 and 3 concerning current PPH-care and existing influencing factors.

THESIS OUTLINE
This thesis aims to get insight into current PPH-care and its obstacles and the facilitators for optimal PPH-care in the Netherlands. Besides this, it aims to develop an improvement strategy tailored to the obstacles and facilitators found.
Main objectives for this thesis are:
1. To develop a valid and reliable set of quality indicators, extracted from evidence-based guidelines and MOET-instructions, to assess actual PPH-care;
2. To gain insight into the actual PPH-care based on the developed quality indicators and into determinants for actual care;
3. To explore the obstacles and facilitators according to patients and professionals that affect the delivery of optimal PPH-care as described in evidence-based PPH guidelines and ATLS-based course instructions;
4. To develop an improvement strategy, tailored to the obstacles and facilitators found for delivering high quality PPH-care.

Study protocol
Chapter two includes the study protocol with a description of the current problems in PPH-care, the corresponding hypotheses and the study methods.

Development of quality indicators for measuring actual care
In chapter three, the first step in assessing actual care is described, particularly a stepwise systematic development of performance and organizational indicators for measuring the whole care process of prevention and management of PPH. A Rand-Modified-Delphi procedure is used to systematically achieve consensus among an expert panel regarding key recommendations for measuring PPH-care, MOET-instructions and international literature. In chapter four we gain insight into the translation of evidence-based guidelines into comprehensive hospital protocols, which is an important step in optimizing PPH-care. The quality of PPH-protocols from 18 different hospitals throughout the Netherlands is evaluated on structure and content using the Appraisal of Guidelines for Research and Evaluation (AGREE-II) Instrument and the quality indicators previously developed.

Actual PPH-care assessment
In chapter five we gain insight into the actual PPH-care and we assess determinants of guideline adherence. The actual PPH-care is assessed by a prospective observational study with the use of previously developed guideline-based quality indicators. In 15 different hospitals, approximately 420 high risk patients for PPH are included. Data collection regarding adherence to quality indicators is extracted from medical records and complemented with prospective video observations of the third stage in the delivery room. Organization of PPH-
care is assessed through a questionnaire that was sent to different professionals delivering PPH-care in the 15 hospitals. In chapter six the quality of the nontechnical-skills of the obstetric teams in the management of PPH is described on the basis of Crew Resource Management. We analyzed 71 video recordings of patients with a quantity of blood loss of more than 700 ml in 12 Dutch hospitals. The nontechnical-skills of the obstetric teams and the team leaders is assessed using two validated list for nontechnical-skills. In addition, the influence of the nontechnical-skills on clinical performance of the teams, measured through adherence to the quality indicators for management of PPH, and the clinical outcome i.e. the total amount of blood loss is calculated.

Influencing factors for delivering high quality care
In chapter seven obstacles for delivering optimal care are investigated at different levels. A framework including features of guidelines, physicians and patients, and features of the social context (e.g., colleagues of the involved physicians and geographic distance to hospital) and the organizational context is used. To detect possible influencing factors regarding optimal PPH-care, a qualitative study consisting of interviews among physicians involved in PPH-care and with PPH-patients is performed. Finally, a survey is performed to quantify the features identified in the interviews among the different professionals.

Development of a tailored improvement strategy
Based on the results presented in chapter 4 and 6, a tailored intervention is developed in chapter eight in order to increase guideline- and ATLS-based course instruction adherence. First a framework of the strategy is created based on obstacles to optimal adherence identified among professionals and patients together with evidence on effectiveness of strategies found in international literature. Second, the tools within the created framework are developed, and lastly the strategy is pilot tested among professionals and patients.

Chapter nine provides a general discussion and future perspectives.

Chapter ten is a summary of the thesis.
REFERENCES

Haemorrhagia postpartum
an implementation study on the evidence-based guideline of the Dutch Society of Obstetrics and Gynecology (NVOG) and the MOET (Managing Obstetric Emergencies and Trauma-course) instructions; the Fluxim study

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ABSTRACT

Background. One of the most important causes of maternal mortality and severe morbidity worldwide is post partum hemorrhage (PPH). Factors as substandard care are frequently reported in the international literature and there are similar reports in the Netherlands. The incidence of PPH in the Dutch population is 5% containing 10,000 women a year. The introduction of an evidence-based guideline on PPH by the Dutch society of Obstetrics and Gynecology (NVOG) and the initiation of the MOET course (Managing Obstetrics Emergencies and Trauma) did not lead to a reduction of PPH. This implies the possibility of an incomplete implementation of both the national PPH-guideline and MOET-instructions. Therefore, the aim of this study is to develop and test a tailored strategy to implement both the PPH-guideline and MOET-instructions.

Methods/Design. One step in the development procedure is to evaluate the implementation of the guideline and MOET-instructions in the current care. Therefore measurement of the actual care will be performed in a representative sample of 20 hospitals. This will be done by prospective observation of the third stage of labor of 320 women with a high risk of PPH using quality indicators extracted from the NVOG guideline and MOET instructions. In the next step barriers and facilitators for guideline adherence will be analyzed by performance of semi structured interviews with 30 professionals and 10 patients, followed by a questionnaire study among all Dutch gynecologists and midwives to quantify the barriers mentioned. Based on the outcomes, a tailored strategy to implement the NVOG guideline and MOET-instructions will be developed and tested in a feasibility study in 4 hospitals, including effect-, process- and cost evaluation.

Discussion. This study will provide insight into current Dutch practice, in particular to what extent the PPH guidelines of the NVOG and the MOET-instructions have been implemented in the actual care, and into the barriers and facilitators regarding guideline adherence. The knowledge of the feasibility study regarding the effects and costs of the tailored strategy and the experiences of the users can be used in countries with a relatively high incidence of PPH.
BACKGROUND
The major cause of maternal death worldwide is post partum hemorrhage (PPH, blood loss of >1000 ml during and after delivery), with about 146,000 deaths annually\(^1\). Although this is largely due to deaths in developing countries, even in the Netherlands it is still in the top four of maternal deaths\(^2\). In this country the reported incidence of PPH is 5% in the secondary care\(^3\). In the Lemmon trial (2004-2006), in which a large part of Dutch hospitals participated, all severe maternal morbidity was documented and PPH in absolute number is the major factor contributing to severe maternal morbidity\(^4\). Causes such as substandard care are frequently reported in the international literature. In a study in France, suboptimal care factors were found in 38% of women with PPH > 1500 ml and in 70% of women who died of PPH. In audits, performed in PPH cases of the Lemmon trial, suboptimal care factors were also common in the Dutch population (unpublished data). A logical assumption is that these factors can be overcome by the use of evidence based guidelines. The Dutch Society of Obstetrics and Gynecology (NVOG) developed and disseminated an evidence-based guideline about PPH, in which the best scientific evidence is summarized\(^5\). Furthermore, in 2003 the MOET course (Managing Obstetric Emergencies and Trauma), an ATLS-based course of the RCOG, translated to the Dutch situation, was introduced, in which stepwise and practical instructions to prevent PPH were given\(^6\). However, without tailor-made implementation, in general large gaps exist between best evidence as described in guidelines and daily practice\(^7,8\). This also applies to PPH. Both the dissemination of the evidence-based guideline about PPH and the MOET course did not lead to a reduction in PPH: nationwide the incidence of PPH was 3.8% in 2003 and 5.2% in 2006\(^3\). An incomplete implementation of both the NVOG-guideline and the MOET-instructions is expected.

METHODS/DESIGN
Objectives
The first objective of this study is to assess to what extent the NVOG guidelines and the MOET-instructions have been implemented in current care in the Dutch practice. The second objective is to study barriers and facilitators for guideline adherence. Finally based on these findings a tailored implementation strategy will be developed and tested on effects, experiences and costs.
Chapter 2

**Design and study population described per step**

**Objective 1**
To assess the actual care of Dutch gynecologists and midwives for patients at high risk for PPH (actual care study).

**Design**

*Developing quality indicators*

Before actual care can be measured, quality indicators have to be developed regarding the process, structure and outcome of care. These indicators have to be based on the key recommendations from the NVOG guideline on PPH and the MOET-instructions. The indicator development will be performed according to the RAND modified Delphi method⁹. First the key recommendations from the NVOG guideline on PPH and the MOET-instructions will be extracted and relevant indicators from international literature will be added. Subsequently, the relevance of all these key recommendations will be tested in two rounds among an independent panel about 15 experts consisting of guideline writers, Dutch MOET board members and instructors, NVOG-members of the subcommittee Implementation and Quality, gynecologists, hematologist and anesthesiologist.

In the first round the gathered recommendations will be edited in a written questionnaires for the expert panel where the experts are asked to score the key recommendations on a 9-point Likert scale ranging from 1 = not relevant to 9 = extremely relevant, with respect to their impact on both ‘health gain’ and ‘overall efficacy’. In addition, a top-5 ranking of recommendations is asked in which they consider ‘most important’ and ‘representative’ to assess the quality of clinical performance. In this round the experts have the possibility to provide comments and add additional items as well. Of the returned questionnaires, the median scores on ‘health gain’ and ‘overall efficacy’ are calculated per recommendation and are rated valid if they match the criteria described by Campbell¹⁰. Secondly, based on the top-5 ranking of recommendations, a list with scores reflecting the weight that experts assigned to each recommendation will be created. In a second round, in a consensus meeting with all the experts these listings will be used as feedback. During this meeting this feedback will be discussed and the former rankings will be reconsidered with the aim to reach consensus about the most important recommendations to assess the quality of clinical performance regarding the adherence to the NVOG guideline on PPH and the MOET-instructions. The selected key recommendations will be operationalized in measurable elements.
The practical measurement of actual care
In an observational multi-centre study, actual care will be measured by video monitoring the third stage of delivery and a medical record search among 320 high risk patients for PPH in 20 hospitals. In all participating clinics, all delivery rooms will be set up with a digital camera. In order to avoid anxiety, bias or refusal of participation among the care-givers, it is made clear that none of the direct colleagues or patients will be able to see the images and that these images cannot be claimed by the patient in case of an adverse outcome. The images will be analyzed by the researcher and in a random selected subset by one of the project leaders to assess the extent of adherence to the developed quality indicators. Additional information for indicator adherence will be searched in the medical records of the videotaped patients. In this manner, deviations from the indicators can be outlined. This study will provide us with reliable information about current practice in the Netherlands.

Study population

Hospitals
In order to obtain a representative view on the actual care in the Netherlands, 20 hospitals of different regions will participate in this trial including 4 university, 8 teaching and 8 non-teaching hospitals. The study is set in a Dutch Perinatal Research Consortium, in which all the participating clinics collaborate.

Patients
All patients 18 years and older with a higher risk for PPH who will deliver in one of the participating hospitals can be included (16 patients per hospital). This will include women with PPH in a previous delivery, multiple pregnancy, polyhydramnion, chorio-amnionitis, uterus myomatosis, grande multiparity, long delivery, clotting disorders or thrombocytopenia (HELLP). Since asking permission during the delivery is difficult and the higher risk of PPH can develop during delivery, all women who visit the antenatal clinic will be asked in advance by research nurses to participate. Informed consent will be asked for filming the third stage of labor and for reviewing these images by a third party; the researcher. The group who declines will be asked permission to study their medical record. In this way, besides the total incidence of PPH in the study period, the incidence of PPH in women who participate and those who do not participate can be recorded.
Chapter 2

**Objective 2**
To detect barriers and facilitators amongst professionals involved in the implementation of the NVOG-guideline on PPH and the MOET-instructions and patients (barriers and facilitators study).

**Design**
A qualitative study will be performed with the aim to discover factors in detail that are “pro” or “contra” adhering to the developed PPH-indicators. This will be performed by focus group interviews among groups of different involved professionals (gynecologists, midwives and gynecologists in training) and experienced patients. The interviewer will explore the following categories of influencing factors: features of the guidelines itself; features of the target group of professionals who should use the recommendations; features of patients who have to accept or contribute to using the recommendations; features of the social setting and social network (e.g. colleagues of the involved professionals); features of the organizational, economic, and administrative context. Subsequently, to assess the ‘prevalence’ of the factors mentioned in the focus group interviews, a survey with questionnaires will be performed among all Dutch gynecologists and midwives. They will receive a web-based questionnaire by e-mail. The data will be gathered in an electronic database.

**Study population**
To select the members of the focus groups, we will contact the national professional associations of respectively gynecologists and midwives and request nominations for opinion leaders and the professionals participating in the actual care study. The different focus groups will consist of respectively 10 gynecologists, 10 midwives, 10 gynecologists in training and 10 patients. To select the participants for the survey with questionnaires, we will contact the national professional associations of respectively gynecologists and midwives and request email addresses.

**Objective 3**
Development and testing an implementation strategy in terms of effectiveness, experiences of participants, process and costs (feasibility study).
Design
Based on the results of step 1 and 2, a tailored implementation strategy will be developed to increase the adherence to the recommendations. Because different barriers at different levels are expected, it is very likely that a strategy with different implementation elements directed at both professional and organizational level will be developed. At this moment, we have some hypotheses about expecting limitations in actual care. At the level of the guideline/MOET-instructions itself we think that the guideline can be more specific; the description of the desired care is not detailed enough. The desired care can be described in a detailed and structural manor by the development of “bundles”. These bundles are defined as a group of interventions related to a disease process that, when executed together, results in better outcome than when implemented individually. A second limitation could be a delayed time interval between events and taken actions, (right actions taken too slowly due to individual decisions or organizational factors). The solution could also be describing the desired care in bundles in the guideline and on organizational level an improvement process can be undertaken if the exact problem can be identified for example; multidisciplinary clear agreements. At the level of the professionals, a lack of knowledge/insight in own performance can be an impending factor. The installed monitors could be used to constant audit and feedback their performance, both individual and in review conferences and team training could be an intervention. However, due to uncertainty of existing barriers and facilitators the strategy cannot be worked out in detail now.

Intervention
The tailored improvement strategy will be implemented and evaluated in a feasibility study in nine months. The study will be performed in 4 hospitals (also participating in the actual care study) and consists of three evaluations:
a) To obtain an indication of the effect of the implementation strategy, the adherence to the developed indicators will be measured before (= actual care study) and after the introduction of the newly developed strategy, using videotaping and a medical record search (see step 1b). For the after-measurement we will include about 100 patients.
b) A process evaluation will be performed to study the experiences of the clinicians and patients with the changed care and also to study the extent by which clinicians and eventually patients use the elements of the strategies and their experiences (e.g. satisfaction and feasibility) with these elements. To achieve this, process information will be gathered in a qualitative study in the 4 participating hospitals.
and individual interviews will take place among the different involved gynecologists, midwives and patients.

c) A cost analysis of the tested implementation strategy will take place. The perspective of this analysis will be the health care perspective. The costs of the implementation strategy will be estimated by an Activity Based Costing approach focusing on activities performed to implement the NVOG-guideline on PPH and the MOET-instructions, with the costs accumulated at the activity level(s) of the health care implementation processes. The costs of implementation of the guidelines and consolidation consist of personnel and material costs. The input of resources will be assessed by collecting volumes of consumed resources and multiplying these by the price of each resource unit. The prices of each resource unit will be based on standard costs, market prices or self-determined costs. In the analysis, the implementation costs will be related to the difference in percentage of patients treated according to the guideline indicators in the situation before and after the implementation of the NVOG-guideline on PPH and the MOET-instructions.

**Study population**

To study the feasibility, four hospitals and their respective gynecologists and midwives will participate in two different regions in the Netherlands. In each region, an academic hospital and a non-academic hospital will participate. The inclusion criteria and course of management for the 100 patients in the ‘after-measurement’ will be the same as in the actual care study. For the process evaluation all gynecologists and midwives of the included patients are asked to participate.

**Outcome measures**

*Actual care study*

The primary outcome measure is the adherence to the quality indicators (derived from the NVOG guideline on PPH and the MOET-instructions). The secondary outcome measure is outcome of care (e.g. the incidence of PPH).

*Barrier and facilitator study*

The main outcome is the different types and frequency of found barriers and facilitators for implementation of the NVOG guideline and MOET-instructions regarding gynecologists, midwives and patients.

*Feasibility study*

To get an indication of the effectiveness of the strategy the primary outcome measure is the adherence to developed quality indicators. Other outcome measures are the experiences of the participants (both professionals and patients)
with the elements of the strategy and with the changed care. Also the cost of the tested strategy will be measured.

Statistical issues
Sample size calculation actual care study and feasibility of recruitment
Assuming accordance with the guidelines of 50%, with an alpha of 0.05, a precision of the estimation of 0.075, 171 patients have to be included. However, taking clustering of data within clinicians into account, this number has to be multiplied by the design effect. With 5 patients per clinician and an intraclass correlation of 0.20 this effect is 1.8. So the minimum number of patients that have to be included is \(1.8 \times 171 = 308\) patients. In order to compensate for lost to follow-up or incomplete data, 320 women have to be included in 20 hospitals in 6-9 months.

Data analysis
Analysis of the actual care study
To analyze actual care, frequencies of adherence per quality indicator will be calculated. Furthermore, the variation in this care between the different hospitals will be calculated.

Analysis of the barriers and facilitators
The barriers and facilitators mentioned in the focus group interviews with professionals and patients will be qualitatively analyzed, using the qualitative software package (Atlas). In the quantification of these barriers, frequencies of found barriers and facilitators will be calculated.

Analysis of the feasibility study
In the effectuation the proportion of patients that are treated in accordance with the guidelines (analyzed on the basis of the indicator set) before and after implementation of the guidelines will be established. Both univariate and multivariate (multi-level) analyses are performed to demonstrate the effect of the implementation strategy in increasing the proportion of patients who are treated according to the guidelines. In addition, for the process evaluation, frequencies are used to assess the experiences of the professionals and patients to the implementation program elements. Analyses of the costs of the implementation strategy will be conducted by multiplying the volumes of consumed resources with the price of each resource unit.
Ethical considerations
The study protocol has been presented to the Medical Ethical Committee (CMO) of the region Arnhem and Nijmegen (ABR no. NL25975.091.08). Ethical approval was not necessary. The protocol is registered in the ClinicalTrials.gov register (NCT00928863).

DISCUSSION
This study addresses an important problem because PPH is currently the major cause of severe maternal morbidity in the Netherlands. Many different factors determine the action that is taken in case of more than average blood loss or once a real PPH sets in. Insight into these factors is of great importance in order to know what kind of activities should be developed to prevent PPH by implementing the NVOG-guideline and MOET-instructions. In literature, the following facilitators and barriers are distinguished: features of the innovations itself, of the target group of professionals who should use the innovation, of patients who have to accept or contribute to the innovation, of the social setting and network and of the organizational, economic and administrative context. To our knowledge the proposed study is the first study on barriers and the development and testing of a tailored implementation strategy for acute care situations in the obstetrics. A randomized controlled study is the next step to measure the effectiveness of the implementation of the obtained strategy if the result of this study is that the strategy is feasible in practice, can be implemented with low costs and indicates to be effective. Ultimately, the generated knowledge and understanding of the implementation process can be used to implement guidelines in different countries with similar problems and hopefully lead to a worldwide reduction of the incidence of PPH.
REFERENCES
3. The Dutch Perinatal Registry (PRN). In, 2011.
Guideline-based development of quality indicators for prevention and management of postpartum hemorrhage

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Hubertina Scheepers
Janine Liefers
Marcus Lance
Johanna Middeldorp
Fred Lotgering
Richard Grol
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ABSTRACT

Introduction. To systematically develop a set of guideline-based quality indicators for postpartum hemorrhage (PPH) as a tool to measure guideline adherence in actual PPH care.

Material and methods. A Rand-modified Delphi procedure was used to systematically achieve consensus among a panel of 22 experts on PPH care on recommendations extracted from evidence-based guidelines, Managing-Obstetrics-Emergencies-Trauma (MOET) instructions and international literature. The selected recommendations were individually rated on health gain (prevention of maternal mortality and morbidity) and overall efficiency by the expert panel. Subsequently, consensus about the most important recommendations to measure quality of PPH care among the panel members was reached, followed by a final approval. Last, definition of the final set by critical appraisal of the recommendations regarding measurability took place. The main outcome measure was a set of valid quality indicators for prevention and management of PPH.

Results. From the 69 extracted recommendations, 50 were selected and translated into 22 quality indicators on professional performance (n=17) and organization of PPH care (n=5). The professional performance indicators covered all fields of PPH care, such as prevention (n=2) and management of PPH, including communication and documentation (n=4), monitoring and prevention of shock (n=3), use of blood products (n=3) and treatment of PPH (n=5). Organizational indicators (n=5) were clustered into protocols and agreements, audit, accessibility and documentation.

Conclusions. This study describes a stepwise systematic development of 22 performance and organizational indicators to use for measuring the whole care process of prevention and management of PPH.
INTRODUCTION

Postpartum hemorrhage (PPH) is responsible for 25% of maternal mortality worldwide. This does not solely have its origin in low resource countries; developed countries also contribute. In these countries PPH is still one of the top reasons of maternal morbidity and death. In addition, an increased incidence has been reported in several countries. Alteration of high-risk groups such as higher maternal age, obesity, multiple birth and increased cesarean section numbers cannot fully explain this rise. Substandard factors, such as treatment delays, are frequently reported. That 30–90% of PPH-cases receive suboptimal care has been reported. Antony and Dildy showed lower PPH incidences in hospitals with a fetal maternal specialist on the staff, and indicated the existence and implementation of PPH protocols as a possible explanation. Briley et al. found deprivation of skills, training and education to be a risk factor in progression to severe PPH.

It is well known that substandard factors can be overcome by the use of evidence-based guidelines. These guidelines provide clinicians with information regarding “the best available evidence-based care” and aim to increase the effectiveness of care and reduce variation in performance between professionals and hospitals. They are important for standardizing and optimizing clinical care and influencing outcomes, such as with regard to maternal mortality and morbidity. Consequently, the World Health Organization (WHO), and many high-resource countries, have developed and disseminated evidence-based guidelines for PPH management and prevention. In addition, by analogy with the emergency care sector, many countries have adapted for their guidelines the instructions based on the Advanced Trauma Life Support (ATLS) for management of massive blood loss, such as the Managing Obstetrics Emergencies Trauma (MOET) course instructions.

However, the dissemination of evidence-based PPH guidelines and introduction of the ATLS-based courses has not led to a reduction in PPH. The increasing incidence of PPH suggests an incomplete implementation of guidelines and courses. This also applies to the Netherlands, where the incidence of PPH increased (4% in 2003, 7% in 2011) despite the introduction of the MOET course and the dissemination of a PPH guideline in 2003. A systematic approach is needed for the implementation of guidelines and the improvement of PPH care. A first step in such a process of effective implementation is to acquire insight into...
actual practice\textsuperscript{24}. Quality indicators, which can be defined as evidence-or consensus-based measurable elements for assessing quality of care, are crucial\textsuperscript{25}. However, valid sets of quality indicators for professional performance and organization are barely available in the field of PPH.

This study aimed to develop systematically a set of valid quality indicators for monitoring the actual care for prevention and management of PPH, as an important first step to improve quality of care and reduce the incidence of PPH.

**MATERIAL AND METHODS**

To develop a set of quality indicators for patients with (a high risk for) PPH, we used the Rand-modified Delphi procedure\textsuperscript{26}. A multidisciplinary panel of 22 professionals included Dutch PPH experts as well as professional guideline users working at various types of institutions, ranging from small regional hospitals to tertiary university hospitals. The panel consisted of maternal-fetal medicine specialists, general obstetricians/gynecologists and residents, members of the national obstetrics guideline development group and the national maternal health group, anesthesiologists, hematologists, representatives of the Dutch MOET board, and MOET instructors. The Medical Ethics Committee (CMO) of the region Arnhem and Nijmegen (ABR no. NL25975.091.08) declared that ethical approval was not necessary. The study was registered at the ClinicalTrials.gov, http://www.clinicaltrials.gov: (NCT00928863).

**Procedure for indicator development**

The Rand-modified Delphi method included five steps (figure 1): (i) selection of recommendations from evidence-based guidelines, course instructions and international literature; (ii) individual rating of the recommendations by the expert panel using a written questionnaire; (iii) face-to-face panel discussions to reach consensus; (iv) consultation of expert panel members for final approval; and (v) critical appraisal regarding measurability by the authors and defining the final set of quality indicators.
Figure 1. Flow chart for the stepwise development of quality indicators for postpartum hemorrhage (PPH): a systemic consensus according to the RAND-modified Delphi method.

Step 1. Selection of the recommendations from the national, international PPH guidelines, MOET course and international literature.

- 19 Guidelines
- 31 MOET
- 17 Guidelines & MOET
- 2 Literature

69 recommendations

Step 2. Questionnaire round: prioritization on criteria health gain, clinical importance and overall efficiency.

- 9 rejected items
- 29 items with high potential
- 31 items with uncertain potential
- 9 newly proposed items

69 recommendations

Step 3. Consensus round on criteria applicability and potential for improvement.

- 38 performance recommendations
- 12 organizational recommendations

Step 4. Written final approval by the experts

Step 5. Critical evaluation on applicability and measurability, categorizing and definition of the final set.

Final set

- 17 clinical performance indicators suitable to measure actual PPH care
- 5 organizational performance indicators suitable to measure organization of PPH care
Step 1: Selection of recommendations
Three authors (MW, RH, HS) individually selected recommendations from national and international PPH guidelines, the MOET course manual of the Royal College of Obstetricians and Gynecologists (RCOG) in the UK, and existing indicators from international (English) medical literature\textsuperscript{14-19}. Discrepancies were discussed until consensus was reached. The extracted recommendations were edited into a questionnaire for individual rating by the expert panel. We used the classification of the “European consensus on prevention and treatment of PPH” and of the MOET manual to arrange the recommendations into domains related to the different degrees of severity of PPH\textsuperscript{27}. The domains included: (i) prevention of PPH in high-risk patients; (ii) management of PPH (500–1000 ml without signs of shock); (iii) management of severe PPH (1000–2000 ml or signs of shock); and (iv) management of ongoing PPH (>2000 ml). A fifth domain concerned recommendations on the “organization of PPH care” at hospital level. Each recommendation was accompanied with evidence as formulated in the guidelines and MOET course instructions (figure 2).

Figure 2. Example of a recommendation presented in the score sheet, submitted to the participating experts

<table>
<thead>
<tr>
<th>Prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>To what extent is the following procedure an important determinant to measure quality of care?</strong></td>
</tr>
<tr>
<td>The practitioner should in case of a high risk patient on PPH...</td>
</tr>
<tr>
<td><strong>Evidence level</strong></td>
</tr>
<tr>
<td>1. Ensure an IV access during labor</td>
</tr>
<tr>
<td>1 2 3 4 5 6 7 8 9</td>
</tr>
<tr>
<td>[------------------------------------------]</td>
</tr>
<tr>
<td>Very poor</td>
</tr>
<tr>
<td>□ In assessable</td>
</tr>
</tbody>
</table>

\*Evidence level is provided for each recommendation

Step 2: Rating the recommendations
Questionnaires with the selected recommendations were sent to the 22 experts. The experts individually rated each recommendation on its capacity to measure quality of care, in terms of improvement of health gain and overall efficiency on a scale of one (inferior measure) to nine (excellent measure). In addition, the experts were asked to provide for each of the aforementioned domains, with a top three or five ranking containing the “most important” and “representative” recommendations for a good assessment of the quality of clinical performance. A top three was
Development of quality indicators

requested for a domain with a small number of recommendations, otherwise a top five. The experts were encouraged to modify and update recommendations when needed. The recommendations were considered valid if they met the criterion described by Campbell et al.\textsuperscript{28}: an overall median score of eight or nine, and agreement between the experts. Agreement was defined as more than 70% of the ratings within a panel being in the lowest (1–3) or the highest tertile (7–9). In addition, prioritizing took place by awarding points to the recommendations according to the experts’ top three or five ranking\textsuperscript{29} (for example: three of five points for a number one ranking; two of four points for a number two ranking, one or three points for a number three ranking and so on).

**Step 3: Consensus meeting**

All participants were invited to participate in a face-to-face consensus meeting to discuss the results of Step two. Each panel member received a personalized feedback report with individual and group results (median rating and prioritization) for each recommendation at the beginning of this meeting. In this report, recommendations were ordered in groups of high, low, or uncertain potential for measuring quality of care, depending on the median and prioritizing scores. At the meeting, the high-potential recommendations were discussed for acceptance and those with low potential for rejection. Recommendations with an uncertain potential were discussed until consensus was reached on acceptance or rejection.

**Step 4: Written consultation for final approval**

The semi-final set of recommendations was sent to the 22 expert panel members for a final check. The panel was requested to control and approve whether the set was indeed a good representative for measuring quality of PPH care in accordance to published material, guidelines and MOET instructions.

**Step 5: Critical evaluation and defining the final set**

The three authors (HS, MW, RH) critically evaluated the set of key recommendations, agreed upon by the experts, as well the comments given by the expert panel. The recommendations were appraised with regard to “applicability” and “measurability” resulting in a final consensus-based set of key recommendations. Subsequently, the recommendations were translated into concrete quality indicators by defining numerators and denominators (figure 3).
RESULTS

The results of the different steps are shown in Figure 1. A total of 69 recommendations were extracted and edited in a questionnaire (Step 1) and sent to 22 experts (Step 2). Twenty questionnaires (91%) were returned fully completed. Twenty-nine recommendations were rated as valid (high potential), nine recommendations were suitable for rejection (low potential), and 31 recommendations had an uncertain potential. The experts suggested nine additional recommendations.

In the consensus meeting (Step 3), with a small, representative delegation of the expert panel (n=5), agreement was conceived on all 29 high potential recommendations. Two recommendations were combined into one, which resulted in a total of 28 accepted recommendations. All nine recommendations with a low potential were rejected. Of the 31 items with uncertain potential and the nine newly added recommendations, 22 were accepted as valid. In total, 50 recommendations were selected (38 regarding professional performance, 12 regarding organization of care). The selection of the representative delegates was presented to the total expert panel and approved by 18 (82%) of the experts in a written round (Step 4).

In defining quality indicators (Step 5), one recommendation was excluded as not being measurable (recommendation: when in doubt of the completeness of the placenta, empty the uterus in the operating room). The final 49 recommendations were translated into 22 concrete quality indicators regarding professional performance (both prevention, management of PPH) and organization of PPH care. The indicators on “management of PPH” were categorized according to the MOET manual classification: (i) communication and documentation; (ii) monitoring and prevention of shock; (iii) use of blood products; and (iv) treatment of PPH (table 1).
Table 1. Guideline-based quality indicators for prevention, management and organization of PPH-care

<table>
<thead>
<tr>
<th>Performance indicators for prevention of PPH</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention</td>
<td>1. 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</td>
</tr>
<tr>
<td></td>
<td>2. To ensure IV access during labor, provide an active management of the third stage of labor and objectively measure blood loss</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Performance indicators for management of PPH</th>
<th>Time (ml)</th>
<th>In case of a patient with PPH the clinician should…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication documentation</td>
<td>&gt;500</td>
<td>1. inform the gynecologist (in training)</td>
</tr>
<tr>
<td></td>
<td>&gt;1000</td>
<td>2. 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</td>
</tr>
<tr>
<td></td>
<td>&gt;2000</td>
<td>3. allocate one member of the team to record vital signs, events, fluids, and drugs</td>
</tr>
<tr>
<td></td>
<td>&gt;500</td>
<td>4. Call for a second obstetrician and inform the radiologist (if applicable)</td>
</tr>
<tr>
<td>Monitoring &amp; prevention of shock</td>
<td>&gt;500</td>
<td>5. monitor vital functions appropriately, take blood samples and replace fluid:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• continuously monitor pulse &amp; oxygen saturation and BP (5-10 minutes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• take blood samples: FBC and cross match screen</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• ensure an IV access (18 gauge) and commence volume replacement (1 liter of saline)</td>
</tr>
<tr>
<td></td>
<td>&gt;1000</td>
<td>6. monitor additional vital functions appropriately, give oxygen and replace fluid:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Give 10-15 liters/minutes oxygen through face mask regardless of her oxygen saturation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• monitor urine production</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• provide a second IV access (18 gauge), and replace volume by using pressure bags and warmed fluid (in case of large volumes)</td>
</tr>
<tr>
<td></td>
<td>&gt;2000</td>
<td>7. call for anesthetic assistance if the airway is compromised</td>
</tr>
<tr>
<td>Blood products</td>
<td>&gt;1000</td>
<td>8. urgently order units of blood and fresh frozen plasma, check and correct clotting status</td>
</tr>
<tr>
<td></td>
<td>&gt;2000</td>
<td>9. follow hospital-wide mass transfusion protocol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10. transfuse uncrossed matched O negative blood if hemorrhage is life threatening, correct clotting status (including platelets &gt;50 or when surgery is planned &gt;80)</td>
</tr>
<tr>
<td>Therapy</td>
<td>&gt;500</td>
<td>11. treat uterine atony:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• continuous uterus massage, bladder catheterization and uterotonic medication in steps;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• in case of retained placenta: perform controlled cord traction followed by placenta removal in the operating room</td>
</tr>
<tr>
<td></td>
<td>&gt;1000</td>
<td>12. treat PPH as an atony till proven otherwise, use prostaglandins IV if other uterotonic treatment fails</td>
</tr>
<tr>
<td></td>
<td>&gt;2000</td>
<td>13. perform or consider following interventions:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• empty uterus, repair genital tract injury (vaginal, cervical uterine rupture)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• (consider) selective arterial embolization as alternative or in addition to surgical intervention, if not successful consider internal iliac artery balloon</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• (consider) Brace suture, arterial ligation and hysterectomy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>14. in an emergency situation to temporarily stop bleeding and catch up resuscitation, organize the next intervention or transport patient to a tertiary centre:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• perform: bimanual compression of the uterus, aorta compression and place Bakri balloon or uterine tamponade through packing (also therapeutically)</td>
</tr>
</tbody>
</table>
Table 1. Continued

<table>
<thead>
<tr>
<th>Organizational indicators for PPH: In every hospital system…</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocols and agreements</strong></td>
</tr>
<tr>
<td>1. the following local protocols and agreement should be available:</td>
</tr>
<tr>
<td>• PPH protocol according to the national guideline and MOET instructions</td>
</tr>
<tr>
<td>• mass transfusion protocol</td>
</tr>
<tr>
<td>• protocol for women refusing blood products;</td>
</tr>
<tr>
<td>• written agreement between the related disciplines (anesthesia, hematology, radiology) for a multidisciplinary approach in the treatment of PPH</td>
</tr>
<tr>
<td>• PPH-protocols and ATLS course-based team training on a regular basis</td>
</tr>
<tr>
<td><strong>Accessibility</strong></td>
</tr>
<tr>
<td>2. It must be clear how to rapidly reach the following staff/departments at any moment:</td>
</tr>
<tr>
<td>• Gynecologist, Anesthesiologist, Hematologist, Intensive care specialist surgery team, blood bank; and resuscitation team</td>
</tr>
<tr>
<td>• there should be clear prior agreements about the time interval between the call and availability of the following staff (gynecologist, anesthesiologist and surgery team)</td>
</tr>
<tr>
<td><strong>Audit and feedback</strong></td>
</tr>
<tr>
<td>3. PPH cases should be:</td>
</tr>
<tr>
<td>• discussed during morning team-gathering in a structured and detailed way, according to local PPH-protocol/ guideline</td>
</tr>
<tr>
<td>• 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</td>
</tr>
<tr>
<td><strong>Documentation and registration</strong></td>
</tr>
<tr>
<td>4. the practitioner must ensure proper documentation for each PPH case, in particular concerning the time course</td>
</tr>
<tr>
<td>5. all cases of PPH (&gt; 1000cc) must be registered</td>
</tr>
</tbody>
</table>

**Final set**

The two indicators for “Prevention of PPH” are mainly focused on increasing awareness and anticipatory behavior of the professionals by pre-identification and timely recognition of PPH among the group of high-risk patients. Regarding the indicators on “management of PPH”, the category communication and documentation consists of four indicators concerning the different type of assistance needed to be able to perform the different actions (consulting other specialists on time, proper documentation of the actions taken). The categories monitoring both shock prevention (three indicators) and use of blood products (three indicators) include indicators concerning sequential actions for vital signs monitoring and the increased use of fluids and blood products while a PPH progresses. The category therapy consists of five indicators related to the different therapeutic options of medication, surgery and treatments such as arterial-embolization to stop the bleeding. All these indicators show that parallel execution of multiple actions is needed as the amount of blood loss increases. The “organization of care” indicators (five indicators) concern the presence of protocols
and agreement, accessibility to staff members, audit and feedback, documentation and registration.

**DISCUSSION**

Twenty-two valid quality indicators, based on evidence-based guidelines on PPH, MOET instructions and international literature, were systematically developed to assess the quality of actual PPH care. This set covers the entire field of PPH care, on both professional performance (prevention and management of PPH) and organizational quality.

Publications on quality indicators for PPH mainly consist of outcome indicators which describe the PPH incidence without giving a clear understanding of the quality of care\textsuperscript{30-32}. In the recent English medical literature only two studies have been published regarding performance indicators\textsuperscript{33,34}. Bonfill et al. generated quality of care indicators from systematic reviews to assess the appropriateness of obstetric care in hospitals. They found four relevant quality indicators of 18 regarding postpartum care, but only one directly concerned PPH care (proportion of women administered uterotonic in the third stage of labor). Talungchit et al. developed evidence-based indicators for severe (pre)-eclampsia and PPH with the Delphi technique and assessed their validity, reliability, and feasibility. Their developed set of PPH indicators concerned diagnosis and management only. Prevention and organizational aspects were lacking but these are very important in such complex care. After all, PPH is mostly preventable if the right procedures have been conducted at the right time\textsuperscript{35}. In addition, to be able to deliver good care, especially due to the complexity of PPH care, a number of basic requirements are imperative, for instance the existence of local protocols\textsuperscript{36,37}.

Bouvier-Colle et al. showed the lack of a 24-h on-site anesthetist to be associated with substandard PPH care\textsuperscript{8}. Until now, no quality indicators concerning prevention and organization were available. Timely responses are essential in PPH care since delays in early diagnosis and treatment are frequently reported \textsuperscript{38,39}. The indicator-set of Talungchit et al. does not indicate when certain performances have to be executed during the care process\textsuperscript{34}. A highly structured approach, as in the trauma care sector, with parallel execution of multiple actions in a clear-cut time frame, such as calling for help, monitoring vital signs, fluid replacement and arrest of bleeding, can prevent PPH escalation\textsuperscript{40}. Our indicator-set covers the entire field of PPH care, both with regard to professional performance and organizational quality. It defines optimal care regarding the
timing of actions, but also what is considered optimal care regarding timely actions. By relating these actions to the degree of blood loss, a more quantitative measurement of delay is achievable. Together with the existing outcome indicators, our set can be used to evaluate the actual care in the whole PPH field, making it possible to pinpoint exactly on which levels and in which stages current care is lacking and improvement is needed.

Until now, to optimize PPH care, many improvement strategies have been implemented without thorough analyses of current care, making the efficacy unclear\textsuperscript{41}. For example, training is usually a prerequisite for improving quality of care in emergency situations; however, as a single intervention, training is not very effective\textsuperscript{42,43}. It is likely that the complexity of the situation needs an approach at different levels. Moreover, the content of training, being directed either at improvement of knowledge or team interaction, depends on the level of current care at which problems occur. Audit and feedback is known to identify substandard care but as a single tool it shows limited effect on quality of care improvement\textsuperscript{44}. The use of flowcharts, checklists, bundles and stop-moments as in the Surgical Safety System (SURPASS) have been proven effective in critical care\textsuperscript{45-47}. It is possible that these tools also apply to PPH care, but we believe that an analysis of current care and studying factors that facilitate and hinder caregivers in supplying optimal care, need to be addressed first\textsuperscript{12}. Based on these analyses, a tailored improvement tool can be developed and evaluated for cost-effectiveness before general implementation\textsuperscript{24}. There are strengths and limitations to consider. A strength was the use of the Rand-modified Delphi method. This technique allows development of indicators in a more systematic and evidence-based fashion compared with the more ad hoc techniques frequently used in obstetric care. The Rand-modified Delphi method has been proven to be effective and is widely used in other medical fields\textsuperscript{48}.

Another strength is that our indicator-set covers the entire field of PPH care, both on professional performance (prevention and management of PPH) and organizational quality, but also what is considered optimal care regarding the timing of actions. Furthermore, we used both national and international guidelines, international publications and the MOET course of the RCOG as starting points for the development of the indicators. Although it can be assumed that guidelines differ between countries due to the different interpretation of evidence and cultural differences, we believe that the majority of the generated indicators are directly, or after slight adaptation, applicable for European and other international users. In
2007 a core consensus was reached between 14 European countries including the Netherlands, on prevention and management of PPH\textsuperscript{27}. In 2009, the WHO disseminated a PPH guideline containing the most recent evidence, as a direction for the development of local guidelines\textsuperscript{17}. Many recommendations of this consensus document and WHO guidelines are comparable with the recommendations which our indicator-set is based on.

There are some limitations to this study as well. The selection of indicators covering performance and organizational aspects reflect the type of recommendations in guidelines and lacks outcome indicators. It is assumed that guideline adherence and good outcome are directly related, however, good results do not necessarily mean that care was well delivered and bad results do not indicate which part of the care process needs to be improved. Therefore, it is important to engage both performance and organizational indicators as care outcome variables, to get a complete insight into the quality of PPH care\textsuperscript{24}. Another restraint is the confined presence of professionals (20\%) in the consensus round. Questions can be posed about the reliability of this round; however, all the decisions made in Step 3 were approved by 18 (81\%) of the 22 professionals in Step 4, which is a broad and reliable consensus.

**CONCLUSION**

We systematically developed a set of 22 quality indicators, both on professional performance and organizational factors, based on the guidelines, MOET instructions and international publications, covering the whole process of PPH prevention and management. This instrument can be used internationally to measure and monitor care delivered to patients with (a high risk of) PPH as a first step towards quality improvement.
REFERENCES

From postpartum hemorrhage 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 suboptimal 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 three University Hospitals (UH), eight Teaching Hospitals (TH) and seven 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.
INTRODUCTION
Postpartum Hemorrhage (PPH) is the number one cause of worldwide maternal death\(^1\). It does not only have its origin in low resource countries, but developed countries also contribute\(^2\)-\(^5\). 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\(^6\)-\(^8\). 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\(^9\).

Evidence-based guidelines can assist professionals in standardizing adequate management and support the clinical evidence-based decision making\(^10\). Advanced Trauma Life Support (ATLS) courses educate the professionals in using a highly structured multidisciplinary approach of obstetric emergencies such as PPH\(^9\). 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\(^10\). Several national societies of maternal-fetal-medicine\(^11,12\) strongly recommend the use of protocols as a way to streamline PPH-care, because compliance of guidelines improves if a protocol is present\(^13\)-\(^15\). 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\(^16\). 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.

MATERIAL & 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 60 Dutch general hospitals. A viable selection of the Dutch hospitals was made and a total of 18 (23\%) PPH-protocols from the 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\(^\text{17}\). 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 seven-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\(^\text{18}\). 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\(^\text{9,12,19-21}\). The indicators for management of PPH were classified into three subsequent stages of seriousness of PPH, in terms of the amount of blood loss and/or signs of shock, namely: 1. > 500 ml, 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 eighteen hospital protocols divided by the maximum amount of items ($Y / 92 \times 18$). 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 three (ranging from 2 (TH and NTH) to 3 (UH)) (Table 1).

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.

Table 1. Quality of the protocols on structure using the AGREE-II instrument

<table>
<thead>
<tr>
<th>AGREE-II domain</th>
<th>Form and Structure</th>
<th>Total* n=18</th>
<th>UH* n=3</th>
<th>TH* n=8</th>
<th>NTH* n=7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope and Purpose</td>
<td>- Objective</td>
<td>1</td>
<td>7</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>- Title with health question</td>
<td>7</td>
<td>7</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>- Patient population</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Rigor of development</td>
<td>- Publication date</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>- Revision date</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>- Externally reviewed</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>- References</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Stakeholder Involvement</td>
<td>- Authors</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>- Target group</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Applicability</td>
<td>- Appendices/tools</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

* expressed in Median (range 1-7); UH = University Hospitals, TH = Teaching Hospitals, NTH= Non Teaching Hospitals

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 2). 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 14% in the NTH. Half of the protocols suggest to consider a B-Lynch suture (33%
From postpartum hemorrhage guideline to local protocol

UH, 43% NTH and 63% TH), however, to consider a timely hysterectomy was found in only one protocol (6% (UH)).

Table 2. Quality of local protocols on content

<table>
<thead>
<tr>
<th>Items</th>
<th>Total (n=18) %</th>
<th>UH (n=3) %</th>
<th>TH (n=8) %</th>
<th>NTH (n=7) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall mean score of the items in the protocols (Range)</td>
<td>46 (20-65)</td>
<td>55 (50-65)</td>
<td>48 (35-64)</td>
<td>39 (20-54)</td>
</tr>
<tr>
<td><strong>Prevention of PPH</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identification &amp; determining policy of patients at high-risk for PPH</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- at outpatient clinic</td>
<td>11 0 25 0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- during labor</td>
<td>33 33 38 29</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active management of the third stage of labor</td>
<td>22 33 0 43</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Objectify (weigh) blood loss of high-risk patients</td>
<td>67 33 63 86</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Management PPH &gt;500 ml</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Call for the gynecologist on ward</td>
<td>72 67 88 57</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuously monitor heart rate</td>
<td>6 0 0 14</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuously monitor oxygen saturation</td>
<td>11 0 13 14</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measure Blood Pressure (5-10 minutes),</td>
<td>28 33 13 43</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ensure drip</td>
<td>94 100 100 86</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assess cross match blood</td>
<td>100 100 100 100</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assess Hemoglobin</td>
<td>94 100 88 100</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continuous uterus massage</td>
<td>78 100 63 86</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bladder catheterization</td>
<td>100 100 100 100</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>To give uterotonic medication in steps</td>
<td>94 100 88 71</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication plan in steps present in protocol</td>
<td>88 100 88 86</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If retained placenta, remove placenta in operating room</td>
<td>72 100 75 57</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Management PPH &gt;1000 ml</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Give 10-15 liters of oxygen by face mask</td>
<td>56 67 75 29</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Order packed cells</td>
<td>94 100 100 86</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provide a second drip</td>
<td>88 100 100 71</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitor urine production</td>
<td>56 100 75 14</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control and correct blood clotting</td>
<td>78 100 75 71</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allocate one member of the team to record events</td>
<td>17 33 13 14</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Call for the anesthesiologist onward</td>
<td>6 33 0 0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Call for the operating team onward</td>
<td>11 33 13 0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Replace volume by using pressure bags</td>
<td>33 67 25 29</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Management PPH &gt;2000 ml</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transfuse uncrossed matched O negative blood if PPH is life threatening</td>
<td>11 0 13 14</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

UH = University Hospitals, TH = Teaching Hospitals, NTH= Non Teaching Hospitals
**Chapter 4**

*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 (figure 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.

**Figure 1. Mean percentage of items with a time indication in the protocols**

![Bar chart showing the mean percentage of items with a time indication in the protocols](image)

**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 items scored below average) compared with the UH and NTH (6 out of 10 items scored below average).
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.

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. 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. 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\textsuperscript{22,24}. 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\textsuperscript{7,11}. Different international guidelines highlight the evaluation of vital signs and recommend more accurate management for PPH if blood loss causes changes in vital signs\textsuperscript{12,20,25}. 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\textsuperscript{15,26}. 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 is 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 \textit{et al.} shows that only 20\% of all protocols in Great-Britain took over all recommendations of the national guideline “Group B Streptococcus” \textsuperscript{27}. 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\textsuperscript{10,28}. Cameron \textit{et al.} investigated current Australian practice in the development of a local policy with regard to prevention, early recognition and management of PPH\textsuperscript{29}. 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\textsuperscript{26}. Improved compliance with protocols is found if there are comprehensive protocols, especially if nurses are involved in the development of these
protocols\textsuperscript{30}. 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\textsuperscript{26,29}. 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\textsuperscript{31,32}. 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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Poor guideline adherence in actual postpartum hemorrhage care in the Netherlands

a prospective observational multicenter study using video recordings of the third stage

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Submitted
ABSTRACT

Objective. To assess adherence to the national Post Partum Hemorrhage (PPH) guideline and Advance-Trauma-Life-Support (ATLS)-based course instructions for obstetric emergency in high-risk patients and its determinants in the Netherlands.

Methods. A prospective observational multicenter study was performed to assess actual PPH-care with guideline-based quality indicators for prevention, management and organization of PPH in 16 Dutch hospitals. Data was extracted from high-risk patients’ medical records and supplemented with data of prospective video-observations. Data of the organization of PPH-care was collected using questionnaires filled in by one obstetrician per hospital. We calculated adherence by using previously constructed algorithms and assessed the determinants at patient and hospital level.

Results. Actual care was assessed through medical records of 398 high-risk patients in 15 hospitals, added with 289 video recordings from 12 hospitals. As expected, video recordings showed that in general the actual care given was considerably underreported in medical records. Overall, a lack of quality in performance, and lack of performance within the optimal timeframe was observed. In almost 40% of high-risk women no active management was performed and in 20% blood loss was not objectified. Although guidelines suggest that care shall be adjusted to both the amount of blood loss and vital signs, in almost 80% the vital signs were not even monitored or monitored not in time. PPH-care in the hospitals was well organized. Fifteen hospitals had a local PPH protocol, in 12 hospitals team trainings were organized. However, there was a wide variance in the number and duration of the trainings. Regarding the determinants at patient and hospital level, University Hospital was mostly associated with better adherence especially monitoring heart rate which was significant.

Conclusion. This study showed low adherence to the guideline-based quality indicators, particularly regarding indicators for management of PPH >1000 ml, clearly indicating a problem of quality care in the Netherlands. Furthermore, the actions taken in the management of PPH were largely untimely performed. Determinants on both patient and hospital level show a significant association with monitoring PPH. Additional video observations proved valuable to pinpoint exactly at which level improvement is needed. One has to develop a tailor-made implementation strategy to improve quality of Dutch PPH-care.
INTRODUCTION
Severe postpartum hemorrhage (PPH), which is defined as more than 1000 ml blood loss in the first 24 hours after birth, contributes to both maternal mortality and to severe maternal morbidity worldwide and is not restricted to low resource countries\(^1\). In developed countries an increase is observed that cannot be explained by a change of frequency of risk factors such as higher maternal age, obesity, multiple birth and increase of the number of Caesarean sections\(^2-4\).

Substandard care is frequently mentioned in cases of PPH, with percentages of 38 up to 76 being reported\(^5-9\). The assumption is that substandard care can be overcome by the use of evidence-based guidelines, for they can assist professionals in standardizing adequate and timely management and support clinical evidence-based decision making\(^10,11\). Guidelines aim at increasing the effectiveness of care and reducing variation in performance between professionals and hospitals\(^11,12\). Many countries and the World Health Organization (WHO) developed and disseminated guidelines for prevention and management of PPH. Furthermore, in analogy with the emergency care, many countries adapted the Advance Trauma Life Support (ATLS) based instructions on the management of massive blood loss to educate the professionals on using a highly structured multidisciplinary approach of obstetric emergencies such as PPH by means of the Airway-Breathing-Circulation (ABC) assessments\(^13\). Streamlining day-to-day PPH-care for every professional, on the basis of evidence-based PPH-guidelines and ATLS-based course instructions is very important for optimizing clinical care and influencing outcomes, such as maternal morbidity and mortality\(^10,14\).

However, publication and dissemination of guidelines is not sufficient to maximize the effect on the quality of care\(^15,16\). For example, in 2003 the Netherlands introduced both the nationwide PPH guideline and ATLS-based course “Management of Obstetric Emergency Trauma” developed by the Royal College of Obstetricians and Gynecologists, while the PPH incidence increased in the second line of care from 3 in 2003 to 7% in 2011\(^17\). To improve the quality of PPH-care, proper implementation of these guidelines and ATLS-based instructions is essential and can only be achieved once the causes for not following guidelines and course instructions on different levels have been identified and overcome\(^11,18\).

A study in France showed that dissemination of an updated PPH guideline accompanied by a multifaceted implementation approach had no effect on the
outcome; worse, the incidence of PPH increased. They did not beforehand investigate the causes for not following guidelines\textsuperscript{19}.

A first step in improving care is getting a good insight into actual care and into deviations from optimal care as described in the guidelines. Insights into actual care can be acquired by using guideline-based quality indicators\textsuperscript{20,21}. Quality indicators are defined as measurable elements of clinical performances for which there is evidence or consensus that they can assess and help change the quality of the care provided\textsuperscript{22}. In addition, it is important to gain knowledge about determinants on both patient and hospital level responsible for gaps between actual and optimal care\textsuperscript{23,24}. We may assume that in highly specialized university hospitals, with a strong emphasis on ATLS-based team training (including ABC assessments) and multidisciplinary discussions, adherence to guideline and ATLS based courses and outcome of care would be better. However, outcome is also depending on the type and quantity of high risk patients for PPH, which are probably higher in these hospitals. Obtaining insights into factors that influence guideline adherence in daily practice both at patient and hospital level may result in a customized implementation strategy to improve PPH-care. Therefore, the objective of this study is to assess to what extent clinical guidelines for PPH are followed in routine Dutch hospitals as regards prevention, management and organization of PPH, and to determine patient and hospital characteristics of influence, as an important step to improve the quality of PPH-care.

**METHODS**

**Design and Setting**
A prospective observational multicenter study was performed in 16 Dutch hospitals throughout the Netherlands to assess the quality of care for patients with a high risk for postpartum hemorrhage (PPH), using both medical records and video recordings of the third stage of labor from patients on the delivery rooms. The study was established within the Dutch Consortium for research in Women’s health, in which 70 hospitals participate.

**Study population**

*Hospitals*
The selection of the 16 hospitals was based on different types of hospitals (University Hospitals, Non University hospitals) with an equal distribution by type.
across the country. The gynecology staff, the work council and the board of directors gave permission to perform the study in all participating hospitals.

Patients
Patients older than eighteen with a higher risk for PPH in the participating hospitals were eligible for inclusion. Since not all high risk is known before the start of labor, and to give women enough time to consider participation, all pregnant women were asked for their informed consent before the onset of actual labor. Women could consent to videotaping and reviewing the third stage of labor by an independent researcher, or to just a study of their medical record. All caregivers working on the labor ward of the participating hospitals were informed in advance by email and were given the opportunity to refuse being videotaped at all times. It was made clear that the videotapes were only to be viewed by the researchers, and were to be legally destroyed after having served their purpose.

Power calculation
Under the assumption that 50% of the PPH-care is performed in line with the guideline, with an alpha of 0.05 and a precision of the estimation of 0.075, 171 patients needed to be included in the study. Taking the clustering of data within clinicians into consideration, this number has to be multiplied by the design effect. With five patients per clinician and an intra-cluster correlation coefficient of 0.20, this design effect is 1.8. For a good insight into actual care in the Netherlands, the minimum number of patients that had to be included is therefore $1.8 \times 171 = 308$. In order to compensate for any loss due to follow-up or incomplete data about 320 women needed to be included, meaning 25 patients per hospital for an equal distribution over the participating hospitals.

Data collection
Quality indicators
To assess the actual PPH-care and its determinants we used a previously developed and validated set of quality indicators for PPH. The quality indicators are based on international evidence based guidelines for prevention and management of PPH, Advance Trauma Life Support (ATLS)-course instructions for obstetric emergencies and international literature. The set encompasses 17 medical performance indicators and five indicators regarding organization of PPH-care (both process and structure indicators), and comprises the entire spectrum of PPH-care: communication and documentation, monitoring and prevention of
shock, use of blood products, treatment of PPH, availability of protocols and agreements, audit, accessibility and documentation. The medical performance indicators consist of four domains: i) prevention of PPH (n=2); ii) management of PPH > 500 ml (n=5); iii) PPH > 1000 ml (n=4); and iv) PPH > 2000ml (n=6). The 22 QI were divided in 36 sub-indicators to make measurement less complex and were operationalized by the construction of a numerator and denominator, each consisting of several variables. The numerator is formed by the proportion of patients in which there is adherence to the indicator and the denominator by the proportion of patients in which the indicator is applicable. To measure the outcome of PPH, we used the incidence of PPH.

**Measurements**

In order to get valid data about performance we used both medical records and video recordings of the third stage of labor (for items see table 2 and 3).

A) Data from the medical records was collected by trained research nurses through web based confidential report form (CRF) (Limesurvey; https://manual.limesurvey.org). The developed CRF contained a part regarding general patients characteristic and high risk factors and a part regarding the indicators, including laboratories results and information about blood products given. The CRF was pre-tested by two research nurses in two different hospitals.

B) Video recording data was collected by using a webcam (QuickCam Sphere AF, Logitech) connected to a computer on a mobile unit. When given consent, the unit was positioned in the delivery room in such a way that the patient could not be recognized on film. After the birth of the baby, the camera stayed switched on for an hour, or longer in case of an on-going PPH. The images were sent to the researchers on a secure encrypted USB device (DTVP, approved by the Hospitals) within 48 hours and deleted locally by the research nurse. The video images were assessed by two researchers using the program software Noldus Observer XT no 9. This program consists of professional event logging software for the collection, analysis, and presentation of observational data. It is used to code and describe behavior in an accurate and quantitative way. A scoring list with items according to the indicators was developed. The four domains of blood loss of the medical performance indicators as mentioned above were included in the scoring list. The list was re-read and tested by an epidemiologist and gynecologist (RH, HS). By scoring an item, the item was 1) quantified, 2) the time from the start of the recording
was recorded, and 3) one of the four domains of blood loss was linked to the item. In this way we were able to point out if action was taken and if it was performed in time (figure 1).

C) Data from the organizational components of actual care for PPH was collected through a web-based questionnaire using Limesurvey. The developed questionnaire included a general information part and a part about organizational factors of the quality indicators (see the items in table 5). The link to the questionnaire was emailed directly to all the obstetricians of the sixteen hospitals. After two and then another two weeks we emailed or called the obstetrician to remind him/her.

D) The outcome, i.e. the incidences of PPH per hospital of the year 2010-2011, were collected by email, by asking the obstetrician of the participating hospitals for their own data from the national quality registry. In the Netherlands, all hospitals are obliged to annually provide the incidences of PPH to the national registry (PRN)

Figure 1. Example of the video recording assessments through Noldus

Patient 1:

<table>
<thead>
<tr>
<th>Time (s)</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Baby born</td>
</tr>
<tr>
<td>1200</td>
<td>Nurse &amp; Midwife present</td>
</tr>
<tr>
<td>600</td>
<td>empty bladder</td>
</tr>
<tr>
<td>1600</td>
<td>CCT</td>
</tr>
<tr>
<td>1800</td>
<td>Calculate BL</td>
</tr>
<tr>
<td>2180</td>
<td>Calculate IV</td>
</tr>
<tr>
<td>2500</td>
<td>Give fluid</td>
</tr>
<tr>
<td>2800</td>
<td>Placenta born</td>
</tr>
<tr>
<td>3000</td>
<td>Uterus massage</td>
</tr>
</tbody>
</table>

T= time, CCT= controlled cord traction, BL= blood loss

Determinants

The determinants of PPH-care were selected because of their potential association with guideline adherence and outcome of care (see table 1). This potential association was based on literature and expert opinion. At patient level, we selected age, parity and high risk factors for PPH. Potentially relevant hospital characteristics were type of hospital (University Hospitals, Non University
Hospitals), the presence of team training, complication discussions and audits (yes/no) and incidence of PPH (%).

**Data analysis**

Medical record data, Noldus data from the video recordings, the responses of the web based questionnaire on the organizational indicators and the incidence data were entered into a database using IBM SPSS Statistics (Version 20.0. Armonk, NY: IBM Corp). Descriptive analyses were performed for each indicator and current practice was expressed as a percentage of adherence to an indicator. For the medical performance indicators the adherence was calculated first for the medical record data. This calculation was then repeated in the hospitals with video recording after the data of the video recordings were added. To measure if an act was performed at the right time related to blood loss, we only used data of the video recordings. We calculated the percentage of acts performed in time, too late or not performed at all. For all indicators we calculated both the total indicator scores and the scores of the sub-indicators. For the organization of PPH-care we calculated the prevalence of the response categories for all participating hospitals together.

To determine patient and hospital characteristics of influence on current practice, we firstly performed univariate analyses to study associations between indicator adherence scores and determinants. Multivariate logistic regression analysis was performed to study associations for those determinants with p<0.20 in univariate analyses. Before entering the relevant determinants into the multivariate logistic regression analysis they were analysed for co linearity, using Spearman-rho correlation test. In case of highly correlated determinants (we found significant correlations between university hospitals and both multidisciplinary discussions and team trainings ($r^2$ 0.53, p <0.0001,$r^2$ 0.68, p <0.0001)), we used those determinants with the strongest association with indicator adherence. Finally, a multilevel logistic regression analysis was used to determine to what extent the indicator adherence scores were influenced by the determinants, taking clustering of data into consideration.

**RESULTS**

**Population**

Table 1 shows the characteristics on hospital and patient level.
Table 1. Hospital and patient characteristics

<table>
<thead>
<tr>
<th>Patient characteristics (n=398)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years) (n=384) (median, IQR)</td>
<td>33 29-36</td>
</tr>
<tr>
<td>Nullipara</td>
<td>147 37%</td>
</tr>
<tr>
<td>BMI (median, IQR)</td>
<td>26 21-39</td>
</tr>
<tr>
<td>Duration of gestation (median, IQR)</td>
<td>39 4/7-38 1/7-40 6/7</td>
</tr>
<tr>
<td>Birth weight (n=360) (median, IQR)</td>
<td>3650 3220-3963g</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>University Hospitals</td>
</tr>
<tr>
<td>Non University Hospitals</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category blood loss (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 500</td>
</tr>
<tr>
<td>500-1000</td>
</tr>
<tr>
<td>1000-2000</td>
</tr>
<tr>
<td>&gt;2000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospital characteristics (n=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital type (n)</td>
</tr>
<tr>
<td>University</td>
</tr>
<tr>
<td>Non University</td>
</tr>
<tr>
<td>Incidence PPH 2011 (median, min-max) (n=13)</td>
</tr>
<tr>
<td>University Hospitals</td>
</tr>
<tr>
<td>Non University Hospitals</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total of patients with a high risk on PPH (n=398) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk factors based on general history</td>
</tr>
<tr>
<td>BMI &gt;30 (n=307)</td>
</tr>
<tr>
<td>Anemia (Hb &lt; 6.5 mmol/l)</td>
</tr>
<tr>
<td>Grande multiparity (&gt;4)</td>
</tr>
<tr>
<td>Bleeding disorders</td>
</tr>
<tr>
<td>Uterus myomatosis</td>
</tr>
<tr>
<td>Jehovah witnesses</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk factors based on obstetric history</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-partum hemorrhage (PPH)</td>
</tr>
<tr>
<td>MPV</td>
</tr>
<tr>
<td>Section Caesarea</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk factors in current pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of therapeutic anti-coagulants</td>
</tr>
<tr>
<td>Multiple gestation</td>
</tr>
<tr>
<td>Polyhydramnion</td>
</tr>
<tr>
<td>Estimated fetal weight &gt; 4 kg or &gt;p 90</td>
</tr>
<tr>
<td>Vaginal blood loss ante partum (2nd, 3rd trimester)</td>
</tr>
<tr>
<td>Gestational hypertension</td>
</tr>
<tr>
<td>Pre-eclampsia/HELLP</td>
</tr>
<tr>
<td>Low lying placenta</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk actors apparent during labor and delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal Fever</td>
</tr>
<tr>
<td>Prolonged labor and/or augmentation of labor</td>
</tr>
<tr>
<td>Induction of labor</td>
</tr>
<tr>
<td>Episiotomy</td>
</tr>
<tr>
<td>Shoulder dystocia</td>
</tr>
</tbody>
</table>

Sixteen hospitals were included in this study. Three non university hospitals refused video recording, but agreed to include patients to measure the medical records. One withdrew from this part of the study due to hospital management.
issues. A total of 398 patients was included, 110 (28%) from the university hospitals and 288 (72%) from the non university hospitals. We received 343 video recordings which 293 were of sufficient quality to be included. The median age was 33. In this group of patients, 40% experienced more than 500 ml blood loss and 17% more than 1000 ml. Comments on management in women with more than >2000 ml blood loss were, due to a small sample size (n=21), unreliable and are therefore not reported.

**Professional performance in actual PPH-care**

Table 2 shows the care as regards the prevention of PPH (n=398). The identification and determination of policy in the outpatient clinic was performed in 33% of the cases, and in 32% also during labor. Particularly the determination and documentation of policy accounted for this outcome. In only 18% of the charts comments on active management were found as opposed to in 60% of the actual video recordings (VR), showing the benefit of this method.
Table 2. Performance scores of PPH prevention indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Adherence (n=15)</th>
<th>Adherence +VR (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In case of a high-risk patient on PPH, the professional should…</td>
<td>n</td>
<td>n</td>
</tr>
<tr>
<td>1. identify a high-risk patient on PPH during pregnancy at the out-clinic, determine policy for parturition and document this (n=202)²⁺³</td>
<td>67 33 NA NA</td>
<td>212 72 NA NA</td>
</tr>
<tr>
<td>- identify a high-risk patient on PPH during pregnancy at the out-clinic (n=293)²</td>
<td>212 72 NA NA</td>
<td></td>
</tr>
<tr>
<td>- determine policy for parturition and document this (n=202)²⁺³</td>
<td>75 37 NA NA</td>
<td></td>
</tr>
<tr>
<td>2. identify a high-risk patient on PPH during pregnancy at the outclinic and during labor, determine or adapt policy for parturition and document this (n=325)⁴</td>
<td>103 32 NA NA</td>
<td>380 96 NA NA</td>
</tr>
<tr>
<td>- identify a high-risk patient on PPH at the outclinic and during labor</td>
<td>380 96 NA NA</td>
<td></td>
</tr>
<tr>
<td>- determine or adapt policy for parturition at the outclinic and during labor and document this (n=321)⁵</td>
<td>108 34 NA NA</td>
<td></td>
</tr>
<tr>
<td>3. ensure IV access during labor (n=387 MC)⁶ (n=289+VR)⁶</td>
<td>326 84 281 97</td>
<td></td>
</tr>
<tr>
<td>4. provide an active management of the third stage of labor</td>
<td>72 18 174 59</td>
<td>338 85 291 99</td>
</tr>
<tr>
<td>- 5/10 U oxytocin IM or slowly IV</td>
<td>338 85 291 99</td>
<td></td>
</tr>
<tr>
<td>- controlled cord traction</td>
<td>83 21 176 60</td>
<td></td>
</tr>
<tr>
<td>5. objectify blood loss</td>
<td>NA NA 234 80</td>
<td></td>
</tr>
</tbody>
</table>

MC: medical chart; VR: video recordings; NA: not applicable; 1: amount of hospitals; 2: no high risk before labor (n=105); 3: missing because of a mistake in the CRF which was adapted after a while (n=91); 4: missing because of a mistake in the CRF which was adapted after a while (n=73); 5: missing because of a mistake in the CRF which was adapted after a while (n=77); 6: not applicable; high risk occurred at the time or after birth

Table 3 shows the management of PPH > 500 ml (n= 158 MC, 112 with VR). In particular the indicators for preventing and monitoring shock, such as monitoring vital signs, ensuring IV access and fluid replacement, showed a low score of 21% and 12% respectively (8% and 10% without VR). Moreover, the first steps in management of blood loss, uterus massage and emptying the bladder, showed 46% of adherence (with VR), but was only documented in 10% of the cases (without VR).
Table 3. Performance scores of PPH management indicators > 500ml

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Adherence (n=15)</th>
<th>Adherence +VR (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>In case of &gt; 500 ml of bloodloss or signs of shock, the professional should…</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>1. inform the gynecologist (in training)</td>
<td>73</td>
<td>46</td>
</tr>
<tr>
<td>2. continuously monitor HR/saturation and BP (5-10 min)</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>- continuously monitor HR and saturation</td>
<td>64</td>
<td>41</td>
</tr>
<tr>
<td>- monitor BP (5-10 minutes)</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>3. ensure IV access (18 gauge) and commence volume replacement (1 liter of saline)</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>- IV access</td>
<td>146</td>
<td>93</td>
</tr>
<tr>
<td>o 18 gauge (n=146 MC)(n=109 +VR)*</td>
<td>23</td>
<td>16</td>
</tr>
<tr>
<td>o Commence volume replacement *</td>
<td>25</td>
<td>17</td>
</tr>
<tr>
<td>o Saline*</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>4. take blood samples: FBC and cross match screen</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>- Hemoglobin</td>
<td>69</td>
<td>44</td>
</tr>
<tr>
<td>- Hematocrite</td>
<td>55</td>
<td>35</td>
</tr>
<tr>
<td>- Cross match screen</td>
<td>109</td>
<td>69</td>
</tr>
<tr>
<td>5. treat uterus atony: continuous uterus massage and bladder catheterization.</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>- continuous uterus massage</td>
<td>22</td>
<td>14</td>
</tr>
<tr>
<td>- bladder catheterization</td>
<td>84</td>
<td>53</td>
</tr>
<tr>
<td>6. treat uterus atony by the use of uterotonic medication in steps according to local protocol.</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>7. if retained placenta: empty the uterus by performing controlled cord tractionfollowed by placenta removal in the theater</td>
<td>NM</td>
<td>NM</td>
</tr>
</tbody>
</table>

1: amount of hospitals; 2: measured as ‘taking blood samples’; 3: determination of uterus atony was not measurable, so for indicator 5 and 6, every woman with blood loss > 500 ml was considered to be having an uterus atony; 4: not measurable, but it was measured in the in depth analysis; NM: not measurable

Table 4 shows the indicators for the management of PPH of more than 1000 ml (n= 69 MC, 45 with VR). Poor adherence for 2/3 of the indicators (adherence <30% (n=11)) was observed. ‘To administer 10-15 L of oxygen’ had a low adherence with and without VR, namely 13% and 9% respectively. The same applies for ‘ordering units of blood and fresh frozen plasma’; 9% and 7% without VR.
Table 4. Performance scores of PPH management indicators > 1000ml or signs of shock

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Adherence (n=15)</th>
<th>Adherence +VR (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In case of &gt; 1000 ml of bloodloss, the professional should…</td>
<td>n (n=69)</td>
<td>n (n=45)</td>
</tr>
<tr>
<td>1. call for the gynaecologist on ward (if the clinician is not a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>gynecologist (n=54 MC)(n=36 + VR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. call for the gynaecologist on ward (if the clinician is not a</td>
<td>22</td>
<td>36</td>
</tr>
<tr>
<td>gynecologist (n=54 MC)(n=36 + VR)</td>
<td>41</td>
<td>100</td>
</tr>
<tr>
<td>2. allocate one member of the team to record events, fluids, drugs</td>
<td>NM</td>
<td>3</td>
</tr>
<tr>
<td>3. monitor additional vital functions appropriately by</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>monitoring urine production by means of a urimeter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Urine production (CAD)</td>
<td>32</td>
<td>20</td>
</tr>
<tr>
<td>- CAD and urimeter (n=32)</td>
<td>1</td>
<td>NM</td>
</tr>
<tr>
<td>4. administer 10-15 liters/minutes of oxygen by facemask (regardless of</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>her saturation)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- administer oxygen</td>
<td>22</td>
<td>18</td>
</tr>
<tr>
<td>- 10-15 liter (n=22MC,n=18 + VR)*</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>- &lt; 10 liter *</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>- unknown *</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>5. provide a second IV access</td>
<td>29</td>
<td>42</td>
</tr>
<tr>
<td>6. replace volume by using pressure bags</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>7. replacement of fluid must be warmed fluid (in case of large volumes)</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8. urgently order units of blood and fresh frozen plasma</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>- units of blood</td>
<td>24</td>
<td>18</td>
</tr>
<tr>
<td>- fresh frozen plasma</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>9. check and correct clotting status</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>- check clotting status</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>- correct clotting status</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10. treat PPH as an atony till proven otherwise</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>- continuous uterus massage</td>
<td>16</td>
<td>23</td>
</tr>
<tr>
<td>- bladder catheterization</td>
<td>48</td>
<td>70</td>
</tr>
<tr>
<td>- use of uterotonic medication in steps (&gt; 1 uterotonic</td>
<td>17</td>
<td>25</td>
</tr>
<tr>
<td>medication and/or IV prostaglandines)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. use prostaglandins IV as last resort if other uterotonic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>treatment fails</td>
<td>13</td>
<td>19</td>
</tr>
</tbody>
</table>

1: amount of hospitals; NM: not measurable
Figure 2. Timely performances > 500 ml (n=112)

* measure blood loss is an action of the preventive indicators (n=293); BP: blood pressure, HR: heart rate

Figure 3. Timely performances > 1000 ml (n=45)

BP: blood pressure, HR: heart rate
The in-depth analysis of the video recordings on the subject ‘timely care’ as recommended by the indicators showed that in 82% the gynecologist (in training) was not informed in time or not informed at all (> 500 ml) (figure 2). In 84% the heart rate was not monitored in time or at all, and if severe PPH occurred, it was only monitored in 38% of the patients (figure 3).

The same accounts for the blood pressure which in 98% was not monitored in time or at all (>1000 ml). Continuous massage of the uterus was performed in 58% of patients with more than 500 ml blood loss and in 14% was only done in time.

**Results of the organization of PPH-care**
The response to the questionnaire was 93% (n=15). Table 5 shows that hospitals organize PPH-care well. All hospitals had a local PPH protocol, however, only 9 of the 15 obstetricians responded to have a hospital wide shock protocol (table 5).

In two hospitals there was a 24/7 presence of all the three specialists (gynecologist, anesthesiologist and OR team), one hospital had a 24/7 presence of only a gynecologist. In all hospitals there was an agreement about the time interval between calling and presence of the staff in the hospital. For most hospitals this was an interval of 30 minutes. Team trainings were organized in 12 hospitals, however, the duration of training and frequency in a year varied widely. Audit or multidisciplinary complication discussions for PPH cases were performed in 6 and 10 of the 15 hospitals with a large variation in frequency per year.
### Table 5. Scores of PPH organization indicators

<table>
<thead>
<tr>
<th>Indicator:</th>
<th>(n=15)</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Audit, feedback and training:</strong> <em>PPH cases should be…</em>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. discussed during morning team gatherings, according to local protocol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. monitored by multidisciplinary audit or complication discussions to identify problems that need reorganization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. In every hospital team training must be organized on a regular basis, based on ATLS based courses</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Protocols and agreements:</strong> <em>In every hospital system…</em>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. the following local protocols and agreement should be available:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- PPH protocol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Shock protocol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Protocol (refusal of blood products)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- written agreements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- intervention radiologists*(n=12)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- hematologist</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Accessibility</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. In every hospital there should be agreements in advance about the time interval between calling and presence of staff/OR in the (night) shifts …</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gynecologist</td>
<td>24/7 present</td>
<td>3</td>
</tr>
<tr>
<td>- 15 minutes</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>- 30 min</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>- unknown</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Anesthesiologist</td>
<td>24/7 present</td>
<td>2</td>
</tr>
<tr>
<td>- 15 minutes</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>- 30 minutes</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>- -unknown</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>OR team</td>
<td>24/7 present</td>
<td>2</td>
</tr>
<tr>
<td>- 15 min (n=10)</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>- 30 min (n=10)</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>- unknown</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>Documentation and registration:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. All cases of PPH must be registered in complication registration</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Three hospitals did not have intervention radiologists.*
Determinants associated with guideline adherence
Table 6 shows the results of the determinant analysis.
At patient level, a significant association was found between high risk for PPH on the one hand and objectifying blood loss at the other. Care provided by a university hospital had a significant association with the indicator on monitoring heart rate, while a trend was seen with indicators concerning high risk assessment on both outpatient clinic and labor ward.

Table 6. Characteristics associated with guideline adherence in PPH

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Characteristics</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR identification (OC)</td>
<td>-incidence of PPH (outcome)</td>
<td>2.54</td>
<td>0.80-8.00</td>
</tr>
<tr>
<td></td>
<td>-university hospital</td>
<td>5.73</td>
<td>0.55-59.30</td>
</tr>
<tr>
<td>HR identification (OC and labor)</td>
<td>-university hospital</td>
<td>2.38</td>
<td>0.40-14.32</td>
</tr>
<tr>
<td>Monitor BP</td>
<td>-multidisciplinary discussions</td>
<td>3.32</td>
<td>0.85-13.01</td>
</tr>
<tr>
<td>Monitor HR</td>
<td>-university hospital</td>
<td>5.92</td>
<td>1.47-23.74</td>
</tr>
<tr>
<td>Objectify blood loss</td>
<td>-high risk on PPH*</td>
<td>2.33</td>
<td>1.20-4.53</td>
</tr>
</tbody>
</table>

HR: high risk, OC: outpatient clinic, BP: blood pressure, HR: heart rate,
OR >1 means a positive association with the indicator; OR <1 means a negative association with the process indicator, * high risk on basis of PPH and retained placenta in previous pregnancies

DISCUSSION
This study is the first to evaluate adherence to the PPH guideline and the ATLS based course instructions using both medical records and video recordings of the third stage. With these observations, we witnessed a lack of quality in performance in Dutch hospitals. In particular, the adherence to indicators for management of PPH > 1000 ml, such as monitoring vital signs, administration of 15 L oxygen, ordering units of blood and fresh frozen plasma, proved to be poor. Furthermore, acts were only partly performed in time. Regarding the determinants for adequate care, University Hospitals was mostly associated with better adherence. However, the lack of adequate care could not be explained by a lack of the organization although there is room for improvement, especially as regards the frequency of team training, audits and complication discussions. Additional video observations proved valuable to measure actual adherence in PPH-care, indicating underreporting of the provided care in the medical records.

PPH-care can change in a short time from a prevention phase, where routine care is provided, to an emergency phase where parallel execution of multiple acts is needed in a clear-cut timeframe to prevent deterioration of PPH\textsuperscript{28}. Preventive measures, such as active management of the third stage and anticipation by
measuring blood loss, particularly in high-risk patients, are essential to avoid the occurrence of PPH\textsuperscript{13,29}. The first step in this process, highlighted by studies and guidelines, is the identification of high-risk patients and documentation of policy before labor\textsuperscript{30-32}. Knowing risks beforehand creates awareness among care providers during labor. In this study, risk assessment with policy documentation was only done in one third of the patients. A Scottish confidential report in 2011 regarding severe maternal morbidity mentions the same results\textsuperscript{33}.

Triggers for professionals to perform management acts in PPH-care are the amount of blood loss and the patient’s vital signs. Different studies emphasize the importance of vital signs in PPH-care since they can help choose the right therapy and prevent over and under treatment\textsuperscript{30,34}. Specific omission of these first steps in the chain of actions could lead to a delayed recognition and treatment of PPH. This study shows that blood loss was measured in most patients, however, the vital signs was hardly ever monitored, or not at all. Even with blood loss of more than 1000 ml, the vital signs were only monitored in one third of the patients.

It is possible that the care providers underestimate the possibility of the occurrence of PPH, especially if the woman is asymptomatic and is enjoying her newborn. The incidence of blood loss of more than 1000 ml in the Dutch hospital setting is 7\%, meaning that the probability of a care provider actually experiencing a case of severe PPH is small and therefore awareness might be lacking. In addition, the PPH guideline, local protocols and team trainings are focused on the management of PPH for more than 1000 ml, implying that most acts will be performed if a PPH of more than 1000 ml occurs. The authors expected adherence to be better for the indicators > 1000 ml. However, despite the awareness of a high risk on PPH, the acts which should be performed at > 500 ml were mostly carried out after severe PPH (1000 ml). Unfortunately, management of PPH >1000 ml was not optimal either.

Factors that are associated with severity of PPH have been described before, such as Non University Hospitals and delay\textsuperscript{35}. In our study, no association was found between our determinants and outcome of PPH-care and we presume it is because the study was underpowered as regard to these questions. However, as hypothesized, university hospitals was frequently found to be positive associated with adherence, especially monitoring vital signs was significant related. A better policy for quality in these hospitals could be an explanation for this. This is
confirmed by our co linearity analyses, in which significant correlations were found between University Hospitals and both multidisciplinary discussions and team trainings.

This study shows that despite following ATLS based courses and the well-organized PPH-care in the Dutch hospitals, it still wasn’t possible to deliver high quality PPH-care. It seems that following an ATLS based course or organizing a few team trainings a year, is insufficient for optimizing PPH-care. We think that the complexity of PPH-care needs a tailored approach on different levels. Besides a highly structured approach such as taught in the ATLS based courses by means of the airway-breathing-circulation (ABC) methodology, the use of standardized early warning scoring systems proved to be valuable for early detection of changes in vital signs\(^\text{13,36}\). Regular team training based on these courses may decrease delays in obstetric emergencies\(^\text{37}\). Audit and feedback on a regular basis of severe PPH cases can help in detecting where improvement is necessary and improve adherence to guidelines and protocols\(^\text{38}\). In addition, flow-charts and checklists are instruments that were proven useful to optimize emergency care and prevent delay\(^\text{39,40}\). We think that PPH-care could benefit from these instruments as well, particularly when they are integrated in frequent team training\(^\text{41}\). Both the WHO and FIGO support the use of checklists in the management of PPH\(^\text{42,43}\).

Unique in this study is the use of video recordings of the third stage. It showed how difficult it is to perform quality care assessment on the basis of medical records in an emergency situation. Video recordings provided exclusive information, which never could have been obtained from medical data records, resulting in a complete overview of the delivered care for patients with a high risk on PPH, including the time factor. A total overview would have been accomplished if we had the video recordings extended to the OR. Detailed information on the different levels of PPH-care could only be achieved by using the predefined guideline and ATLS course based quality indicators for prevention, management and organization of PPH-care, which is another strength of this study.

There are also some limitations that need to be addressed. In our study, the caregivers were informed about the video observation of a high-risk PPH-patient. It is possible that knowledge of being recorded could have influenced the care that was given. However, despite this awareness, the adherence to the indicators was not optimal. The actual care in the everyday situation may be even worse. Another
limitation of this study is the inclusion of one fifth of all Dutch hospitals that perform obstetric care. However, we included different types of hospitals evenly distributed throughout the country and we therefore think that we have an adequate representation of actual PPH-care in the Netherlands. Another limitation could be the international applicability of our findings. Although one can assume that PPH-care differs between countries due to a different interpretation of the evidence and cultural differences, PPH-care is still based on guidelines in which the main information is similar and based on the same principles. Furthermore, we used guideline-based quality indicators based on national and international guidelines as a measurement tool.

CONCLUSION
This study showed low adherence to the guideline-based quality indicators for prevention, management and organization of PPH-care, clearly indicating an implementation problem in the Netherlands. Determinants on both patient and hospital level showed a significant association with monitoring PPH. Additional video observations proved valuable to pinpoint exactly what level improvement is necessary. A tailor-made implementation strategy should be developed to improve quality of Dutch PPH-care.
REFERENCES


Nontechnical-skills assessment in actual postpartum hemorrhage-care importance for clinical performances and outcome

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Submitted
ABSTRACT

Objective. To assess nontechnical-skills of Dutch obstetric-teams and team-leaders based on Crew-Resource-Management in the actual postpartum hemorrhage (PPH)-care and to evaluate its influence on clinical performance based on the best evidence and outcome of care.

Design. A prospective, observational multicenter.

Setting/population. This study was a part of a study on guideline adherence for PPH. Seventy one video-recordings from 12 different hospitals of women, with > 700 ml blood loss in the postpartum period, were included.

Methods. Clinical-Teamwork-Scale and Ottawa Crisis-Resource-Management-global-rating-scale were used to assess nontechnical-skills of obstetric-teams and team-leaders. Clinical performance was measured through adherence to previously developed guideline indicators for management of PPH. Clinical outcome was established by the quantity of blood loss of each patient. Spearman's rho was used to compute correlations between nontechnical-skills and clinical performance and outcome.

Main outcome measures. Quality of nontechnical-skills of obstetric-teams and team-leaders in the actual PPH-care

Results. Fifty seven video recordings were included. The median nontechnical-skills score of obstetric-teams was 45 on a scale of 90, and for the team-leaders, 25 on a scale of 56. The lowest scoring items were communication items, problem-solving and situation awareness. The items situation awareness, decision making and problem-solving were significantly correlated with clinical performance and clinical outcome.

Conclusions. In the current postpartum hemorrhage-care, nontechnical-skills of obstetric-teams and team-leaders can improve in the domains of communication, situation awareness and problem-solving. Nontechnical-skills, especially situation awareness, decision making and problem-solving skills seems essential to deliver high quality postpartum hemorrhage-care.
INTRODUCTION

Postpartum hemorrhage (PPH) is an obstetric emergency situation in which several actions have to be taken by different team members in a limited timeframe. In order to make correct team decisions, different skills, such as achieving individual and team based situation awareness and timely (shared) decision making, are required. PPH is still a main cause of maternal morbidity in developed countries. A high ratio (72-90%) of the morbidity of PPH is considered preventable if adequately managed. Clinical performance conformed to the best practices established by evidence-based guidelines and Advanced Trauma Life Support (ATLS)-based courses for obstetric emergency, is necessary to deliver high quality care. Evidence-based guidelines can assist professionals in standardizing adequate management and support clinical evidence-based decision-making. ATLS courses educate professionals in using a highly structured approach of obstetric emergencies such as PPH. Therefore, many developed countries have introduced both guidelines and team-training for clinical performance.

However, several human factors, such as lack of situational awareness leading to delayed decision making, may lead to substandard PPH-care. Suboptimal teamwork and communication were the most common contributors found in cases of maternal mortality and severe morbidity. Different health organizations have advocated teamwork and communication as a factor to be addressed in PPH-care and recommended implementation of communication and teamwork training such as Crew Resource Management (CRM) to improve team performance of health professionals. In these training sessions nontechnical-skills such as leadership, individual and team situational awareness, risk management and communication are key elements. In the emergency department, it resulted in a significant improvement of the clinical performance, 56% reduction of medical errors and a better attitude towards teamwork. Similar effects were described in the obstetric emergency care in simulated settings, although studies on effects of the outcome of care, such as the incidence of PPH, remain scarce. In daily care, the exact quality of nontechnical-skills of obstetric-teams is unknown, as well as its influence on clinical performance and outcome. Therefore, the aim of this study is to assess the quality of nontechnical-skills of obstetric-teams and team-leaders in the actual PPH-care according to the concepts of CRM in the Netherlands, and to evaluate its effect on clinical performance according to the best evidence, and the quantity of blood loss.
MATERIAL AND METHODS

Design and setting

We performed a prospective, observational multicenter study, which was part of the Fluxim-study. The Fluxim-study evaluated the care for women at a high risk of developing PPH with the use of video recordings of the third stage\(^\text{22}\). This study was performed within the Dutch Consortium for research in Women’s health, in which 70 hospitals participate. A total of 16 hospitals was involved in the Fluxim-study, 12 of which gave permission to make video recordings (table 1). Digital cameras were installed in every delivery room. Women older than 18 years with high risk of PPH were included in the Fluxim-study after their informed consent was obtained. All caregivers working on the labor ward were informed by email and were given the opportunity to refuse being filmed at all times. The Medical Ethical Committee (CMO) of the region Arnhem-Nijmegen (ABR no. NL25975.091.08) declared that ethical approval was not necessary. For this secondary analysis, we used 71 video recordings from the Fluxim-study that monitored the care for women in the postpartum period who suffered at least 700 ml blood loss.

Study group

PPH is defined as blood loss of more than 500 ml, in which additional action has to be taken according to different international guidelines. In this secondary analysis, we included video recordings from the Fluxim-study that monitored the care for women in the postpartum period who suffered at least 700 ml blood loss in the expectation that both clinical and nontechnical team performances would be initiated to prevent deterioration.

Table 1. Characteristics and clinical performance

<table>
<thead>
<tr>
<th></th>
<th>All videos</th>
<th>UH</th>
<th>NUH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total hospitals</td>
<td>12</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Included videos</td>
<td>57</td>
<td>22</td>
<td>35</td>
</tr>
<tr>
<td>Excluded videos</td>
<td>14</td>
<td>10</td>
<td>4</td>
</tr>
<tr>
<td>700-1000 ml</td>
<td>18</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>&gt; 1000 ml</td>
<td>39</td>
<td>17</td>
<td>22</td>
</tr>
<tr>
<td>Clinical performance(^2) (%)</td>
<td>45 (SD 0.217 (n=43))</td>
<td>37 (SD 0.157 (n=15))</td>
<td>50 (SD 0.235 (n=28))</td>
</tr>
</tbody>
</table>

\(^1\) expressed in median and minimum-maximum range, \(^2\) mean percentage adherence to all performance indicators
Nontechnical skills in postpartum hemorrhage-care

Measurement instruments nontechnical-skills of obstetric-teams and team-leaders
We used two validated lists to evaluate the nontechnical-skills of obstetric-teams and team-leaders, both according to Crew Resource Management concepts: 1) The Clinical-Teamwork-Scale (CTS), and 2) The Ottawa Crisis-Resource-Management-global-rating-scale (GRS); nontechnical-skills.

The Clinical-Teamwork-Scale (CTS) was developed especially for evaluation of obstetric-teams, and assigns a Likert scale score of 0-10 for each of the five behavioral domains: Communication, decision-making, role responsibility, situational awareness and patient-friendliness. We used the most concrete items applicable to the PPH-setting (table 2). Patient-friendliness could not be assessed because the patients were unrecognizable in all videos, and was therefore excluded from this study. The teams were evaluated on 9 items of the remaining four domains, with a possible total score of 0-90 points.

The Ottawa Crisis-Resource-Management-global-rating-scale; nontechnical-skills (GRS) was developed for reviewing nontechnical-skills performances of individual team members in a simulated setting. It consists of five categories: problem-solving, situational awareness, leadership, resource utilization and communication. Each category has a seven point anchored scale to rate performance with specific examples of good, moderate and poor performances. These explanatory anchors along the scale were adapted to the specific obstetric problem PPH by an obstetrician and a communication scientist including the Airway, Breathing and Circulation (ABC)-assessment according to the ATLS-based courses for management of obstetric emergencies, in order to provide guidelines and reduce personal bias. GRS was used to assess team-leaders with a total possible score of 5-56 points. Two items on the GRS list, namely situation awareness and problem-solving, were also scored without the ABC-assessment, as in obstetric-care the tendency is to mainly use the amount of blood loss in the assessment and management of PPH.

Data collection
Nontechnical-skills
The teams involved in the management of PPH in the 71 cases were evaluated on the basis of these two validated scoring lists. All recordings were reviewed
separately for each scoring list by the same researcher. The observer reliability was assessed by having a second researcher review 10% of the recordings.

**Clinical performance and clinical outcome**

We used guideline adherence assessments from the Fluxim-study as a measure for clinical performance. The adherence assessments were performed by medical charts and video recordings using a previously developed set of quality indicators \( n=22 \).\(^{25} \) The indicator-set was predisposed to measure prevention, management and organization of PPH and was based on international PPH-guidelines, literature and ATLS-based instructions. We used the assessments of the indicators for the management of blood loss \( (500-2000 \text{ ml } (n=9)) \) (figure 1).

**Figure 1. Clinical performance indicators for management of PPH >500 ml of blood loss**

<table>
<thead>
<tr>
<th>Time (ml)</th>
<th>Indicator: In case of a patient with PPH the clinician should…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication documentation</td>
<td>&gt;500 1. Inform the gynecologist (in training)</td>
</tr>
<tr>
<td></td>
<td>&gt;1000 2. Call for the obstetrician on ward (if the clinician is not a gynecologist), the anesthetist and surgery personnel, and transport patient to the theatre if the bleeding persists 3. Allocate one member of the team to record vital signs, events, fluids, and drugs</td>
</tr>
<tr>
<td>Monitoring and prevention of shock</td>
<td>&gt;500 4. Monitor vital functions appropriately, take blood samples and replace fluid:  • Monitor pulse &amp; oxygen saturation continuously and BP (5-10 minutes)  • Take blood samples: FBC and cross match screen  • Ensure an IV access (18 gauge) and commence volume replacement (1L saline)</td>
</tr>
<tr>
<td></td>
<td>&gt;1000 5. Monitor additional vital functions appropriately, give oxygen and replace fluid:  • Give 10-15 liters/minutes oxygen by face mask regardless of her oxygen saturation  • Monitor urine production  • Provide a second IV access (18 gauge), and replace volume by using pressure bags and warmed fluid (in case of large volumes)</td>
</tr>
<tr>
<td>Blood products</td>
<td>&gt;1000 6. Urgently order units of blood and fresh frozen plasma, check and correct clotting status</td>
</tr>
<tr>
<td>Therapy</td>
<td>&gt;500 7. Treat uterine atony: continuous uterus massage, bladder catheterization and uterotonic medication in steps according to local protocol 8. In case of retained placenta: perform controlled cord traction followed by placenta removal in the operating room</td>
</tr>
<tr>
<td></td>
<td>&gt;1000 9. Treat PPH as an atony till proven otherwise, use prostaglandins IV as a last resort if other uterotonic treatment fail</td>
</tr>
</tbody>
</table>

The total score on guideline adherence to the management indicators was used as an indicator for clinical performance. The clinical outcome, i.e. the quantity of blood loss of each patient, was gathered from the medical charts and video recordings.
The nontechnical-skills and clinical performance were scored by different observers and were blinded for mutual observations.

**Data-analysis**

The characteristics and nontechnical-skills scores of both obstetric teams and their team-leaders were displayed in the tables with a median score, a range and an inter quartile range (IQR). The total score for nontechnical-skills of obstetric-teams (CTS) was calculated by adding all scored items, resulting in a score of minimum 0 and maximum 90. The sub-items of the CTS, meaning the domains of the CTS, were calculated by adding the scored items pertaining to each domain. The total score for nontechnical-skills of team-leaders (GRS) was calculated by adding all scored items with a minimum of 8 and maximum of 56.

For both observation lists the interclass correlation coefficient (ICC) was calculated for 10% of the measurements. An ICC >0.60 indicates moderate agreement between reviewers.

The clinical performance score, meaning the total score for adherence to the indicators for the management of PPH, was calculated as follows: A score of 1 was given if the performance adhered to the corresponding indicator, and a score of 0 if not. All the results were added up and divided by the total number of applicable indicators.

To examine the relationship of nontechnical-skills (total score of the sub-items of both lists), clinical performance and clinical outcome we calculated the Spearman-rho correlation coefficient. A correlation was considered statistically significant if the p-value was <0.05. Analyses were done in IBM SPSS Statistics for Windows, version 20.0 (IMB Corp., Armonk, NY, USA).

**RESULTS**

In total, 71 women had more than 700 cc blood loss and were eligible for analysis. Fourteen (20%) recordings were excluded due to insufficient image or sound quality. Table 1 shows the characteristics, including the clinical performance and outcome parameters, of the remaining 57 recordings. Median blood loss was 1200 ml (IQR 850-1978), with 18 (32%) recordings of patients with blood loss between 700-1000 ml and 39 (68%) patients with more than 1000 ml. None of the women observed in the delivery rooms exceeded 2000 ml, by then the hemorrhage had been either stopped or the women were transported to the operating room. The clinical performance was measured with PPH-management indicators from the
500-2000 ml blood loss domains and was not available for a total of 15 (26%) patients; for 13 patients the clinical performance was not assessable because they were transported to the operating room with less than 500 ml blood loss and two patients had no data from the medical chart. The mean clinical performance (mean total adherence to the nine PPH-management indicators) was 45% with 50% for the non University Hospitals and 37% for the University Hospitals.

Nontechnical-skills of obstetric-teams
Table 2 shows nontechnical-skills scores of Dutch obstetric-teams dealing with PPH, with a total median score of 45 (IQR 35-49) out of a maximum score of 90. The nontechnical-skills items with the lowest score were all in the domain of communication, namely feedback of orders in the sense of closed loop communication (median 3, IQR 2-5), structured information transfer to a new member by using Situation-Background-Assessment-Recommendation (SBAR) tool (median 4, IQR 2-6) and direct communication (median 4, IQR 2-7). The item Role clarity, clarity on which team member has which specific role, scored best with a median of 8 (IQR 7-8).

Table 2. Clinical Teamwork Scale (CTS); nontechnical-skills of obstetric-teams

<table>
<thead>
<tr>
<th>CTS (scale 0-10) (n=57)</th>
<th>Median</th>
<th>Range</th>
<th>IQR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domain Communication</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orient new team members (SBAR) (N=38)</td>
<td>4</td>
<td>1-9</td>
<td>2-6</td>
</tr>
<tr>
<td>Transparent thinking</td>
<td>6</td>
<td>2-9</td>
<td>4-7</td>
</tr>
<tr>
<td>Directed communication</td>
<td>4</td>
<td>1-8</td>
<td>2-7</td>
</tr>
<tr>
<td>Closed loop</td>
<td>3</td>
<td>1-8</td>
<td>2-5</td>
</tr>
<tr>
<td><strong>Domain Situation awareness</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resource allocation</td>
<td>7</td>
<td>2-9</td>
<td>4-8</td>
</tr>
<tr>
<td>Target fixation</td>
<td>6</td>
<td>2-9</td>
<td>2-7</td>
</tr>
<tr>
<td><strong>Domain Decision making</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prioritize</td>
<td>7</td>
<td>3-9</td>
<td>5-8</td>
</tr>
<tr>
<td><strong>Domain Role responsibility</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Role clarity</td>
<td>8</td>
<td>3-9</td>
<td>7-8</td>
</tr>
<tr>
<td>Perform as a leader</td>
<td>7</td>
<td>3-9</td>
<td>6-8</td>
</tr>
<tr>
<td><strong>Total score nontechnical-skills Obstetric-teams</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total CTS score (min of 0, max of 90) (N=38)</td>
<td>45</td>
<td>29-61</td>
<td>35-49</td>
</tr>
<tr>
<td>Total CTS score excl. SBAR (min of 0, max of 80)</td>
<td>44</td>
<td>22-61</td>
<td>34-50</td>
</tr>
</tbody>
</table>

SBAR: Situation Background Assessment Recommendation; 1: exclusion: in the recordings there were no new team members to perform the SBAR
Nontechnical-skills of team-leaders
Table 3 shows nontechnical-skills results of team-leaders dealing with PPH, with a total median score of 25 (IQR 21-28) out of a maximum score of 56. The nontechnical-skills items with the lowest score were situation awareness and problem-solving ability by using ABC-assessment (both a median 2, IQR 1-3).

Without the ABC-assessment (table 4) the score improved, but both items still scored the lowest. The item that scored best among team-leaders was leadership (median of 6, IQR 5-6) (table 3).

Table 3. Ottawa crisis resource management global rating scale (GRS): nontechnical-skills of team-leaders

<table>
<thead>
<tr>
<th>GRS (scale 1-7) (n=57)</th>
<th>Median</th>
<th>Range</th>
<th>IQR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall use of nontechnical-skills</td>
<td>5</td>
<td>2-6</td>
<td>4-5</td>
</tr>
<tr>
<td>Leadership</td>
<td>6</td>
<td>3-7</td>
<td>5-6</td>
</tr>
<tr>
<td>Problem-solving ability</td>
<td>2</td>
<td>1-6</td>
<td>1-3</td>
</tr>
<tr>
<td>Situation awareness</td>
<td>2</td>
<td>1-6</td>
<td>1-3</td>
</tr>
<tr>
<td>Resource allocation</td>
<td>5</td>
<td>3-7</td>
<td>4-6</td>
</tr>
<tr>
<td>Communication with team members</td>
<td>5</td>
<td>3-7</td>
<td>4-6</td>
</tr>
<tr>
<td><strong>Total score nontechnical-skills team-leaders</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score (max of 56)</td>
<td>25</td>
<td>16-37</td>
<td>21-28</td>
</tr>
</tbody>
</table>

Table 4. Use of ABC-assessment in GRS-items

<table>
<thead>
<tr>
<th>GRS items (scale 1-7) (n=57)</th>
<th>Median</th>
<th>Range</th>
<th>IQR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem-solving (with ABC)</td>
<td>2</td>
<td>1-6</td>
<td>1-3</td>
</tr>
<tr>
<td>Problem-solving (without ABC)</td>
<td>4</td>
<td>1-7</td>
<td>3-5</td>
</tr>
<tr>
<td>Situation awareness (with ABC)</td>
<td>2</td>
<td>1-6</td>
<td>1-3</td>
</tr>
<tr>
<td>Situation awareness (without ABC)</td>
<td>4</td>
<td>1-7</td>
<td>3-6</td>
</tr>
</tbody>
</table>

The interclass correlation coefficient (ICC) was 0.85 for CTS and 0.79 for GRS, indicating little difference between the evaluations of the two researchers.

Correlation nontechnical-skills obstetric-teams, team-leaders with clinical performance and clinical outcome
Table 5 shows the relation between nontechnical-skills of obstetric-teams, team-leaders, clinical performance and clinical outcome (ml blood loss). A positive but non-significant relationship was found between the summed nontechnical-skills score of both obstetric-teams (CTS), team-leaders (GRS) and clinical performance (CTS: $r^2$: 0.211, $p$: 0.175, GRS: $r^2$ 0.203 $p$: 0.191). No correlation was found
between the summed nontechnical-skills score of the obstetric teams or team-leaders and clinical outcome.

Table 5: Correlation nontechnical-skills and clinical performance and clinical outcome

<table>
<thead>
<tr>
<th>GRS items (team-leaders)</th>
<th>Clinical outcome(^1) (n=57)</th>
<th>Clinical performance (n=43)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(r^2)</td>
<td>(p)</td>
</tr>
<tr>
<td>Leadership</td>
<td>-0.208</td>
<td>0.120</td>
</tr>
<tr>
<td>Problem-solving ability</td>
<td>0.141</td>
<td>0.295</td>
</tr>
<tr>
<td>Problem-solving ability (without ABC)</td>
<td>0.310</td>
<td>0.019*</td>
</tr>
<tr>
<td>Situation awareness</td>
<td>0.191</td>
<td>0.154</td>
</tr>
<tr>
<td>Situation awareness (without ABC)</td>
<td>0.318</td>
<td>0.016*</td>
</tr>
<tr>
<td>Communication with team members</td>
<td>0.043</td>
<td>0.794</td>
</tr>
<tr>
<td>Total GRS score</td>
<td>0.098</td>
<td>0.468</td>
</tr>
<tr>
<td>CTS items (obstetric-teams)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communication (transparent thinking, direct communication and closed loop)</td>
<td>0.169</td>
<td>0.208</td>
</tr>
<tr>
<td>Situation awareness total (resource allocation and target fixation)</td>
<td>0.109</td>
<td>0.491</td>
</tr>
<tr>
<td>Decision making (prioritize)</td>
<td>0.188</td>
<td>0.161</td>
</tr>
<tr>
<td>Role responsibility (role clarity and leadership)</td>
<td>-0.026</td>
<td>0.851</td>
</tr>
<tr>
<td>Total CTS score (without SBAR)</td>
<td>0.084</td>
<td>0.532</td>
</tr>
</tbody>
</table>

\(^1\): total blood loss; *correlation is significant at the 0.05 level (2-tailed)

On the subject of nontechnical-skills sub-items (table 5), a statistically significant correlation was found between clinical performance and situation awareness- and problem-solving-skills of the team-leaders (GRS: \(r^2 0.345\) p=0.024, \(r^2 0.374\) p=0.014). Moreover, a significant correlation was found between the item decision making and clinical performance for the obstetric teams (CTS: \(r^2 0.411\) p=0.006). For the clinical outcome, we found a significant correlation with team-leaders’ situation awareness- (GRS: \(r^2 0.318\) p=0.016) and problem-solving-skills (GRS: \(r^2 0.310\) p=0.019), both without ABC-assessment.

**DISCUSSION**

This is the first study to assess nontechnical-skills of obstetric-teams dealing with an obstetric emergency (PPH) by using video recordings of the actual care. Additionally, the nontechnical-skills of the obstetric teams were related to clinical performance and clinical outcome.

This study reports a below the average score of the scoring lists for nontechnical-skills through CRM concepts among Dutch obstetric-teams and team-leaders in the actual PPH-care, indicating that CRM concepts are not sufficiently integrated into PPH-care. Low scoring items regarding obstetric-teams are mainly in the
domain of communication, and regarding team-leaders, in situation awareness and problem-solving skills. Moreover, this study reports a significant positive correlation between situation awareness and problem-solving skills and clinical performance and clinical outcome. This underlines the importance of nontechnical-skills in the management of PPH.

Implementation of CRM concepts may be used to reduce the incidence of errors and complications caused by human factors\textsuperscript{26}. As a result of improved communication, team situation awareness, plan development and shared mental model, the number of adverse events should decrease. Good teamwork with clear communication was associated with a 23\% decrease of adverse events and 13\% decrease in the seriousness of events\textsuperscript{27}. However, this study shows that CRM is only used moderately in Dutch clinics, in particular as regards communication. Studies have shown that these specific items are easy to implement because they are easy to understand and clearly described\textsuperscript{13,18}.

In our study, a positive relationship was suggested between the total nontechnical-skills score of both obstetric-teams and team-leaders and clinical performance, but no correlation was found with clinical outcome. Possible explanations could be the limited number of patients in this study, or the dilution of the total nontechnical-skills score by sub-items of possibly lesser importance. We did find a significant correlation between situation awareness, decision-making and problem-solving, and clinical performance for both obstetric-teams and team-leaders. A recent study in trauma-care also found a significant correlation between these specific sub-items and clinical performance\textsuperscript{28}. Moreover, as regards clinical outcome we found a significant positive correlation with team-leaders’ situation awareness and problem-solving skills (without ABC-assessment). This indicates that specific items of nontechnical-skills are essential factors in the assessment and management of patients with PPH and should be specifically addressed in order to improve quality of PPH-care and clinical outcome. Furthermore, the presence of statistical significance even in this small cohort of patients does demonstrate an important link between nontechnical-skills and PPH-care. Due to the fact that this was a subset of a larger study, no sample size calculation was performed and therefore the current findings need to be confirmed in a broader study.
The clinical evaluation by means of ABC-methodology could contribute to improved situation awareness and problem-solving. The ATLS-based course for obstetric emergencies, a single course, was widely introduced in the Netherlands to familiarize obstetricians with clinical evaluation by means of ABC-methodology in order to detect early respiratory and circulatory instability in obstetric situations and subsequently reduce preventable mortality and morbidity. This study shows that systematic ABC-evaluation is hardly ever applied in the treatment of PPH. We think that in current care the quantity of blood loss is often used as an indicator as to when to perform different acts, instead of both the amount of blood loss and the vital signs of the patient. Without repeated systematic ABC evaluation, important vital signals may be missed, such as signs of compensating shock in patients with existing anemia or hypertension and just 500ml of blood loss. Moreover, it is known that the quantity of blood loss is frequently estimated instead of measured and therefore often underestimated.

To our knowledge, this is the first observational study aimed at evaluating nontechnical-skills within a team in the actual PPH-care. Most studies were performed in a simulation setting, which makes it difficult to compare with our results. In emergency-care, however, a comparable observational study was recently performed in the actual trauma-care. They found a similar relationship between nontechnical-skills and clinical performances. In the obstetric simulation setting, one study evaluated the effect of team training on nontechnical-skills and clinical performance. They used the CTS list to evaluate nontechnical-skills in both groups. It was observed that team training had a significant effect on nontechnical-skills in the domain of communication and on clinical performance. If we compare our results of nontechnical-skills of obstetric-teams with nontechnical-skills results of the trained and untrained group, our results are comparable with the untrained group, except in the domain of communication, with slightly lower scores on the different items (SBAR: median score of 4 (our study) vs. 4.5 (untrained group), transparent thinking 6 vs. 5, direct communication 4 vs. 5, closed loop 3 vs. 4.5). This might suggest that nontechnical-skills of obstetric-teams in a simulated setting could be comparable with the actual care; however, in our study there is no information as to what extent team training has been incorporated in the observed hospitals. Further investigation is necessary to demonstrate its similarity.
Strengths and limitations
The strength of this study was the use of actual care video recordings of PPH-patients to evaluate nontechnical-skills of obstetric-teams and clinical skills. Most studies performed to evaluate nontechnical-skills of obstetric-teams were performed in a simulation environment and the question is how closely this reflects reality\textsuperscript{17,31}. In our study the obstetric-team was informed about the video observation of a high risk PPH-patient, which could be considered a limitation. However, despite this awareness, they scored low as regards nontechnical-skills. Another limitation of this study is the limited number of hospitals included. However, we included different types of hospitals evenly distributed throughout the country and we therefore think that we have an adequate representation of nontechnical-skills in obstetric-teams dealing with PPH in the Netherlands.

CONCLUSION
In the current PPH-care, nontechnical-skills of obstetric-teams can improve in the domains of communication, situation awareness and problem-solving. Situation awareness, decision making and problem-solving skills seems critical for giving high quality PPH-care. Further research should be done to confirm these results. Team training on nontechnical-skills, in particular through ABC-assessment could have a positive effect on the improvement of PPH-care.
REFERENCES

Influencing factors for high quality care on postpartum hemorrhage in the Netherlands

patient and professional perspectives

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Evelien Belfroid
Janine Liefers
Richard Grol
Hubertina Scheepers
Rosella Hermens

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ABSTRACT

Background. Postpartum hemorrhage (PPH) remains a major contributor to maternal morbidity even in high resource settings, despite the development and dissemination of evidence-based guidelines and Advance-Trauma-Life-Support (ATLS) based courses for optimal management of PPH. We aimed to assess current influencing factors (obstacles and facilitators) for the delivery of high quality PPH-care from both patient and professional perspective.

Methods. We qualitatively explored influencing factors for delivering high quality PPH-care, by having individual interviews with PPH-patients and focus group interviews with the different types of professionals working in the delivery room. For both perspectives, the theoretical frameworks of Grol and Cabana were used to classify the influencing factors for optimal PPH-care (factors of the guidelines, of professionals, of patients, of the social setting and of the organization). In order to assess the importance of the influencing factors found among the professionals, we quantified these factors in a web-based questionnaire.

Results. A total of 12 patients and 41 professionals participated in the interviews, and 315 complete surveys were analyzed. The main obstacle for high quality PPH-care identified by patients was the lack of information given by the professionals to the patient and partner before, during and after the PPH event. An informative patient website, a patient leaflet and a follow-up consultation were mentioned as facilitators. The main obstacles according to the professionals were: lack of clarity of the guidelines, lack of knowledge and failing team-communication. Team training and checklists/flowcharts were considered facilitators.

Conclusions. Different obstacles to the delivery of high quality PPH-care were identified by both patients and professionals. These data can be used to develop a focused strategy to improve PPH-care.
Influencing factors for high quality PPH-care

**BACKGROUND**

Postpartum hemorrhage (PPH) remains to be the leading cause of severe maternal morbidity in several high-income countries\(^1\)-\(^3\). Moreover, PPH rates continue to increase in these countries, including the Netherlands where the incidence of PPH increased from 3% in 2003 to 8% in 2011\(^4\)-\(^6\). It is common knowledge that enhanced adherence to evidence-based guidelines and better technical and non-technical skills improve patient care and outcome\(^7\)-\(^9\). However, the development and dissemination of evidence-based PPH guidelines (intended to assist professionals and patients in the prevention and management of PPH-care) or the introduction of training innovations such as Advance Trauma Life Support (ATLS) based courses (to improve knowledge and technical and non-technical skills among teams dealing with obstetric emergencies such as PPH) are not enough to close the existing gap between guidelines, course-instructions and daily practice\(^10\)-\(^12\). Substandard care is regularly mentioned for women with a PPH\(^1\),\(^13\),\(^14\). In a French study, in 38% of the women with a PPH of more than 1500 ml and in 70% of the women who died as a result of a PPH, suboptimal care factors were detected.

In fact, PPH-care consists of two phases, the prevention and the treatment phase, where professionals give routine care followed by emergency care. Different action must be taken by different professionals, consecutively or simultaneously, in a limited timeframe\(^15\),\(^16\). Streamlining PPH-care for every professional, founded on evidence-based PPH guidelines and ATLS-based course instructions, is necessary to provide high quality PPH-care\(^17\). Proper implementation of these guidelines and instructions is therefore essential and can only be achieved once the causes for not following guidelines and course instructions on different levels have been identified and overcome\(^12\),\(^18\). Therefore, to improve PPH-care, an in-depth analysis identifying influencing factors (both obstacles and facilitators) for the delivery of high quality PPH-care will provide information for focusing an implementation strategy to improve this care\(^19\). Currently, little is known about contemporary obstacles and facilitators for high quality PPH-care from both patient and professional perspective. Therefore, the objective of this study is to perform an in-depth analysis to identify obstacles and facilitators for providing high quality PPH-care, from both patient and professional perspective. This knowledge will make it possible to develop a focused implementation strategy to improve PPH-care.
METHODS

Setting
To explore and classify the influencing factors for delivering high quality PPH-care from both patient and professional perspective, two theoretical frameworks were used, the frameworks of Grol and Cabana\textsuperscript{20,21} in particular. These frameworks facilitate exploration and description of potential barriers using five categories: guideline factors and recommendations (I); factors of the professionals who should use the guideline (II); factors of patients who have to accept or contribute to using the guideline (III); social setting factors (e.g. colleagues of the involved professionals) (IV); and organizational factors (V)\textsuperscript{22-25}. The Committee on research Involving Human Subjects of the region Arnhem-Nijmegen of the Netherlands assessed the study and concluded that our study (ABR no. NL25975.091.08) would be carried out in accordance with the applicable rules concerning the review of research ethics committees and informed consent.

Design and population

Patients: To explore the influencing factors for high quality PPH-care from the patient perspective, a qualitative study among patients with postpartum hemorrhage in the past was performed through semi structured one-on-one interviews. Patients who delivered a baby and lost more than 1000 ml of blood after delivery were eligible for inclusion. Patients were asked to participate by means of a notice on childbirth forums on the Internet in order to obtain as many variations as possible in hospitals throughout the country (www.babybytes.nl, www.zwangerschapspagina.nl). PPH-patients who delivered in two different university hospitals were also approached by letter to contact us if they were willing to participate. We excluded patients who had a delivery in primary care or had a Caesarean Section because we mainly wanted to evaluate the care in delivery rooms and not in operating rooms.

Professionals: To explore the influencing factors for high quality PPH-care from the professional perspective, four focus group interviews were conducted with four different groups of professionals involved in the Dutch PPH-care: 1. obstetricians, 2. obstetricians in training, 3. midwives working under the supervision of an obstetrician and 4. obstetric (OB) nurses working in the delivery rooms. Professionals from 21 different hospitals (University Hospitals (UH), Teaching Hospitals (TH) and Non-Teaching Hospitals (NTH) with a similar distribution by type across the country) were invited to participate. In all the participating hospitals
we contacted the obstetrician in charge of the obstetric division by email and requested one or two delegates per type of professional aforementioned to discuss obstacles and facilitators in their daily postpartum hemorrhage care. Information concerning the dates and place of the meetings was included in the request and if we did not get a reply of attendance within two weeks, we telephoned the obstetrician as a reminder.

*Surveys among the professionals:* In order to quantify the identified influencing factors (obstacles and facilitators) from the focus group interviews of professionals, so as to assess the importance of the influencing factors using the same theoretical frameworks, a national questionnaire survey was held among the four different professional groups. For this survey, all Dutch obstetricians and obstetricians in training (n=1230) received the questionnaire through the e-mail service of the Dutch Society of Obstetrics and Gynecologists (NVOG). Additionally, contact information of midwives was retrieved from a national registration of midwives working in secondary care. They were all sent an invitation letter with the link to the questionnaire (n=175). As no national registration existed for OB-nurses, we approached the head-nurses of delivery rooms of 26 Dutch hospitals to distribute the web link of the questionnaire to their personnel. Since we did not directly contact the OB-nurses, the number of approached OB-nurses is unknown. In order to get as much response as possible, all professionals got a reminder.

**Data collection**

*Patients:* Permission was obtained to audiotape the semi-structured interview. The one-on-one interviews took 30 to 45 minutes and were conducted individually by two experienced researchers (MW, EB). The semi-structured interviews gave the patients the chance to talk freely, as well as to express their personal feelings about the experienced obstacles and facilitators for optimal care. Interviews were structured in the following manner: we asked them to describe their experience with PPH-care received in all phases of the care procedure (during pregnancy at the outpatient clinic, during and after delivery and in the follow-up phase of the outpatient clinic). As soon as obstacles or facilitators came up we explored them in detail, using the two theoretical frameworks (guideline-, professional-, patient-, social setting- and organizational factors). Data collection was finalized when no new influencing factors were found and saturation was reached\(^{26}\).
Professionals: A chairperson with expertise in PPH-care moderated the focus group interviews. Participants were asked for permission to audiotape the interview. The structure of the interview was based on previously developed quality indicators and the two theoretical frameworks. The quality indicators, which were based on PPH-guidelines and ATLS-based course instructions, consisted of the following five domains: 1) Prevention of PPH, 2) Management of patients with >500 ml blood loss, 3) Management of patients with >1000 ml blood loss or with signs of shock and 4) Organization of PPH-care and 5) Management of patients with >2000 ml blood loss. All participants were asked to mention obstacles and facilitators for providing high quality care on the subjects of the first four domains, particularly regarding adherence to evidence-based guidelines and ATLS-based course instructions. In addition, the obstetricians were asked about influencing factors for optimal care in the fifth domain (patients >2000 ml blood loss); midwives and nurses did not take care of patients with >2000 ml blood loss.

The focus group interviews were structured in the following manner: we asked respondents to describe obstacles and facilitators regarding the specific quality indicators. We explored more specifically whether in their own hospital they experienced any obstacle or facilitator of the five categories of the theoretical frameworks: guideline, professional, patient, social setting and organizational factors.

Surveys among the professionals: For the national survey, the influencing factors found in the four focus group interviews were converted into a web-based questionnaire using Limesurvey (https://manual.limesurvey.org). The questionnaire consisted of two sections: first, general information such as age, gender and profession; and second, 103 Likert-scale items regarding the identified obstacles and facilitators from the focus group interviews. The 103 items were structured in categories according to the same theoretical frameworks we used in previous projects. If necessary, questions were transformed so that the answers ‘agree’ or ‘totally agree’ displayed an obstacle (5 point Likert-scale, ranging from totally agree to totally disagree). The questions were adjusted to the different professional groups based on the content of their work. There was room for comment at the end of the questionnaire. The questionnaire did not accept unanswered items; however, it was possible to stop doing the questionnaire at any time. In those cases, the completed questionnaires were not saved and only the attempt to do so was registered. The questionnaire was tested by an
epidemiologist and gynecologist (RH, HS) and adjusted if a question was not clear enough.

Analysis

Patients and professionals: The interviews were fully transcribed and the obstacles and facilitators were extracted separately by two researchers (EB, MW) with the qualitative program Atlas.ti (version 6.2.23, Atlas.ti Scientific Software Development GmbH; Berlin, Germany), and categorized according to the two theoretical frameworks. The transcripts and categorization were (re)-read by MW, EB, HS, and RH to ensure reliability of the data. Differences in coding were discussed and final decisions on items and categories were made in consensus.

Surveys among the professionals: The questionnaire data were gathered in an electronic database and analyzed descriptively in terms of frequencies using IBM SPSS Statistics (Version 20.0. Armonk, NY: IBM Corp). The percentages of responders who considered an item an obstacle were calculated on all 103 items by combining the score ‘totally agree’ and ‘agree’ of the 5 point Likert-scale. We analyzed the obstacles, both for the whole group of professionals and for the four different groups of professionals. To assess the reliability of the questionnaire, internal consistency per domain was calculated by Cronbach’s alpha.

RESULTS

Study population

Patients: Twelve patients participated in the semi-structured interviews. In the 11th interview no new information was acquired, nor in the 12th interview, meaning saturation was reached. Three patients derived from the two university hospitals and 9 from the forum. Five patients had a one-on-one interview at the request of the patient, 7 were interviewed by telephone. The patients delivered in 11 different hospitals. The median blood loss post-partum was 3.4 liters and the median age 28.5 years. All types of hospitals (University Hospitals, Non-University-, Teaching and Non-Teaching Hospitals) were represented.

Professionals and survey among professionals: In total, 41 professionals participated in the four focus group interviews, of which nine obstetricians (from 8 different hospitals), eight obstetricians in training (from 6 different hospitals), fifteen midwives (from 10 different hospitals) and nine OB-nurses (from 9 different hospitals). Seventeen percent of the professionals worked in a non-teaching
hospital, 46% in a teaching hospital and 36% in a university hospital. The four different types of professionals and the different types of hospitals in combination with the distribution of hospitals across the country display a diverse group of professionals and different care settings.

The survey with questionnaires yielded 499 responses of which 318 were complete. Three were excluded because the questionnaire was not completed by a target group member. In total, 315 questionnaires were used for analysis; 37% concerned obstetricians, 30% obstetricians in training, 19% midwives and 14% OB-nurses. Table 1 outlines the general information of the respondents. These respondents include all types of obstetrical caregivers working in Dutch delivery rooms. The Chronbach’s alpha for the questionnaire was more than 0.820 and that renders the questionnaire reliable.

Table 1. General characteristics of professionals from the completed surveys (quantitative study)

<table>
<thead>
<tr>
<th></th>
<th>N (318)</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>64</td>
<td>20</td>
</tr>
<tr>
<td>Female</td>
<td>254</td>
<td>80</td>
</tr>
<tr>
<td>Position</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obstetricians</td>
<td>119</td>
<td>37</td>
</tr>
<tr>
<td>Obstetricians in training</td>
<td>94</td>
<td>30</td>
</tr>
<tr>
<td>Midwives</td>
<td>61</td>
<td>19</td>
</tr>
<tr>
<td>Nurses</td>
<td>44</td>
<td>14</td>
</tr>
<tr>
<td>Type of hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>University Hospital</td>
<td>105</td>
<td>33</td>
</tr>
<tr>
<td>Teaching Hospital</td>
<td>155</td>
<td>49</td>
</tr>
<tr>
<td>Non-Teaching Hospital</td>
<td>58</td>
<td>18</td>
</tr>
<tr>
<td>No. of deliveries per year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1000</td>
<td>38</td>
<td>12</td>
</tr>
<tr>
<td>1001-1500</td>
<td>110</td>
<td>35</td>
</tr>
<tr>
<td>1501-2000</td>
<td>75</td>
<td>24</td>
</tr>
<tr>
<td>&gt;2000</td>
<td>95</td>
<td>30</td>
</tr>
</tbody>
</table>

Influencing factors from patient perspective
From the patient interviews, we identified 38 obstacles and 4 facilitators in the five domains of the two theoretical frameworks (domain of the guideline, professional, patient, social setting and organization). Most obstacles were cited at professional and organizational levels. The main influencing factors for high quality PPH-care per domain are shown in table 2 and described beneath. Figure 1 illustrates quotes, inter alia, from PPH-patients.

“Professional factors”: Patients particularly mentioned the poor information provision about PPH (9 patients). They often received no information or incorrect information on the risk factors for PPH and the medical procedures, and had no knowledge prior to delivery of their risk for PPH.
**Figure 1. Patients & professionals quotations concerning obstacles of quality of PPH-care delivered**

<table>
<thead>
<tr>
<th>Guideline-related obstacles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>O:</strong> The high risk groups for PPH are not very well specified in the guideline. It will be a whole different story if that would be realized</td>
</tr>
<tr>
<td><strong>O:</strong> I think the guideline is not well accessible, because I have to go look it up in the computer</td>
</tr>
<tr>
<td><strong>OIT:</strong> Some recommendations of the guideline and ATLS-based courses are lacking in our local protocol</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Professional-related obstacles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OIT:</strong> Even if it is stated in the protocols, still team members doubt its content which leads to tedious discussions. It is mainly caused by lack of knowledge</td>
</tr>
<tr>
<td><strong>P:</strong> The first information my husband received after waiting for 1.5 hours was that rigorous decisions had to be made, because they did not manage to stop the bleeding yet</td>
</tr>
<tr>
<td><strong>M:</strong> No, I weigh the blood loss only if it looks like a lot</td>
</tr>
<tr>
<td><strong>P:</strong> I would have been less disturbed if I had known that it takes longer before you recover after PPH</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Organizational-related obstacles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>M:</strong> We don’t have digital scales in every delivery room. We have to leave the room to weigh the amount of blood loss</td>
</tr>
<tr>
<td><strong>P:</strong> I certainly would have had benefit receiving information from a central website. I have the feeling that I’m not the only one who received poor aftercare</td>
</tr>
<tr>
<td><strong>M:</strong> How many team trainings? The goal is twice a year</td>
</tr>
<tr>
<td><strong>O:</strong> In the night it takes time before the OR team arrives in the hospital. This is a financial aspect</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Social-related obstacles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>O:</strong> I wanted to give Fresh Frozen Plasma but anesthesiologist refused</td>
</tr>
<tr>
<td><strong>N:</strong> The inexperienced professionals are often the one to take very important decisions</td>
</tr>
<tr>
<td>Do you feel that you can speak freely? <strong>OIT:</strong> That depends on the obstetrician</td>
</tr>
</tbody>
</table>

*P: Patients, O: Obstetricians, OIT: Obstetricians in Training, M: Midwives, N: nurses*

If PPH occurred, patient, partners and family were not informed or received insufficient information on the medical condition of the patient. They received insufficient or confusing information on the risks and medical procedures during the treatment of PPH, and they thought that the professionals showed panic when
PPH occurred. In the recovery period, patients received inconsistent information on the duration of recovery and the policy of future deliveries. Moreover, patients often felt not being taken seriously by health care professionals.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Obstacles</th>
<th>Nº of patients (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The professionals (n=18)</td>
<td>-Poor information to the patient about PPH</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>-Poor information to the partner/family about the patient’s medical condition, the risks and medical procedures</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>-Patient feels not being taken seriously by the professional</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>-Professionals panic when PPH occur</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>-Incorrect/no information about policy of future deliveries</td>
<td>4</td>
</tr>
<tr>
<td>The organization (n=7)</td>
<td>-Lack of information material like folders and website</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>-The patient has to deal with many different clinicians</td>
<td>3</td>
</tr>
<tr>
<td>Facilitator (n=4)</td>
<td>-Patient information material/website is facilitating for patient information</td>
<td>3</td>
</tr>
</tbody>
</table>

“Organizational factors”: Patients noted that they did not receive an informative leaflet (7 patients) and that extensive digital information was not available. Patients identified the need for receiving information about PPH during pregnancy, an informative patient website, a patient leaflet about PPH and a follow-up talk as facilitators. In addition, premature discharge from the hospital and dealing with many different clinicians were considered obstacles by at least three patients.

Influencing factors from professional perspective (interviews and survey)
In total, 83 obstacles and 30 different facilitators for high quality PPH-care were identified in the four focus group interviews. Obstetricians identified 43 unique obstacles, obstetricians in training 39, midwives 47 and the OB-nurses 31. We selected the most frequently cited influencing factors that were identified in at least 3 out of 4 focus group interviews (table 3), categorized according to our frameworks: 1. The guideline; 2. Professional; 3. Patient; 4. Social setting; and 5. Organization.

For the quantification by means of questionnaires, we used all influencing factors found. Table 4 shows the main influencing factors for the different types of professionals, and in total, identified in the survey. Presented are the influencing factors with total scores of 25% or more. We will discuss these factors per category in more detail, using more in-depth information of the focus group
Influencing factors for high quality PPH-care

interviews as well. Figure 1 represents quotes of the professionals regarding the different domains.

Table 3. Obstacles and facilitators related to guideline and ATLS-based course adherence according to professionals (focus group interview results: qualitative study)

<table>
<thead>
<tr>
<th>Domain</th>
<th>Obstacles</th>
<th>Mentioned in N° of interviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guideline</td>
<td>Items of the PPH-guideline and ATLS-based course instructions are not included in the local hospital protocol</td>
<td>4</td>
</tr>
<tr>
<td>(n=18)</td>
<td>-The PPH-guideline is difficult to obtain at the delivery ward</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Recommendations and definitions in the PPH-guideline are unclear</td>
<td></td>
</tr>
<tr>
<td>Professional</td>
<td>-Professionals lack awareness regarding the importance of the recommendations of the guideline and ATLS-based course</td>
<td>4</td>
</tr>
<tr>
<td>(n=28)</td>
<td>-Professionals experience a feeling of time pressure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Professionals overestimate their knowledge regarding identifying the patient categories at risk for PPH and regarding the treatment of HR-patients and patients with PPH</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>-Professionals are overconfident regarding their ability to estimate the blood loss without the use of a weighing-scale</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>-Professionals lack to detect high-risk patients at the outpatient clinic</td>
<td>4</td>
</tr>
<tr>
<td>Social setting</td>
<td>-Lack of communication in the team responsible for the patient, about the risks, policy, seriousness of the situation or actions that need to be taken</td>
<td>4</td>
</tr>
<tr>
<td>(n=7)</td>
<td>-Uncertain leadership caused by lack of knowledge about each other’s knowledge and expertise. This is caused by inexperienced professionals and frequent change of team composition</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>-Disagreement between team members and with personnel of other disciplines about the seriousness of the situation (blood-bank personnel &amp; anesthesiologists)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>-Lack of team collaboration as orders are not followed and team members prefer following their own instincts in treatments, which leads to inconsequent policy</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>-Presence of hierarchy leads to dread, for team members find it difficult to call in a gynecologist who is at home and speak freely against the supervisor when there is a disagreement about policy</td>
<td>3</td>
</tr>
<tr>
<td>Organization</td>
<td>-Materials necessary for treatment of patients with PPH are not direct available</td>
<td>3</td>
</tr>
<tr>
<td>(n=30)</td>
<td>-Shortage of (qualified) staff</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>-Skills/team trainings are not organized or not organized on a regular basis</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>-Lack of practical tools at the delivery rooms, such as checklist/flowchart for easier and practical use of the guideline</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>-Lack of finance</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>-Complication discussions are not organized on a structural basis because it is too time consuming</td>
<td>3</td>
</tr>
<tr>
<td>Facilitators</td>
<td>-The availability of a checklist/flowchart about PPH at the delivery rooms would improve care</td>
<td>4</td>
</tr>
<tr>
<td>(n=30)</td>
<td>-Training on using a checklist/flowchart about PPH would improve care</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>-Skills/team trainings on a regular basis improve care</td>
<td>3</td>
</tr>
</tbody>
</table>

“Guideline factors”: Table 3 and 4 show the results of the most important factors related to the guideline. The most frequently cited factor (55%) was the need for a flowchart or checklist in the delivery room, particularly among the obstetricians in training (69%). Another important factor cited was the lack of inclusion of main
guideline recommendations or ATLS-based course instructions in the local protocols.

Table 4. Obstacles according to professionals (web-based survey results: quantitative study)

<table>
<thead>
<tr>
<th>Domain: Guideline</th>
<th>Overall (%)</th>
<th>O (%)</th>
<th>OIT (%)</th>
<th>M (%)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The national guideline lacks a flowchart to use in acute situations</td>
<td>55</td>
<td>54</td>
<td>69</td>
<td>48</td>
<td>39</td>
</tr>
<tr>
<td>My local protocol does not say you should establish a policy for the delivery of a high-risk patient*</td>
<td>39</td>
<td>33</td>
<td>38</td>
<td>48</td>
<td>43</td>
</tr>
<tr>
<td>My local protocol does not say you should consider a manual placenta removal at 500 ml blood loss*</td>
<td>39</td>
<td>34</td>
<td>36</td>
<td>59</td>
<td>30</td>
</tr>
<tr>
<td>I have to find out myself that there is an update of the guideline</td>
<td>35</td>
<td>29</td>
<td>36</td>
<td>34</td>
<td>50</td>
</tr>
<tr>
<td>The guideline is difficult to obtain in our delivery room</td>
<td>27</td>
<td>27</td>
<td>23</td>
<td>30</td>
<td>34</td>
</tr>
<tr>
<td>My local protocol does not say you should weigh blood loss for every high-risk patient*</td>
<td>26</td>
<td>17</td>
<td>27</td>
<td>27</td>
<td>25</td>
</tr>
<tr>
<td>You cannot use the national PPH-guideline in acute situations</td>
<td>25</td>
<td>24</td>
<td>29</td>
<td>25</td>
<td>16</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Domain: Professional</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Measuring the urine output is low on my list of priorities</td>
<td>57</td>
<td>44</td>
<td>65</td>
<td>66</td>
<td>55</td>
</tr>
<tr>
<td>I don’t have enough skills to perform surgical interventions (B-lynch etc)</td>
<td>50</td>
<td>30</td>
<td>77</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Professionals are not aware that warm saline infusion is beneficial</td>
<td>50</td>
<td>35</td>
<td>63</td>
<td>61</td>
<td>50</td>
</tr>
<tr>
<td>The recommendations for &gt;1000 ml blood loss are less important when a patient lost 1000 instead of 1500 ml</td>
<td>25</td>
<td>23</td>
<td>30</td>
<td>31</td>
<td>14</td>
</tr>
<tr>
<td>We do not weigh the blood loss for every high-risk patient when it is estimated as little</td>
<td>36</td>
<td>24</td>
<td>49</td>
<td>44</td>
<td>32</td>
</tr>
<tr>
<td>I don’t have enough knowledge to perform surgical interventions (B-lynch etc.)</td>
<td>27</td>
<td>7</td>
<td>53</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>I don’t have enough knowledge about bimanual compression</td>
<td>26</td>
<td>11</td>
<td>33</td>
<td>56</td>
<td>NA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Domain: Social setting</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of experience of the team members with the use of warm saline infusion</td>
<td>50</td>
<td>45</td>
<td>53</td>
<td>56</td>
<td>48</td>
</tr>
<tr>
<td>Working with inexperienced obstetricians (in training) is an obstacle</td>
<td>30</td>
<td>20</td>
<td>36</td>
<td>34</td>
<td>39</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Domain: Organization</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>There is a need for more skills and drills</td>
<td>53</td>
<td>42</td>
<td>67</td>
<td>57</td>
<td>50</td>
</tr>
<tr>
<td>In my hospital it is not possible to give a patient warm saline infusion</td>
<td>50</td>
<td>40</td>
<td>49</td>
<td>59</td>
<td>68</td>
</tr>
<tr>
<td>Complication discussions are not multidisciplinary</td>
<td>44</td>
<td>31</td>
<td>65</td>
<td>43</td>
<td>34</td>
</tr>
<tr>
<td>Time is an obstacle for organizing skills and drills</td>
<td>38</td>
<td>36</td>
<td>51</td>
<td>31</td>
<td>27</td>
</tr>
<tr>
<td>Not every delivery room has material to measure urine output</td>
<td>36</td>
<td>18</td>
<td>33</td>
<td>57</td>
<td>61</td>
</tr>
<tr>
<td>The multidisciplinary arrangements are not tight enough</td>
<td>33</td>
<td>2</td>
<td>42</td>
<td>30</td>
<td>27</td>
</tr>
<tr>
<td>Organizing debriefings is too time consuming</td>
<td>32</td>
<td>29</td>
<td>39</td>
<td>33</td>
<td>23</td>
</tr>
<tr>
<td>Complication discussions are not organized on a regular basis</td>
<td>30</td>
<td>17</td>
<td>48</td>
<td>31</td>
<td>25</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Facilitators</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A flowchart about PPH in the delivery room would improve care</td>
<td>63</td>
<td>50</td>
<td>73</td>
<td>68</td>
<td>58</td>
</tr>
<tr>
<td>A checklist about PPH in the delivery room would improve care</td>
<td>57</td>
<td>51</td>
<td>56</td>
<td>63</td>
<td>60</td>
</tr>
<tr>
<td>There is a need for more skills and drills</td>
<td>53</td>
<td>42</td>
<td>67</td>
<td>57</td>
<td>50</td>
</tr>
<tr>
<td>A second gynecologist on duty for only emergencies would help me to quickly consult an extra gynecologist</td>
<td>30</td>
<td>26</td>
<td>34</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

O: Obstetrician, OIT: Obstetrician in training; M: Midwife; N: Nurses; *Respondents without a local protocol were excluded from this question (n=12); NA: questions not applicable for these professionals
The most frequently cited missing items were ‘to establish a policy for the delivery of a high-risk patient’ (39%) and ‘manual placenta removal at 500 ml blood loss’ (39%). Other important missing items were: weighing the blood loss for every high-risk patient (26%) and recommendations regarding the prevention of PPH (20%). The missing items were particularly important for the midwives (highest scores). Other obstacles in this domain were related to the availability of the guideline/local protocol in the delivery rooms (25%). This was particularly important for the OB-nurses (34%).

“Professional factors”: In the domain of the professionals we found factors related to attitude, knowledge and skills (Table 3 and 4). Professionals lacked awareness about the importance of some recommendations causing that these recommendations were skipped or had a lower priority to be enforced, such as measuring the urine output (57%) and weighing the blood loss for every high-risk patient (36%), among obstetricians in training and midwives in particular. In all focus group interviews, professionals mentioned that they could properly estimate the amount of blood loss without using a weighing-scale. Also an overestimation of proper knowledge was cited, for example, of which patient-category is at risk. Professionals’ knowledge related to the benefits of warm saline infusion in PPH (50%), surgical interventions (27%) (both highest for obstetricians in training) and bimanual compression (26%), particularly among midwives, could be improved. Skills related to surgical interventions (50%) fall short, particularly among obstetricians in training (77%). In all focus group interviews time pressure was considered another major reason not to follow the guideline, but this did not score higher than 25% in the survey.

“Patient factors”: Professionals did not mention influencing factors at the patient level.

“Social setting factors”: In the social setting (table 3 and 4), for all professionals, in general the main obstacles were related to working with inexperienced physicians in training (30%). An obstacle cited in all focus group interviews, but without scores over 25% in the survey, was a lack of communication about the policy on the delivery of the high-risk patient, the steps to be taken and the steps already taken. Besides communication, team collaboration (following orders from team members) and hierarchy (criticizing the actions of a leading team member) were cited in all focus group interviews, in particular the lack of clarity in leadership, uncertainty
about knowledge and experience levels of team members, resulting in a lack of confidence regarding their skills and ability. The frequent changes in staff and working in different team compositions with inexperienced professionals were considered causes for these problems. Professionals indicated that skills- and team training (53%) were important facilitators.

“Organizational factors”: In the domain of the organization (table 3 and 4), professionals and in particular obstetricians in training (67%) mentioned a need for more frequent skills- and team training (53%). In addition, professionals stated that skills- and team training was not organized at all (11%) or not multidisciplinary (12%) (data not shown). Time (38%) and cost (14%) were obstacles for organizing these training sessions. Another main obstacle was the lack of material available for providing warm saline infusion (50%). Material to measure urine output (36%) and for high-pressure fluid replacement (19%), and monitoring facilities (16%) were lacking in the delivery rooms as well.

In addition, according to the respondents, discussions on complications were often not performed multidisciplinary (44%) and not organized on a regular basis (30%) because this was considered time-consuming (32%). Moreover, multidisciplinary arrangements lacked clarity and concreteness (33%).

Professionals indicated that flowcharts/checklists (63%/57%) in the delivery rooms could be important facilitators for the delivery of high quality PPH-care. Obstetricians in training, midwives and OB-nurses in particular thought the use of checklists/flowcharts could be helpful, because multiple actions had to be performed in a very short period of time. The use of these tools should be incorporated in skills-and team training, leading to a proper application.

**DISCUSSION**

This study is the first to describe an in-depth analysis to identify influencing factors (obstacles and facilitators) for providing high quality PPH-care, from both patient and professional perspective. The main obstacle from the patients’ perspective was at a professional level; predominantly the lack of information provided by the professionals to the patient, partner or family, before, during and after the PPH event. An informative patient website regarding PPH and a follow-up consultation were mentioned as facilitators.

The obstacles identified by the professionals were in all domains, except the patient domain. Their main obstacles were: lack of clarity of the guideline, absence
of various guideline recommendations in local protocols, lack of knowledge and failing team communication. Team training and checklists or flowcharts were considered facilitators for better care.

The lack of communication and information provision to patients and family is a frequent obstacle found not only in this study, but also in studies in other areas of healthcare\textsuperscript{24,28,29}. As regards PPH this was also observed in a simulated setting, where not any team member addressed the family members to let them know what was going on with their loved one during the PPH simulation\textsuperscript{30}. It may be that informing the patient and family, especially in an emergency situation, is not the first thing that is done. However, above all in an emergency situation, the patient and family are vulnerable and scared, and diagnostic uncertainty or lack of information will leave a negative impression\textsuperscript{31}. Although PPH can suddenly emerge, care providers can nonetheless anticipate on risk factors, especially if a high risk for PPH is present, by giving the patient information beforehand, during pregnancy, about the risks. Patients and family can seek information about PPH and be a partner in their own care. A study by Harrison et al regarding patient satisfaction in high risk pregnancies, reported that the majority of the women wanted to be an active partner in their own care\textsuperscript{32}. In other areas of healthcare, an active patient participation has led to better outcomes\textsuperscript{33,34}. As the patients mentioned in our study, an active patient participation can be supported by the development of a reliable, informative website, and a patient leaflet about PPH. Moreover, in this study, professionals did not mention obstacles at the patient level, which means that this factor requires extra attention.

A common obstacle from professional perspective in literature is the poor quality of the guidelines and protocols\textsuperscript{21,22,29}. Particularly the lack of clarity and concreteness of the guideline for application in normal practice and the lack of essential recommendations from both guidelines and course instructions in the local PPH-protocols were mentioned in this study. For PPH-care, these are main obstacles, since PPH-care is characterized by two phases: The prevention phase (performing routine care); followed by the treatment phase (emergency-care phase) where different action must be taken by different professionals, consecutively or simultaneously, in a limited timeframe\textsuperscript{15,16}. Streamlining PPH-care, according to clear, descriptive protocols that are founded on concrete evidence-based guidelines and ATLS-based course instructions, is necessary for every professional to provide high quality care\textsuperscript{12,35}. However, guideline recommendations
are rarely specified in precise behavioral terms such as who does what, when, where, and how, and therefore local protocols are essential to close the gap between best evidence and practice\textsuperscript{36-38}. Proper implementation of evidence-based PPH-guidelines and ATLS-based courses are essential for high quality PPH-care and can only be achieved once the causes for not following guidelines and instructions on different levels have been identified and overcome\textsuperscript{7,39}. From literature it is known, that transformation of guideline recommendations into clear and descriptive local protocols requires time, skills in protocol development and convincing evidence or guideline recommendations\textsuperscript{40,41}. Furthermore, different studies report lack of agreement with guideline recommendations by the professionals\textsuperscript{42,43}. The use of checklists and flowcharts, based on evidence-based guidelines and ATLS-based course instructions, could be important facilitators for the delivery of high quality PPH-care, particularly in case of performing multiple actions in a limited timeframe. Use of checklists and flowcharts has been proven effective in critical care\textsuperscript{44-46}. This is indeed indicated by the professionals as a facilitator.

Other obstacles to delivering high quality care are the lack of the professionals’ knowledge and skills regarding actions for both prevention and management of PPH and team communication and collaboration\textsuperscript{29}. Professionals often lack knowledge and skills about proactive actions to prevent exacerbation of PPH, but also about high risk factors for PPH. They sometimes overestimate their knowledge of the management of patients with PPH, but also their ability to estimate the blood loss without using a weighing-scale. It is known that estimating blood loss often means an underestimation\textsuperscript{47}. Furthermore, insufficient team communication and collaboration, particularly the lack of clarity in leadership, were obstacles mentioned in all focus group interviews. Different studies reported the lack of effective leadership to promote and implement guideline recommendations as a barrier for effective guideline implementation\textsuperscript{20,48}. These obstacles could lead to inadequate team performance and a lack of standardized care, which is crucial in the emergency care setting, such as the management of PPH phase. Furthermore, the identified obstacles correspond with improvement factors identified in a simulated setting (unclear team roles, team communication problems, unidentified team leader, resulting in chaos and lack of documentation)\textsuperscript{30}. However, whether it corresponds with the actual care is still unknown and has to be researched.
The difficulty of keeping up with literature due to lack of time is reported in this study and not only in the obstetrical field\textsuperscript{21,29}. Guidelines should facilitate the professional in this, but overall, professionals are often unaware of the existence or content of new guidelines\textsuperscript{21,29}. Prior education and team training to improve knowledge, skills, team communication and collaboration are important elements to improve PPH-care\textsuperscript{49,50}. Furthermore, since training on the total content of the guideline is often not feasible, training on the use of checklists and flowcharts could be more effective. All professionals mentioned both these factors as a facilitator in the delivery of high quality PPH-care.

The strong point of our study is its systematic approach to obtain information on influencing factors to the delivery of high quality care using both qualitative and quantitative research methods\textsuperscript{39}. Another strong point is the multidisciplinary approach, including all professionals involved in PPH-care, and the patients. We organized focus group discussions to identify potential obstacles to guideline adherence and performed an extensive questionnaire study among Dutch professionals involved in the PPH-care to quantify the prevalence and intensity of the different barriers. We realize that there are some limitations in our study as well. The international general applicability of our findings may be questionable. Nevertheless, our results apply to international guidelines, because we used guideline-based quality indicators, previously developed from international guidelines as a guide for the focus group interviews\textsuperscript{51}. The limited response to the survey is another limitation; the quantitative results confirm the qualitative results, however. Therefore, it contributes to a broad support of the, yet to develop, tailor made strategy to improve the implementation of the national evidence-based PPH guideline and ATLS-based course instructions.

CONCLUSION
In conclusion, obstacles as well as facilitators for the delivery of high quality PPH-care were identified, from both patient and professional perspective. Patient obstacles mainly concerned the lack of information provided by professionals. Checklists and flowcharts were mentioned as concrete tools to facilitate high quality care. For professionals, obstacles to the delivery of high quality PPH-care were identified in all domains, except the patient domain. These data can be used to develop a focused strategy to improve PPH-care. An additional step in the improvement strategy is to objectively measure the actual PPH-care.
REFERENCES

Development of a tailored strategy to improve postpartum hemorrhage guideline adherence

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Submitted
ABSTRACT

Background. Despite the introduction of evidence based guidelines and practical courses, the incidence of postpartum hemorrhage shows an increasing trend in developed countries. Substandard care is often found, which implies an inadequate implementation. We aimed to reduce the gap between evidence-based guidelines and clinical application, by developing a strategy, tailored to current barriers for implementation.

Methods. The development of the implementation strategy consisted of three phases, supervised by a multidisciplinary expert panel. In the first phase a framework of the strategy was created, based on barriers to optimal adherence identified among professionals and patients together with evidence on effectiveness of strategies found in literature. In the second phase, the tools within the framework were developed, leading to a first draft. In the third phase the strategy was evaluated among professionals and patients. The professionals were asked to give written feedback on tool contents, clinical usability and inconsistencies with current evidence care. Patients evaluated the tools on content and usability. Based on the feedback the tools were adjusted.

Results. We developed a tailored strategy to improve guideline adherence, covering the trajectory of the third trimester of pregnancy till the end of the delivery. The strategy, directed at professionals, comprehending three stop moments includes a risk assessment checklist, care bundle and time-out procedure. As patient empowerment tools, a patient passport and an information website was developed. The evaluation among the expert panel showed all professionals to be satisfied with the content and usability and no discrepancies or inconsistencies with current evidence was found. Patients’ evaluation revealed that the information they received through the tools was incomplete. The tools were adjusted accordingly to the missing information.

Conclusion. A usable, tailored strategy to implement PPH guidelines and ATLS course-instructions was developed. The next step is the evaluation of the strategy in a feasible trial.
INTRODUCTION
Worldwide postpartum hemorrhage (PPH) is the main cause of severe maternal morbidity (SMM). A recent study in the United States estimated PPH to be responsible for almost half of the cases of SMM (47.6%)\(^1\). Globally the incidence of PPH is estimated around 10.5% and in high resource countries an increasing trend in PPH incidence has been seen\(^2\). For example, in the Netherlands the incidence increased from 3% in 2003 to 8% in 2011 in second line care\(^3\).

A review on PPH guideline adherence found that 38% of the women with \(\geq 1500\) ml blood loss received substandard care\(^4\). Substandard health care is often suggested as a possible cause for inadequate reduction of morbidity\(^5\). It seems that evidence-based guidelines are not optimally adhered to, leading to substandard care and a gap between evidence-based medicine and clinical application\(^6\).

Guideline dissemination without a tailored implementation strategy to improve spread among professionals and adherence to guidelines is often ineffective\(^7\). A review evaluating implementation strategies within the field of obstetrics concludes that a prospective identification of efficient strategies and barriers to change is necessary to improve clinical practice guideline implementation\(^8\). The strategy choice needs to be tailored to the setting for best possible results, consisting of the right tools to increase guideline adherence. In this paper we describe the development of an implementation strategy for a high resource obstetric setting to improve guideline adherence regarding postpartum hemorrhage (PPH).

METHODS
Setting
The current study is part of the FLUXIM trial\(^9\). In this trial we developed quality indicators on PPH care (a); studied the adherence of these indicators in actual care (b), and analyzed barriers and facilitators for optimal care among both professionals, women and their partners (c). In the last part of the Fluxim trial the outcomes of these data were aggregated and formed the basis of the development of a strategy to improve guideline adherence.

Development strategy
The development of the implementation strategy consisted of three phases (figure 1). In the first phase the selection of the tools to be included in the implementation strategy was performed by a multidisciplinary expert panel of eight
obstetricians, two anesthesiologists and two opinion leaders on quality of care research through an iterative process.

**Figure 1.** The three phases for the development of the implementation strategy to improve PPH guideline adherence.

*The first phase consisted of the analyses of barriers for guideline implementation and the search of international literature of strategy effectiveness, leading to the creating of the strategy framework. The second phase was the content detailing of the created framework and the development of the individual tools. A first draft was made, which in the third phase was pilot tested among professionals and patients.*

**Phase one: Strategy selection**

International literature was searched for evidence on effectiveness of strategies to serve as a base for the selection of the tools to address the barriers and to incorporate the identified facilitators (i.e. the potential tools). The search covered three areas: tools and strategies within the obstetric health care, effective tools outside the field of obstetrics and patient oriented tools. Articles were searched on Medline and experts in the field of implementation science were consulted for recent literature. The search results were presented to the expert panel combined with the barriers and facilitators that were considered most important and the low adherence scores of the actual care study\(^\text{10,11}\). In short, most important barriers experienced by professionals were lack of knowledge, team communication and leadership. They mentioned the use of checklists and flowcharts as factors to improve adherence to the guideline. Patients mentioned lack of information before, during and after the PPH as main barriers and an informative patient website and leaflet as main facilitator for optimal care. Actual care was particularly not in accordance with guidelines with regard to the high risk identification and documentation of policy for PPH on the outpatient clinic and during labor, vital signs monitoring, and the different steps in the management of PPH. Furthermore, acts regarding management of PPH were only partly performed in time.
Phase two: Content detailing and tool development
In the second phase the selected potential tools were developed. The tool content was derived from international guidelines, ATLS-based courses (Advanced Trauma Life Support, e.g. the Managing Obstetric Emergencies and Trauma course), and international literature. They give recommendations based on the stage of delivery the patient is in, and on the progression of the PPH. There are preventive measures, measures when the blood loss reaches 500 cc and when there is ongoing blood loss above the liter or 2 liters. These phases are also to be found in the division of the quality indicators. The tool setup and content follow this setup of PPH care, and places actions in relation to the stage of amount of blood loss the patient is in.

According to both the Dutch and the international guidelines, identification of high-risk patients forms the basis of PPH care. However, most guidelines did not clearly define all risk factors for PPH and there was discrepancy between different guidelines. Therefore an additional search was performed using the Dutch PPH guideline, 6 international guidelines\textsuperscript{12-17} and international literature. We searched for additional risk factors and odds ratios (OR’s), and only OR’s with confidence intervals available were considered. Medline was searched using the search terms ‘PPH’ and ‘risk factors’ and synonyms, followed by a snowballing search of the articles and reference lists of the guidelines if available. Furthermore, risk factors found in a multivariate analysis of the Netherlands Perinatal Registration (DPR) by the LEMMoN study were considered (unpublished data, personal correspondence: J. Zwart, Severe Maternal Morbidity in the Netherlands. The LEMMoN study. 2009) as well. Ultimately, all risk factors listed in the Dutch guideline were selected to be included in the tools, as well as all risk factors that were mentioned in at least two of the other six guidelines and found significant in either international literature or in the DPR analysis.

Phase 3: Feedback round expert panel and patients
In phase three, the developed tools, was presented in a feedback round among the expert panel. The nine members of the expert panel were asked to evaluate the tools on accuracy of the medical contents, clinical usability and control for inconsistencies with the current best evidence care as provided by the Dutch guideline, and to provide written feedback on these three items.
Patients were recruited to evaluate the patient materials developed for the strategy. Both high-risk patients and experienced patients (women whom experienced a PPH in the previous year) were asked for the evaluation. High-risk patients were recruited from the obstetrics clinic in one of the participating hospitals. The experienced patients were recruited by placing messages on childbirth forums. The women were asked to evaluate our website by means of a questionnaire. The questionnaire consisted of 37 questions, of which 29 were yes-no questions, evaluating six specific domains, and two general categories with eight open questions for points for improvement. The domains evaluated were the usability, speed of the website, website menu navigation, the completeness and clarity of the information provided, the layout and the risk-identification test available on the website.

RESULTS
In the three steps described above we have created a strategy to improve the adherence to evidence based guidelines and the ATLS-based course for prevention and treatment of PPH. The strategy, shown in figure 2, consists of three stop moments, a checklist for PPH treatment for the professionals and two patient tools.

Patients were recruited to evaluate the patient materials developed for the strategy. Both high-risk patients and experienced patients (women whom experienced a PPH in the last year) were asked for the evaluation. High-risk patients were recruited from the obstetrics clinic in one of the participating hospitals. The experienced patients were recruited by placing messages on childbirth forums. The women were asked to evaluate our website by means of a questionnaire. The questionnaire consisted of 37 questions, of which 29 were yes-no questions, evaluating six specific domains, and two general categories with eight open questions for points for improvement. The domains evaluated were the usability, speed of the website, website menu navigation, the completeness and clarity of the information provided, the layout and the risk-identification test available on the website.
Phase one: Strategy selection

The professionals’ barriers and facilitators on which the expert panel reached consensus to include them in the tools, are listed in table 1, those of the patients are shown in table 2.10

When reviewing the literature on strategies for guideline implementation within the field of obstetrics, a systematic review8 on evidence-based strategies for obstetric guideline implementation provided an overview of effective strategies. Of the tools they reviewed, educational tools showed mixed effects, audit & feedback was generally effective, strategies based on opinion leaders, quality improvement tools and academic detailing were ineffective or showed mixed effects. Reminders showed to be overall effective.8

Outside the field of obstetrics two types of effective tools were found that seemed applicable in an obstetric setting by the expert panel. The first were checklists, showing to be successful in reducing the complication rate in surgical settings18-21, and revealing an increase in adherence to safety indicators and guidelines18,20. Checklists can provide an overview in a complicated situation, and reduces room for human error and the number of omitted treatments. Furthermore, checklists can improve documentation of care, facilitate (team- and interdisciplinary) communication and leadership, and minimize information loss during transfer.
between professionals. Secondly, care bundles, initiated of the Institute for Healthcare Improvement, have in multiple settings shown to increase compliance to quality indicators and reduced complications and mortality.

Table 1. Main barriers and facilitators addressed by professionals

<table>
<thead>
<tr>
<th>Barriers</th>
<th>N*</th>
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<tbody>
<tr>
<td>1. Lack of checklist/flowchart about PPH at the delivery rooms</td>
<td>4</td>
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<tr>
<td>2. The guideline is difficult to obtain at the delivery ward</td>
<td>3</td>
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<tr>
<td>3. Recommendations and definitions in the guideline are unclear</td>
<td>3</td>
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<tr>
<td>4. Professionals overestimate their knowledge regarding identifying the patient-categories at risk for PPH and regarding the treatment of high-risk patients and patients with PPH</td>
<td>4</td>
</tr>
<tr>
<td>5. Professionals lack to detect high-risk patients at the outpatient clinic</td>
<td>4</td>
</tr>
<tr>
<td>6. Tools: need for practical tools for easier and practical use of the guideline</td>
<td>3</td>
</tr>
<tr>
<td>7. Lack of communication in the team responsible for the patient, about the risks, policy’s, seriousness of the situations or actions that need to be taken</td>
<td>4</td>
</tr>
<tr>
<td>8. Unclearness in leadership trough lack of knowledge of each other’s skills and ability, because of inexperienced professionals and the frequent change of team composition.</td>
<td>4</td>
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<tr>
<td>9. Disagreement between team members and with personnel of other disciplines about the seriousness of the situation (blood-bank personnel and anesthesiologists)</td>
<td>3</td>
</tr>
<tr>
<td>10. Lack of team collaboration, for orders are not followed and team members prefer following their own instincts in treatments that leads to inconsequent policy.</td>
<td>3</td>
</tr>
<tr>
<td>11. Presence of hierarchy leads to dread, for team members find it difficult to call in a gynecologist who is at home and speak freely against the supervisor when there is a disagreement about policy</td>
<td>3</td>
</tr>
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</table>

Facilitators

<table>
<thead>
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<th>Facilitators</th>
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<tbody>
<tr>
<td>1. The availability of a checklist/flowchart about PPH at the delivery rooms would improve care</td>
</tr>
</tbody>
</table>

*Amount of focus groups that mentioned the barrier of facilitator

Table 2. Main barriers and facilitators addressed by patients

<table>
<thead>
<tr>
<th>Barriers</th>
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<tbody>
<tr>
<td>1. poor information supply to the patient about PPH</td>
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<tr>
<td>2. poor information supply to the partner and/or family about the medical condition, risks and procedures</td>
</tr>
<tr>
<td>3. lack of information material (e.g. folders or website)</td>
</tr>
<tr>
<td>4. patient’s perception of delay in transfer to the operation room</td>
</tr>
</tbody>
</table>

Facilitators

<table>
<thead>
<tr>
<th>Facilitators</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. information about PPH before the delivery</td>
</tr>
<tr>
<td>2. a request for patient information material</td>
</tr>
</tbody>
</table>

Patient empowerment is an important topic in health care and refers to the enhanced ability of patients to actively understand and influence their own health status and health care. According to the WHO, interventions with empowerment characteristics have shown significant impact in improving health and quality of life in chronically ill patients. Web-based interventions seem effective in empowering
patients and with a relative young target population a viable option for patient empowerment in PPH care.

Based on the barrier analysis and the literature, the expert panel decided on a multifaceted strategy with separate tools addressing different barriers at different levels, visualized in figure 2. The strategy encompassed the complete trajectory starting in the third trimester and ending after the third stage of delivery is finished and the patient is stable. For the professionals, it comprised three stop moments (with a risk assessment checklist, care bundle and time-out procedure), and a PPH treatment checklist. For the patients, a patient-passport was created to provide to high-risk patients and a website for both pregnant and PPH-experienced women to provide preparation information before the delivery and information to process their recent experience.

**Phase two: Content detailing and tool development**

After selection, the individual tools were developed. Standard prototypes of the professional tools were developed based on the latest guidelines and literature. These prototypes can be adjusted to local protocols (e.g. specific medication choice and dose, telephone numbers of emergency services) before disseminating and implementing them in the different Dutch hospitals. The content of the patient part was written by an obstetrician (MW) with expertise in PPH care. The text was checked by another obstetrician (HS) for accuracy and a layman (RH) for readability and understandability. As the strategy exists of four stop moments, four separate tools were created as can be seen in figure 2.

The first stop moment is at the outpatient clinic where the physician has to fill in a risk assessment checklist. The checklist could be filled in from 34 weeks of gestation or beyond. As described in the methods section a risk assessment checklist was developed by the Fluxim study as there is currently no such list available. To create the risk assessment checklist, in total 34 risk factors were selected for inclusion: 25 risk factors from the Dutch national guideline and an additional nine risk factors were found in at least two international guidelines with significant odds ratios. The risk factors could be divided into four categories: general health history, obstetric history, factors related to the current pregnancy and factors apparent during labor and delivery. The checklist is designed to make the professionals aware of PPH risk factors, alert them on the increased risk and appropriate policy and remind them to inform the patient on the increased risk.
The patient tools that were created for the strategy could be used to inform the patient, facilitating the professional and ensuring consistent and comprehensive supply of PPH patient information. The tools consisted, as mentioned above, of a patient passport that allows patients to identify themselves as high-risk patient to professionals they meet later on in the pregnancy. It also provides written information about PPH and possible preventive measures professionals can take during the delivery. The second tool is a website available to all patients who attended the participating hospitals in the Fluxim trial for their antenatal care (as the website was used within the study trial it was not publicly available, which can be adjusted after the study is finished and all information is (inter)nationally available).

The second stop moment is upon entrance of the labor ward. At this stop moment professionals need to check if a risk assessment had been performed. In case it has not been done, the checklist has to be provided at that moment.

The third stop moment is near the end of the first stage of labor, closely before entering the second stage. During this stop moment the whole team has to be gathered in the room with the patient for a time-out procedure. It encompasses the checking of the patients' risk status and corresponding policy, and additional risk factors have to be listed (those that may arise during the first stage of delivery and those possibly arising during the second stage of delivery). As the time-out requires the team to come together in the room with the patient, it stimulates team communication and increases knowledge of all professionals working on the labor ward. A care bundle consisting of preventive interventions has to be incorporated, aiding in the standardizing of procedures.

As last of the professional tools, a checklist for PPH treatment was created. This checklist can be used by professionals at a blood loss of 500 ml and ongoing. It guides professionals through consecutive treatment options, gives advice on when to control for what factors (e.g. vital signs, coagulation status, etc), gives an indication of time elapsed and shows when to consult other professionals (i.e. an obstetrician or anesthesiologist). Furthermore, the checklist provides areas for the writing down of times of actions undertaken and vital signs; a procedure advised by ATLS-based courses for Obstetric emergencies.
Phase 3: Feedback round expert panel and patients
The expert panel was satisfied with the content and usability of the individual tools of the strategy and there were no points reported concerning inaccuracy of the medical contents, clinical unfeasibility or inconsistencies with the PPH guideline. Sixteen patients evaluated the website. Of these, 6 were patients within their third trimester of the pregnancy and had an increased risk for PPH, 9 patients had experience PPH in a recent delivery and of one returned questionnaire it was not clear if the correspondent was pregnant or post partum. Suggestions were made for improvement on the website, of which the most important improvement was the adding a section about recovery after PPH. All comments were taken into consideration for change and those that were feasible were changed. As some suggestions were not feasible they were not included in the adaptation process. An example of a non-feasible recommendation is the adding of percentages of increased risk per risk factor, which is not feasible as there is no consensus within the literature on the OR’s of the risk factors. Information added to the website included information on the recovery after PPH, information for the partner and information about low-lying placenta’s. Other changes that were made were the adding of images and suggestion on clearer color schemes.

DISCUSSION
We developed a tailored strategy to improve adherence to the evidence-based guideline on PPH care within secondary and tertiary care hospitals in the Netherlands. The strategy is based on current care, a barrier analysis and literature. A strategy with 3 stop moments, a care bundle and patient empowerment tools, was developed starting in the third trimester of the pregnancy and lasting till the end of the third stage of delivery. Tools used during the three stop moments are a checklist for risk assessment, patient empowerment tools, a time-out closely to the start of the second stage of delivery, a PPH preventive care bundle and a checklist for PPH treatment.

Safety checklists, such as the surgical safety checklists, have been derived from aviation and other high-risk industries where they have shown to be effective in reduction of adverse events. The Institute of Medicine published in 1999 the renowned report “To err is human” on medical errors, patient safety and the development of safety systems. They made recommendations to reduce the reliance on human memory and to implement systems that standardize and simplify processes. A checklist is such a system that forces a time-out to
summarize the situation and to prepare the professionals for what is coming. It facilitates leadership and open communication, and reduces reliance on memory and the number of omitted procedures. Various types of surgical safety checklists have proven that these systems can be translated to the medical field and successfully reduce complications\textsuperscript{18,19,21}. A delivery is an acute process where we heavily rely on the memory of the professionals, and where the room for error is large. A recent review on obstetric checklist development confirmed the need to standardize work in the maternity and labor ward, and listed PPH as 6\textsuperscript{th} in their top ten areas that have high priority on checklist development\textsuperscript{29}.

Involving patients in the perinatal care process creates a shared responsibility and creates opportunity for women to take the lead in the creation of their own care plan. In 2010 an advisory committee ("pregnancy and birth") of the Dutch Ministry of Health has written a report with advice on how to approach pregnancy and childbirth healthcare from a current and reliable perspective\textsuperscript{30}. The aim of the report is to improve (perinatal) health, not solely with the women are sick but in general thus preventing sickness, and to reduce health inequalities. The committee states seven cornerstones, two of which are related to patient empowerment (mother and child in the lead and well informed pregnant patients with shared responsibility). To reach this level of involvement of patients listening to patients and their needs is essential. Including patients in the barrier analysis gave us the opportunity to listen to patients carefully, leading to tools that are actually wanted by patients and filling the current information gap in perinatal care.

Currently, there is a discussion, outside the field of obstetrics, about the added effectiveness of multi-faceted strategies over single-faceted strategies. Although earlier reviews claimed that combinations of many different interventions are often effective\textsuperscript{31,32}, Grimshaw found that a higher number of intervention components was not related to higher effectiveness\textsuperscript{33}. It seems plausible that combined interventions are only more effective than single interventions, if these address different barriers at different levels. This is also the conclusion of Chaillet et al \textsuperscript{8}. Their review shows that in the field of obstetrics multi-faceted strategies are more effective, with the prerequisite that each strategy facet is targeted at its own barrier. Furthermore they showed that a prospective identification of the barriers would enhance its effectiveness, a recurrent finding in reviews on strategy effectiveness\textsuperscript{8,31,32}. We have created such a multi-faceted, tailor-made strategy with each separate tool developed to address specific barriers.
The framework of our strategy to improve the provision of optimal PPH care in high resource settings is based on barriers found among professionals and patients from the Netherlands, optimizing the strategy for the Dutch setting. However, we believe that the barriers are rather universal, and the framework would thus be applicable in similar obstetric setting in other countries. We detailed the contents of the individual tools in accordance with the Dutch national PPH guideline, international guidelines and literature. As the focus of guideline committees per country can differ, and (conflicting) evidence in literature sometimes leaves room for interpretation, guidelines can vary between countries, organizations and in time. Developing a strategy that is flexible to content, and thus adjustable to updates or different surroundings allows it to be constant up-to-date and adaptable for other high-resource countries. As the strategy is low in development cost and maintenance, it could be applicable in low-resource countries, though this still needs to be investigated.

The main strength of our strategy is the fact that it is tailor-made to the field of PPH. Professionals in the field suggested the barriers and facilitators, which most likely facilitates the acceptance of the strategy in a clinical setting. Limitations of the strategy development lie within the scarce amount of knowledge available for strategy selection. It is known that tailor-made strategies perform better, yet there is no explicit model prescribing which strategy or tool is to be expected most effective in a certain setting.

**CONCLUSION**

To our knowledge, the developed tailored strategy is the first in the acute setting of obstetric care encompassing the whole process from prevention to treatment of PPH. The next steps are testing the feasibility and effectiveness of the strategy in the clinical practice. Before setting up a large randomized controlled trial to evaluate the effectiveness of the trial, a feasibility trial has to be conducted. In such a feasibility trial, the strategy has to be evaluated on usability, time consummation and possible points for improvement. Additionally, an indication towards possible effectiveness and costs can be received. This will allow for optimization of the strategy before testing its (cost-) effectiveness in a robust study design.
REFERENCES


ADDENDUM: Fluxim strategy

“Fluxus implementatie strategie”
Hemorrhagie postpartum (HPP)

Stopmoment 1
Doel stopmoment 1: checklist risicomanagement, beleidsbepaling en
patienten informeren

1. Risicomanagement

- In te vullen op de polikliniek bij AD ≥ 34 weken
- Indien 1 risico factor van toepassing, dan patiënt beschouwen als verhoogd risico

Voorgeschiedenis
Algemene voorgeschiedenis
- BMI > 35 kg/m²
- Atlantische etniciteit
- Pre-existentie hypertensie
- Trombocytopenie/priënie
- Stollingsstoornis
- Uterus myomatous

Obstetrische voorgeschiedenis
- Hemorrhagie postpartum
- MPV
- Sectio caesarea
- Grande multipara (para >3)

Huidige graviditeit
- Grote uitstorting
  - (meerling, groei >95, polyhydramnion)
- Bloedverlies 2/3 'e trimester
- Antistolling gebruik durante partu
- Zwangerschapshypertensie
- Preeclampsie of HELLP-syndroom
- Hb <6.5 mmol/l (3e trimester)

Placenta
- Placenta praevia
- Placenta accreta/increta/percreta

Checklist risk assessment PPH outpatient clinic

2. Beleid bepalen en noteren

Indien geen verhoogd risico op HPP:
- Afnemen checklist in dossier genoteerd

Indien hoog risico op HPP volgende beleid genoteerd:
- Waakzenuis duurante partu
- Gedurende bloedverlies
- Actief nageboortetijdspen
  - 5 EIU oxytocine iv
  - Gevolgd door 10 EIU oxytocine in 4 uur
  - Frequentie controle tonus van de uterus
- Bloedverlies meten

CAVE: individueeliseren beleid en handel proactief bij Jehovah’s getuige, placenta praevia of
accreta/increta/percreta

3. Patienten voorlichting en informatie

- Patient geïnformeerd over verhoogd risico & beleid
- Fluxus passpoort uitgereikt en patiënt geïnformeerd over aanvullende informatie op
  www.bloedverlies-postpartum.nl

COLOFON
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Deze checklist is opgesteld door de Fluxim projectgroep in samenwerking met de
Nederlandse vereniging voor Obstetrie en Gynaecologie. De inhoud correspondeert met
de NVOG richtlijn hemorrhagia postpartum dd 18-11-2013.
www.studies-obsyn.nl/fluxim
1. Risicomanagement
   - Risicofactoren: Coagulatiestoornissen, bloedarmoede, vorige PPH
   - Preventie: Tour de force bij zwangere bloedarmoede, preventie van vooral het vorige PPH
   - Overzicht:
     - Risico geval van doorgang via parat bei

2. Aanpassing van de tijdsscenario's
   - Aanpassing van het fenomenologie van PPH
   - Overzicht:
     - Aanpassing van de tijdsscenario's voor PPH

3. Controle
   - Controle van de tijdsscenario's
   - Overzicht:
     - Controle van de tijdsscenario's

4. Afspraken
   - Afspraken over de tijdsscenario's
   - Overzicht:
     - Afspraken over de tijdsscenario's

Stopmoment 2
Intake verloskamers

Checklist risk assessment PPH delivery rooms and Time-out
Management of PPH checklists
De risicotest geeft aan dat u een verhoogd risico heeft op het krijgen van een fluxus omdat:

Een verhoogd risico op een fluxus betekent niet per definitie dat u ook een fluxus zult krijgen. Doordat we weten dat u een verhoogd risico heeft, kunnen we een aantal maatregelen bij de bevalling nemen. Dit kan onder leiding van uw verloskundige (verplaatste thuisbevalling). Door deze maatregelen wordt de kans op het krijgen van een fluxus een stuk kleiner.

Hoe verder?

Bij vrouwen met een verhoogd risico dient de bevalling in het ziekenhuis plaats te vinden. Dit kan onder leiding van uw verloskundige (verplaatste thuisbevalling). Dat u een verhoogd risico op een fluxus heeft zal in uw dossier genoteerd worden samen met het beleid. Bij binnenkomst op de verloskamer zal dit met u worden besproken.

U kunt het ook altijd zelf aanvragen door bijvoorbeeld dit fluxus paspoort te laten zien.

Bloedgehalte hier noteren

Mijn bloedgehalte (Hb) bij ± 30 weken was: ......................

Maatregelen om Fluxus te voorkomen en/of vroegtijdig te behandelen

Uw behandelaar kan de volgende maatregelen nemen om bij u een fluxus te voorkomen of al vroeg in het proces te behandelen.

Op de polikliniek

- Noteren in uw dossier: verhoogd risico op een fluxus en het beleid, zodat iedere hulppverlener op de hoogte is
- Controle van het bloedgehalte (Hb) in het derde trimester (± 30 weken)
- Voorschrijven van ijzertabletten indien u een te laag Hb heeft (< 6,5 mmol/l)

Nacontrole

- Bespreken en noteren hoog risico en maatregelen voor een eventuele volgende zwangerschap
General discussion
The FLUXIM-study, an implementation study on postpartum hemorrhage (PPH) guidelines and Managing Obstetric Emergency Trauma (MOET) course instructions investigated whether hospital care for patients with PPH could be improved by introducing a tailored improvement strategy. This tailored strategy aimed at both patients and professionals (gynecologists (in training), midwives working in secondary care, and obstetric (OB) nurse). This thesis concerns the first part of the FLUXIM study, from defining optimal PPH-care to development of a tailored strategy to improve PPH-care.

We started by defining optimal PPH-care and getting insight into the actual PPH-care and possible obstacles that influence PPH-care (problem analysis). We concluded with the development of a multifaceted, tailored improvement strategy based on the problem analysis, to be evaluated in a future feasibility study.

In this chapter, the main findings of the first part of the FLUXIM study are presented and discussed in the light of knowledge acquired in this thesis and existing literature. Furthermore, the methods that were used are discussed and the implications for future research, clinical practice and policymaking are provided.

**MAIN FINDINGS**

**Defining optimal PPH-care**

We successfully developed a set of 22 evidence based quality indicators to measure adherence to the guideline and Advance-Trauma-Life-Support (ATLS)-based course (MOET) instructions in actual PPH-care. It covers all fields of PPH; prevention, management and organization of PPH-care on different levels such as communication, documentation, treatment of shock and PPH, presence of protocols, audits and multidisciplinary agreements (*chapter 3*).

The quality of the local PPH-protocols on PPH-care showed much room for improvement. Regarding their structure, most protocols scored below average on the different items of the AGREE-II domains, particularly protocols of the teaching hospitals. Regarding the content, less than half (46%) of the guideline recommendations were found in the local hospital protocols, in particular the protocols of the non-teaching hospitals. Furthermore, for most items with a time indication, the description (when or under what condition certain actions have to be taken) was lacking in the local protocols (*chapter 4*).
The quality of PPH-care
We found high improvement potential in the participating hospitals using the 22 evidence-based quality indicators regarding prevention, management and organization of PPH-care. Overall, a lack of quality in performance, and lack of performance within the optimal timeframe was observed. Low adherence was found in particular regarding indicators for management of PPH > 1000 ml. The lack of adequate care could not be explained by a lack of the organization although there is room for improvement, especially as regards the frequency of team training, audits and complication discussions. Determinants on both patient and hospital level showed a significant association with monitoring PPH. Additional video recordings proved valuable for they provided a complete overview of the delivered care (chapter 5).

Moreover, we found that nontechnical-skills were not fully integrated in PPH-care. The items that showed most room for improvement were aspects of communication, the use of ABC-assessment of the PPH patients, situation awareness, decision making and problem solving skills. Situation awareness, decision making and problem-solving skills were critical in PPH-care now that a significant correlation was observed with clinical skills and outcomes (chapter 6).

Influencing factors for delivering high quality PPH-care
From a patient perspective, a lack of information provision by professionals was seen as the most prominent problem. From a professional perspective, a lack of clarity of the guidelines, lack of knowledge and failing team-communication were most important. Checklists and flowcharts were mentioned as concrete tools to facilitate high-quality care (chapter 7).

Development of a tailored improvement strategy
We developed an improvement strategy based on the above mentioned information, focusing on standardization of care and involving patients in their own care. The strategy is tailored to current care, the analysis on influencing factors and literature. For professionals it included checklists to identify high-risk patients and to determine policy before parturition, a timeout for shared mental modeling of the team by means of a preventive care bundle, a checklist for PPH treatment including all the steps to be taken when and by whom.
For patients we developed a patient-information leaflet, a patient passport for patients with a high risk, and an information website about PPH (chapter 8). The feasibility and the cost effectiveness of the strategy need future testing.

DISCUSSION OF THE MAIN FINDINGS
The first part of the Fluxim study described in this thesis, taught us that objective care assessment using evidence based quality indicators and assessment of perceived obstacles among patients and professionals can identify domains of PPH-care that show suboptimal guideline and ATLS-based course instruction adherence. This information is very helpful to develop strategies to improve actual PPH-care. However, this study evokes topics for discussion that will be addressed further on.

Defining optimal PPH-care
Optimal quality of care is often defined by outcome indicators such as morbidity and mortality. However, these do not provide information on where performance can be improved. In PPH-care, the incidence of PPH is used as a quality indicator, together with maternal and newborn morbidity and mortality. This type of outcome indicators is included in the national quality registries1. These quality registries show an increase in PPH incidences over the years without providing insight into which performance should be adhered to improve outcome. For that reason we developed 22 quality indicators founded on evidence based PPH guidelines and ATLS-based courses for obstetric emergency (MOET-course) to help us get a better understanding of the quality of the PPH-care process (chapter 3). Issues concerning the content and validity of the quality indicators, and the use of outcome indicators are subsequently described.

Our ultimate set of quality indicators consisted mainly of indicators focusing on effective and timely care covering the entire field of PPH-care, both with regard to medical performance and organizational quality. It defines optimal care with respect to the required clinical actions and conditions in order to be able to provide this care. Furthermore, it defines what is considered optimal care as regards timely actions by relating these actions to the degree of blood loss. This makes it possible to achieve a more quantitative measurement of delay of actions, which is unique.
However, our set lacks indicators from the patient perspective. Despite requesting patients’ perspectives on influencing factors of delivering optimal PPH-care, as described in chapter 7, we did not involve patients beforehand in defining high-quality PPH-care. Including patients in the process of defining high-quality care is valuable, as evidenced in the study of den Breeijen et al.\textsuperscript{2}. This study shows that the quality indicator development process regarding patient-centeredness and organization of care is strongly affected by patient involvement. However, the question is whether the same results will be achieved for PPH-care, because PPH-care mostly relates to acute situations, and is probably less influenced by patients. Besides, evidence of the best approach for involving patients in quality indicator development is scarce, particularly when it concerns complex medical care\textsuperscript{3}. To develop patient-centered quality indicators, and a separate patient panel to define high-quality care from patients’ perspectives may be important and may add to the clinical indicators\textsuperscript{4,5}.

Another aspect of our set of quality indicators is their validity and reliability. Despite the use of a systematic RAND-Delphi method\textsuperscript{6} and a national expert panel to reach consensus about ‘high-quality PPH-care’ the clinimetric characteristics of the quality indicators require further discussion as to whether they indeed reflect quality PPH-care and meet the criteria such as discriminatory capacity, high applicability, high improvement potential and low complexity. By measuring actual care with this set, we particularly assessed applicability and improvement potential, but discriminatory capacity and complexity was paid less attention to.

\textbf{Protocols}

We found that both the structure and content of the local PPH protocols varied largely in the participating hospitals (chapter 4). Less than half of the recommendations from both guideline and ATLS-based courses were found. Specific omission in these protocols of high-clinical relevant items such as identifying a high-risk patient, monitoring blood loss in high-risk patients or monitoring vital signs could lead to a delayed recognition and treatment of PPH. Furthermore, delay and deterioration of PPH may also occur if it is not clearly indicated which actions must be taken for what amount of blood loss or for the condition the patient is in. However, guideline recommendations are rarely specified in precise behavioral terms such as who does what, when, where, and how\textsuperscript{7,8}. Therefore, local protocols are crucial to close the gap between best evidence and practice\textsuperscript{9}. Midwives and nurses who are the professionals primarily
responsible for ensuring patient safety and who are responsible for early recognition of PPH, tend to use protocols as their only source of knowledge and guide in daily care\textsuperscript{10,11}. In addition, local protocols were lacking clearness, in particular an indication \textit{when} to take certain actions (\textit{chapter 4}).

Transformation of guideline recommendations into clear and descriptive local protocols proved to require time, skills in protocol development and, as a basis, convincing evidence\textsuperscript{12}. In this thesis we made clear that the quality of local PPH protocols is suboptimal. In order to improve adoption of guideline-recommendations into local protocols and reduce variation in structure and content of the protocols, guideline developers should define understandable and well founded recommendations\textsuperscript{13}. Moreover, they should provide a template or highly structured model protocols with all the relevant guideline-recommendations, which can be adapted to local needs\textsuperscript{10,12}. Such a template may be supplemented with additional materials such as a summary document, flowcharts, educational tools, patient leaflets, or computer support to help improve compliance\textsuperscript{14,15}. Checklists and flowcharts, based on evidence-based guidelines and ATLS-based course instructions, which have been proven effective in critical care, may be important facilitators for the delivery of high quality PPH-care, particularly in case of performing multiple acts in a limited timeframe\textsuperscript{16-18}.

**Evaluating PPH-care:**

PPH-care was evaluated at different levels (\textit{chapter 5 and 6}): adherence to the guideline and ATLS-based course instruction indicators (medical performance and organizational quality) and its determinants, the quality of nontechnical-skills (NTS) of teams dealing with PPH, and the relation of NTS with medical performances and clinical outcome (amount of blood loss).

This thesis indicates that adherence to guideline based quality indicators is not optimal in Dutch hospitals, especially as regards the indicators for clinical management of PPH (\textit{chapter 5}). Because PPH can deteriorate quickly and parallel execution of multiple actions in a clear-cut timeframe can prevent PPH escalation, it is important that professionals know which acts have to be performed first \textsuperscript{19}. It is imaginable that in an acute situation, performing the right acts at the right time can be difficult \textsuperscript{20,21}. A structured clinical evaluation of the patient’s situation by means of airway-breathing-circulation (ABC) methodology as taught in the ATLS based-course and calculating the amount of blood loss creates
awareness of the situation and helps to prioritize the actions\textsuperscript{22}. Calculation of blood loss was performed in most patients, however, we found that clinical evaluation by means of the ABC methodology was hardly ever used (\textit{chapter 6}). The ABC methodology consists of assessing the patient’s condition by means of vital parameters, such as oxygen saturation, heart rate and blood pressure. We found a 21\% adherence to the indicators as regards monitoring vital parameters (\textit{chapter 5}). This could indicate limited situation awareness in the Dutch PPH-care. This is in line with the results of \textit{chapter 6}, in which we found that especially the situational awareness and problem solving skills of team leaders were lacking. Flowcharts and checklists may help in providing the highly structured approach required in case of PPH.

Another aspect in prioritizing which acts have to be performed first is knowledge of their importance. We suggest that, when relying on memory in the short time when PPH deteriorates some actions are overlooked. Team communication, coordination, plan development and shared mental models are crucial in preventing such errors\textsuperscript{23-25}. Checklists and flowcharts may reduce the number of omitted procedures, and facilitate leadership and open communication\textsuperscript{19}. After all, PPH is largely preventable if the right procedures are conducted at the right time, especially considered the complexity of PPH-care\textsuperscript{26}. In \textit{chapter 5} is shown that the nontechnical-skills of the obstetric teams, especially communication skills and team leaders’ performance, are below average. Upfront education and team training to improve knowledge, skills, team communication and collaboration are important elements\textsuperscript{27-29}. Furthermore, since training on the total content of the guideline is often not feasible, training on the use of checklists and flowcharts may be much more effective\textsuperscript{30}. It is likely that the complexity of the situation requires an approach at different levels. Moreover, the content of training, being either directed at improvement of knowledge or team interaction, depends on the level at which problems arise in current care.

\textbf{Influencing factors}

Optimal use of evidence-based PPH-guidelines and ATLS-based instructions is essential for high quality PPH-care and can only be achieved once the causes for not following guidelines and instructions at different levels have been identified and overcome\textsuperscript{31,32}. In the in-depth analysis as described in \textit{chapter 7}, both professionals and patients identified influencing factors for delivering high quality PPH-care. What stands out in this thesis is, that the influencing factors mentioned
by the professionals fully subscribe the findings of defining and measuring PPH-care. A few examples; i) What was indicated as a problem in the study of the local protocols (chapter 4) was confirmed in the influencing factors study: professionals mentioned a lack of clarity of guidelines and the absence of various guideline and ATLS-based course recommendations in local PPH protocols as a main obstacle; ii) In the evaluation of the actual PPH-care heated infusion was almost never applied and urine production was hardly ever monitored (chapter 5). Professionals mentioned a lack in knowledge regarding the importance of these factors; iii) Communication skills of obstetric teams and team leaders show much room for improvement (chapter 6). An obstacle cited in all focus group interviews was a lack of communication about the policy on the delivery of the high-risk patient, the steps to be taken and the steps already taken. In other fields of care similar obstacles are found on professional level, particularly regarding lack of leadership and team communication problems 33,34.

The main obstacle for high quality PPH-care identified by patients was the lack of information given by the professionals to the patient and partner before, during and after the PPH event. A lack of information on patient level is also a frequently mentioned obstacle in other fields of care 35-37. Our study on influencing factors among patients had a high added value because professionals did not put forward the barriers mentioned by the patients, as we expected. Differences in barriers perceived by patients and professionals as described in our study are probably not uncommon, but not often described as such 38. Common sense tells us, that it is more convenient for professionals to focus on knowledge, skills and organizational aspects, rather than barriers related to their behavior, such as communication and information provision. Professionals must become more aware of the patients’ perspective concerning quality of care and the barriers they perceive. To do so, more extensive communication about patients’ experiences is essential for professionals.

As regards facilitators for optimal care, professionals mentioned frequent team training and the use of checklists and flowcharts as factors to improve adherence to the guideline. Patients mentioned an informative patient website, leaflet and a follow-up consultation as facilitators for optimal care. These factors will be addressed in the next paragraph, “Improving PPH-care”.
Improving PPH-care

There are many improvement strategies that may be valid and effective, provided that they are adapted to the specific improvement points of guideline adherence, the target group, the setting and the barriers encountered\textsuperscript{15}. The evaluation of the actual PPH-care and the in-depth analysis from patient and professional perspectives pinpointed where exactly improvement was needed in the Dutch PPH-care. With this information, supplemented with literature, an improvement strategy could be tailored to improve quality of PPH-care.

In \textit{chapter 7} professionals mentioned checklists and flowcharts as the most important facilitators, and as suggested in the previous paragraph these tools could be helpful to neutralize obstacles mentioned. Safety checklists, such as the surgical safety checklists, have indeed shown to be effective in the reduction of adverse events\textsuperscript{39,40}. Especially given the influencing factors found in \textit{chapter 7}, we believe that a checklist and flowcharts would be beneficial in PPH-care, particularly in combination with a timeout to summarize the situation and to prepare the professionals for what is coming. Checklists and flowcharts facilitate leadership and open communication, and reduce reliance on memory and the number of omitted procedures\textsuperscript{19}. It creates standardization of care\textsuperscript{16,41}. PPH is an acute process where the memory of the professionals is heavily relied on, and where the room for error is large. A recent review on obstetric checklist development confirmed the need to standardize work in the maternity and labor ward, and listed PPH as 6\textsuperscript{th} in the top ten areas that have high priority on checklist development\textsuperscript{16}. Therefore, in our improvement strategy, we developed different checklists for different moments, starting in the third trimester of the pregnancy and lasting till the end of the third stage of delivery. The aim was to improve risk selection, awareness, transfer, knowledge, team communication and cooperation, shared mental model and documentation and timely standardized care for the emergency situation.

A second part of the strategy was aimed at patient empowerment. In \textit{chapter 7}, patients mentioned lack of information provision by the professionals about PPH, not only to the patients, but also to their partner and family. Patient empowerment is an important topic in healthcare and refers to the enhanced ability of patients to actively understand and influence their own health status and healthcare\textsuperscript{42,43}. According to the WHO, interventions with empowerment characteristics have shown significant impact on improving health and quality of life in chronically ill
patients. In the developed strategy, patient tools were created to facilitate information transfer from the professionals to the patients and to stimulate the patients to be critical of their physicians and midwives and to ask for appropriate care. Putting the women and child in the lead, as advised by the report ‘a good beginning’ of the steering committee ‘pregnancy and birth’, can be achieved by making an individualized care plan together with the pregnant woman and her partner. The autonomy of the pregnant woman and her partner is leading, as described in the medical treatment agreement law (WGBO). To make a responsible choice regarding the individual care plan and the possible place of birth can only be accomplished if both the patient and her partner are well informed about her risks. The traditional doctor-patient role must change through tools like providing patients with more knowledge about their own care pathway and indirectly about professional guidelines. The initial experience with the use of our tailored strategy is positive.

**Main message in the light of future developments**

It is high time that professionals realize that most cases of PPH, or worsening of PPH, come as a surprise if there is insufficient situation awareness. As mentioned in (inter)-national guidelines, proper risk assessment is the first step in providing high-quality care.

Ideally, every pregnant woman deserves an individual assessment of her particular situation, to as such get appropriate information and advice. The pregnant woman and her partner can be empowered by being informed upfront and be prepared if an emergency situation occurs. The patient herself or her partner can actively participate in her own care by asking information about her situation.

In the current system it is believed that it is possible to distinguish low and high-risk pregnant women, but the risk selection is inadequate (this thesis). This is troublesome because transfer of patients during pregnancy is not uncommon in the Netherlands. Of all pregnant women, 80% consult both primary and secondary care.

The organization structure within which one intends to narrow these transfer problems is an integrated care system without boundaries, as advocated by the steering committee “pregnancy and birth”, with the purpose of improving perinatal care. A good functioning risk selection will be all the more important. In this
General discussion

system it is highly important to establish a pro-active approach through prevention, and to timely identify problems and risky situations. Using checklists to identify who is at risk, documenting policy and informing the patient as suggested in this thesis, is the first step in creating situation awareness and a pro-active attitude. When the patient goes into labor and affects a completely new team, the pre-determined risks of the patient and its policy in the medical chart will create an informed team, a shared mental model and team anticipation. Furthermore, transfer of information by an informed team, preferably structured through S-Barr, will then contain substantively appropriate information. In addition, information loss will be less if, at the essential moments, the team that is taking care of the patient is well informed through the use of timeouts and paying attention to the patient's total situation.

Professionals must realize that PPH-care must be regarded as emergency care with different disciplines involved and that standardization of care is crucial, similar to critical or trauma care. Standardized assessment of the situation in critical moments with the help of flowcharts, checklists and bundles could lead to better adherence to guideline or protocols. A obligated yearly team training on skills and nontechnical-skills for every professional delivering obstetric emergency care such as the yearly basic life support course, will provide better teamwork and therefore must be facilitated by the hospitals and advocated by the societies for medical specialists as a structural quality indicator.

In 2015, the Minister of Public Health advocated the establishment of obstetric-care organizations to be effectuated by 2017 in connection with the start of integral funding. It is crucial that the report “a good beginning” which is the most important part of the work, is followed by “a good implementation plan” to lead to “a better perinatal care and outcome”. One medical chart for all the professionals will be paramount to diminish information loss. However, it is essential that the chart contains the proper content and policy (this thesis).

Defining high-quality care in this new system will be important and professionals must take a leading position. This requires binding agreements about quality of care, registries, accountability and transparency (e.g. quality indicators, registries or standards). Transparency and quality assessments should be considered as opportunities to provide insight into those aspects of actual care where improvement is needed. The use of process and organizational quality indicators
besides the current outcome indicators as used in the Netherlands perinatal registry (PRN) can provide insight and quality assessment. In addition, the results of these assessments will provide an opportunity to educate and guide professionals towards a more optimal care. A closer collaboration with all stakeholders, especially the patient, must play an essential role in reaching optimal obstetric care.

**Methodological considerations**

*The study design:*

The variation in PPH-care found is similar to the results of other studies\textsuperscript{62,63}. It is known that medical charts underreport actual performances, especially in emergency settings such as the delivery rooms\textsuperscript{64}. Therefore, we used video recordings to acquire additional information, resulting in more reliable indicator scores. Furthermore, video recordings provided important additional information on when specific acts were performed. The obstetric-teams were told about the taped observation of the high-risk patient, which could be considered a limitation. This could have influence on the documentation in the medical charts or the way they performed or communicated. Literature about the use of video recording in observations shows that it influences performances in a positive way\textsuperscript{65}. Our study showed low adherence to the guideline, implying that care without the influence of video recording would not be any better. We conclude that the use of video recordings in quality of care research has added value and should be used more often.

However, this method was not easy. It influenced the number of hospitals included and the time to prepare the hospitals for the study because of legal aspects. The Committee of research Involving Human Subjects of the region Arnhem-Nijmegen of the Netherlands assessed the study and concluded that our study should be carried out in accordance with the applicable rules concerning the review of research ethics committees and informed consent. The legal aspects of the use of video recordings were assessed and the committee’s conclusion was that the obtained video recordings had to be destroyed after they served their purpose\textsuperscript{66}. Furthermore, permission of the works council and board of directors from every hospital was advised, and all the staff working in the delivery rooms had to be informed by email about the study stating that they could always object to being filmed.
Before commencing the study, twenty hospitals signed a participation statement. During the procedure eight hospitals refused video recordings because of shortage of research staff and refusal of gynecology staff. In the end, twelve hospitals consented to use video recordings on the delivery ward and four hospitals consented to using medical charts only. However, we don’t think that the loss of four and in the end five hospitals from our study, influenced the reliability of our data. We increased the number of patients from 20 to 25 per hospital, which provided the amount of inclusions we aimed for. Furthermore, the hospitals included were well distributed both in type and location across the country.

Another factor contributing to the reliable dataset is the gathered information from the video recordings of the third stage. The video recordings provided unique information that never could have been obtained from medical data charts, resulting in a complete overview of the care delivered to patients with a high risk on PPH on the delivery ward. However, a total overview of PPH-care would have been accomplished if we had the video recordings extended to the OR, because there we also expect underreporting of the care given.

**IMPLICATIONS FOR FUTURE RESEARCH AND CLINICAL PRACTICE**

Based on the main findings and the discussion, several implications for future research and clinical practice can be formulated. The implications are presented separately for the relevant stakeholders involved.

**Implications for future research**

- Although we had most positive experiences, we need to study the impact of the new developed strategy on processes and outcomes of PPH-care, in particular the effects of checklists, timeouts and patient involvement.

- More research is needed to investigate which determinants are associated with the adherence to PPH guidelines and outcome of PPH.

- It is advisable to investigate whether the use of video recordings in the daily care, in particular in obstetric emergency care, is of additional value as an instrument for quality monitoring and feedback of teamwork and leadership.

- The importance of involving patients in all aspects of quality of care research, including the development of quality indicators, should be acknowledged and
brought into practice. More evidence about the best approach as to how to do this must be obtained.

- The tailored strategy, developed to improve PPH-care may also be important for obstetric care in general. Whether our tools for PPH-care such as risk assessment and a timeout before every delivery could impact the quality of obstetric care is worth investigating.

**Implications for clinical practice**

*Professionals*

- Professionals must realize that pro-active participation in the prevention and management of postpartum hemorrhage is necessary to reduce the incidence of PPH in the Netherlands; still a total of 33 women a day lose more than 1000 ml blood after birth in this country. Prevention, early recognition and timely management of PPH can be achieved through an informed team, which provides better team cooperation, communication, awareness and anticipation. To achieve an informed team during delivery, an appropriate risk selection should be made and a policy should be formulated for all pregnant women beforehand at the out-patient clinic or before parturition.

- In the Netherlands, the Minister of Public Health advocated integrated obstetric care by 2017 and one integral funding system, meaning that there will be no boundaries between the different professionals in obstetric care. Obstetric care must change from professional-led to patient-led care. Proper risk analysis in the third trimester with the help of checklists and determination of place of birth with a patient-led individualized care plan founded on evidence based care will be essential in the prevention of PPH.

- Professionals must become more aware that PPH is an obstetric emergency that can deteriorate in a short time where rapid simultaneous actions are needed from different professionals. As in emergency care, standard operating procedures, clear protocols, checklists and flowcharts can help the professionals in dealing with the complexity of PPH. Team training, use of flowcharts and checklists on a regular basis can improve PPH-care.
Patients

- Information provision in actual practice is insufficient according to patients. Professionals should take the responsibility to improve communication with their patients, in the outpatient clinic and during labor by giving information about high risk on PPH, by providing information during PPH and in the aftercare and by paying attention to the longer recovery time by planning an extra appointment after three months for example. An informational website or leaflets could help to improve this aspect of care. Extra attention must be paid to the partner and family during PPH, especially when they are separated from the patient.

- Involving patients in guideline and quality indicator development should be a key issue for the near future. E-tools or websites can increase patients’ knowledge about the professional guidelines and empower patients to make informed decisions concerning their health.

Societies for medical specialists and hospitals

- Guideline makers must provide the guideline with an implementation toolset including a model protocol that can be adjusted to local needs, a model flowchart and checklists and information leaflets for patients. These added tools must be clear and comprehensible for every professional who uses it. The tools should focus on the 5 W-items; Who, What by Whom and When, and Which Way. Furthermore, clear local multidisciplinary agreements must be developed in order to prevent discussion and different points of view, and therefore delays at the most crucial moments.

- Transparency and quality assessments should be considered opportunities to provide detailed insight into those aspects of care that need to be improved rather than making a general statement that care is insufficient. Change from the current outcome perspective to a more process related and patient-centered perspective will provide detailed insight into aspects of care that should be looked at more closely. We propose to add a subset of concrete process indicators in the national quality registers (PRN).

- Obstetric emergencies such as PPH require professionals to react adequately and fast; however, they do not occur every day. Therefore, professionals must be educated and trained regularly through team training in order to be able to
recognize the situation and act fast. Policy makers and hospitals must facilitate this in the same way as the mandatory yearly basic life support course. The society of gynecologists must change its recommendations, which differ from being hospital-related (frequent team training must be organized) to professional-related (every professional working on the labor ward must be trained at least once a year).

**FINAL CONCLUSION**
This thesis describes the level of improvement potential for PPH guideline adherence, variation in PPH-care and its possible determinants, barriers and facilitators as perceived by PPH patients and professionals involved in PPH-care. All these aspects provide a valid base for the development of tailored improvement tools. An evaluation of the developed tools as regards feasibility, effectiveness and cost is the next step in the improvement strategy of PPH-care. Lastly, this thesis discusses several facets of PPH-care, and considerable challenges for further research still remain. This includes further exploration of collaboration between professionals and hospitals, and probably of regional networks, transparency about delivered care, the influence of policy makers on daily practice, the value of including patients' perspectives in improving quality of care and the growing role of quality registries. This should be taken up by the different stakeholders involved, which may help to evolve durable tools for improving guideline adherence and the quality of care.
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10
SUMMARY
This thesis focused on improving the quality of postpartum hemorrhage care for patients with a high risk of PPH in the Dutch setting.

Chapter 1: General introduction
The rationale of the study is described in chapter one. Together with chapter two the main objectives are formulated. Postpartum hemorrhage (PPH) is still the major cause of maternal morbidity worldwide and a high proportion of the morbidity of obstetric hemorrhage is considered to be preventable if adequately managed. The literature and several international healthcare organizations indicate the following requirements for delivering high quality PPH-care: i) Clinical guidelines to help professionals provide evidence and consensus based care; ii) Advance-Trauma-Life-Support (ATLS) -based courses for obstetric emergencies to educate professionals in using a highly structured multidisciplinary approach in PPH; iii) local PPH-protocols based on evidence based guidelines and ATLS-based course instructions to streamline PPH-care for all professionals delivering PPH-care; and iv) nontechnical skills. However, despite the introduction of a national evidence-based guideline on PPH and initiation of ATLS-based courses for all Dutch gynecologists the incidence of PPH in the Dutch population still increased. We hypothesize that insufficient implementation of both the NVOG guideline and the ATLS-based course may be the cause of the high incidence of PPH in the Netherlands.

Chapter 2: Study protocol
describes the study protocol starting with a description of the current problems in PPH-care, the corresponding hypotheses and the study methods. Because PPH incidences increase in the Netherlands despite the introduction of evidence based guidelines and ATLS-based course instructions, we expect this to be due to an implementation problem. To improve the quality of PPH-care, proper implementation of these guidelines and ATLS-based instructions is essential and can only be achieved once the causes for not following guidelines and course instructions on different levels have been identified and overcome. A systematic approach is necessary to improve the implementation and consequently the PPH-care. Acquiring insight into actual practice with the use of evidence based quality indicators and identifying influencing factors for delivering high quality care is required in the process of effective implementation. Based on these findings a tailored implementation strategy can be developed.
The following main objectives for this thesis are described in chapter one and two:

1. To develop a valid and reliable set of quality indicators, extracted from evidence-based guidelines and MOET-instructions, to assess actual PPH-care;
2. To gain insight into the actual PPH-care based on the developed quality indicators and into determinants for actual care;
3. To explore the influencing factors according to patients and professionals that affect the delivery of optimal PPH-care as described in evidence-based PPH guidelines and ATLS-based course instructions;
4. To develop an improvement strategy, tailored to the obstacles and facilitators found for delivering high quality PPH-care.

Chapter 3: Development of quality indicators for measuring actual care
In chapter 3 we aimed to develop a valid guideline and an ATLS-based course indicator set for PPH as a tool to measure guideline adherence in actual PPH-care. A systematic Rand-Modified-Delphi procedure was used to develop a set of key recommendations based on PPH-guidelines, ATLS-based course instructions and international literature. Expert opinions were used to appraise recommendations on health gain (prevention of maternal mortality and morbidity) and overall efficiency. As a result a set of 22 quality indicators on professional performance (n=17) and organization of PPH-care (n=5) was selected from 69 initial recommendations. The professional performance indicators covered all fields of PPH-care, such as prevention (n=2) management of PPH, including communication and documentation (n=4), monitoring and prevention of shock (n=3), use of blood products (n=3) and treatment of PPH (n=5). Organizational indicators (n=5) were clustered into protocols and agreements, audits, accessibility and documentation. This set of indicators can be used to measure the complete care process of prevention and management of PPH.

Chapter 4: Quality of local PPH-protocols
An important step in optimizing PPH-care is the translation of evidence-based guidelines into comprehensive hospital protocols. In chapter 4 we aimed to evaluate the quality of PPH-protocols on structure and content using the Appraisal of Guidelines for Research and Evaluation (AGREE-II) Instrument and the quality indicators from chapter 3. Eighteen PPH-protocols from 3 University Hospitals (UH), 8 Teaching Hospitals (TH) and 7 Non-Teaching hospitals (NTH) throughout
the Netherlands were acquired. The quality of the protocols for postpartum hemorrhage for both structure and content varied widely between the different hospitals, and all showed room for improvement. The protocols scored below average on the different items of the AGREE-II Instrument (8 out of 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. 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.

Chapter 5: Guideline adherence in PPH-care
In chapter 5, a prospective observational multicenter study was performed to assess the actual PPH-care and its determinants at both patient and hospital level using guideline-based quality indicators for prevention, management and organization of PPH in sixteen (4 University, 9 teaching, and 3 non-teaching) Dutch hospitals. Data-extraction was collected from medical records of 398 high-risk patients and was supplemented with prospective video observations of the third stage. As expected, video recordings showed that in general the actual care given was considerably underreported in medical records. Overall, a lack of quality in performance, and lack of performance within the optimal timeframe was observed. Particularly the indicators for management of PPH for more than 1000 ml had low scores, clearly indicating an implementation problem. The hospitals did organize the PPH-care well, especially as regards the existence of team training, complication discussions and audits. However, there is room for improvement in for instance the number of training/audits and complication discussions per year. University hospitals were mostly associated with better adherence, especially monitoring heart rate, which was significant. Additional video observations proved valuable to pinpoint at which level improvement is needed. A tailor-made implementation strategy, taking the determinants into account, has to be developed to improve quality of Dutch PPH-care.

Chapter 6: Nontechnical skills in PPH-care
Clinical performance based on the best evidence, and nontechnical-skills based on Crew-Resource-Management (CRM) of obstetric-teams are both indispensable for delivering high quality PPH-care. In chapter 6 we aimed to assess nontechnical-skills of obstetric-teams and team-leaders in the actual PPH-care and
to evaluate its influence on clinical performance and outcome. Video recordings from twelve different Dutch hospitals of 71 deliveries of women in the postpartum period with 700 ml blood loss or more were assessed. The nontechnical-skills of the obstetric-teams was assessed through the Clinical-teamwork-scale (CTS). The Ottawa Crisis-Resource-Management-global-rating-scale (GRS) was used to assess the team-leaders. Clinical performance was measured through adherence to the guideline indicators for management of PPH. The clinical outcome was measured using the total amount of blood loss of each patient. In the end, 57 video recordings were included. In current PPH-care, nontechnical-skills of obstetric-teams needs improvement in the domains of communication, situation awareness and problem-solving; situation awareness, problem-solving skills of the team-leaders and decision making seem critical for PPH-care because these sub-items were significantly correlated with clinical performance and the quantity of blood loss.

Chapter 7: Influencing factors for high quality PPH-care
In Chapter 7, we qualitatively explored influencing factors for delivering high quality PPH-care among patients and professionals through individual interviews with PPH-patients and focus group interviews with different types of professionals working in the delivery room. In order to assess the importance of the influencing factors found in the focus group interviews among the professionals, we quantified the factors in a web-based questionnaire. To classify the influencing factors for optimal PPH-care (factors of the guidelines, of professionals, of patients, of the social setting and of the organization) the theoretical frameworks of Grol and Cabana were used. The main obstacle for high quality PPH-care identified by patients was the lack of information to the patient and partner before, during and after the PPH event. An informative patient website, a patient leaflet and a follow-up consultation were mentioned as facilitators. The main obstacles to high quality of care according to the professionals were: lack of clarity of the guidelines, lack of knowledge about PPH-care and failing team communication. Team training and checklists/flowcharts were considered as facilitators. Different obstacles to the delivery of high quality PPH-care were identified by both patients and professionals. These data can be used to develop a focused strategy to improve PPH-care.
Chapter 8: Development of a tailored improvement strategy
To reduce the gap between evidence-based guidelines and clinical application, we aimed in chapter 8 to develop an implementation strategy tailored to the identified gaps and barriers in current care. A framework of the strategy was created, tools were developed and the strategy was evaluated among professionals and patients. The tailored strategy to improve guideline adherence covered the trajectory of the third trimester of pregnancy till the end of the third phase of delivery. The strategy directed at professionals consisted of a high-risk identification checklist, a care bundle for PPH prevention, and a PPH treatment checklist for the labor ward. As patient empowerment tools, a patient passport, a website with information on PPH and a risk calculation tool were developed. The evaluation among the expert panel of professionals showed that all professionals were satisfied with the content and usability of the tools and no discrepancies or inconsistencies with current evidence were found. The evaluation among patients revealed that the information they received through the tools was still incomplete and the tools were adjusted accordingly. We succeeded in developing a usable, tailored strategy to implement PPH-guidelines and ATLS-based course instructions. The next step is the evaluation of the strategy in a feasibility trial.

Chapter 9: General discussion
In the 9th and final chapter the research questions from the introductory chapter are answered, conclusions drawn and findings discussed in the light of available literature. Methodological considerations of the performed studies were taken into account while interpreting the results. We described suggestions for future research on improving guideline implementation. Testing the effectiveness and efficiency of the implementation strategy is a logical next step. In light of future developments in obstetric care, such as the creation of integrated care teams, research can be done on implementing risk assessments, improvement of team communication and how to improve the implementation of guidelines. Furthermore, practice and policy implications for both healthcare providers and patients are mentioned in this final chapter. We stated for example, that beside outcome indicators, a convenient assessment of process and structure indicators should be facilitated by adopting these indicators in the national registration data. This enables solid assessment of less frequent conditions and complications. Finally, the major effort that is generally put into guideline development should be equaled by efforts put into guideline implementation activities and research.
SAMENVATTING

Hoofdstuk 1: Algemene inleiding
Haemorrhagia Post Partum (HPP), gedefinieerd als meer dan 1000 cc bloedverlies binnen 24 uur na de bevalling, is wereldwijd nog steeds een van de belangrijkste oorzaken van ernstige morbiditeit en mortaliteit onder moeders. Dit heeft niet alleen zijn oorsprong in ontwikkelingslanden, maar ook de ontwikkelde landen dragen hieraan bij. In de afgelopen jaren zien we in meerdere westere landen een stijging van het aantal moeders met een HPP. Dit is ook het geval in Nederland waar het aantal vrouwen met een HPP gestegen is van 4% in 2003 naar 7% in 2011 en het op nummer één staat wat betreft maternale morbiditeit. Toename van maternale leeftijd, obesitas, meerlingen en toename van het aantal keizersneden kunnen deze stijging niet geheel verklaren.

Een groot deel van de vrouwen met een HPP kan worden voorkomen indien de risicofactoren en het optreden van HPP tijdig herkend worden en er tijdig adequate maatregelen genomen worden om HPP te voorkomen oftewel te behandelen. Om adequate HPP-zorg te kunnen verlenen wordt tegenwoordig in vele landen het beleid rondom preventie, diagnostiek en behandeling in richtlijnen beschreven. Richtlijnen ondersteunen het best aantoonbare bewijs (evidence based genaamd) voor klinische besluitvorming, verminderen de diversiteit van handelen en maken het handelen transparant. In aanvulling daarop wordt in de verloskunde net zoals in de acute geneeskunde steeds meer gebruik gemaakt van trainingen op vaardigheden als communicatie en leiderschap in team verband. De volgende kaders om HPP-zorg van goede kwaliteit te kunnen leveren worden in de literatuur en door inter -nationale gezondheidsorganisaties beschreven:

i) Klinische richtlijnen om professionals te ondersteunen bij het verlenen van zoveel mogelijk evidence-based zorg;

ii) Advanced-Trauma-Life-Support (ATLS) cursus voor obstetrische noodgevallen (Managing Obstetric Emergency Trauma (MOET)-cursus) om deskundigen te onderwijzen in het hanteren van een goed gestructureerde multidisciplinaire benadering van een patiënt met HPP;

iii) Een goed lokaal HPP-protocol, gebaseerd op de evidence based richtlijn en MOET-principes om de HPP-zorg te stroomlijnen voor alle deskundigen die HPP-zorg verlenen;

iv) Vaardigheden op het niveau van teamsamenwerking zoals teamcommunicatie en leiderschap (niet-technische vaardigheden genoemd).
In 1998 is in Nederland door de Nederlandse Vereniging voor Obstetrie en Gynaecologie (NVOG) een HPP-richtlijn ontwikkeld. Daarnaast is in 2003 de cursus Management of Obstetric Emergencies and Trauma (MOET) geïntroduceerd, welke wordt aanbevolen voor alle Nederlandse gynaecologen, gynaecologen in opleiding en anesthesisten. Deze cursus, welke gebaseerd is op de Advanced Trauma Life Support (ATLS)-cursus, bestaat uit stapsgewijze, praktische instructies en trainingen om acute situaties in de verloskunde, zoals HPP te voorkomen en te behandelen. Zowel de HPP-richtlijn als de MOET-cursus hebben niet geleid tot een reductie in HPP. Dit leidt tot de vraag in hoeverre de aanbevelingen uit de landelijke richtlijn en de MOET-instructies in de huidige zorg worden nageleefd oftewel zijn geïmplementeerd.

Het doel van dit proefschrift is om te onderzoeken hoe de kwaliteit van zorg voor vrouwen met een hoog risico op overmatig bloedverlies na de geboorte van hun kind, oftewel HPP, verbeterd kan worden in de Nederlandse ziekenhuizen.

Hoofdstuk 2: Studie protocol
Het studieprotocol met de corresponderende hypotheses en de studiemethoden wordt hierin beschreven. Om de kwaliteit van HPP-zorg te verbeteren is een optimale implementatie van de richtlijn en MOET-principes essentieel. Optimale implementatie kan alleen bewerkstelligd worden indien het helder is wat de oorzaken zijn voor het niet opvolgen van de richtlijn en MOET-principes zowel op professioneel, patiënt- als organisatieniveau. Om deze oorzaken op de verschillende niveaus helder te krijgen is het noodzakelijk allereerst inzicht te verkrijgen in de huidige HPP-zorg in Nederland. Inzicht in de huidige zorg kan worden verkregen door middel van kwaliteitsindicatoren. Daarnaast is het belangrijk om inzicht te verkrijgen inde factoren die van invloed zijn op het leveren van hoge kwaliteit van zorg. Op basis van deze bevindingen kan er een op maat gemaakte strategie ontwikkeld worden om de HPP-richtlijn en MOET-principes te implementeren.

In hoofdstuk 1 en 2 worden tevens de hoofd onderzoeksvragen van dit proefschrift beschreven:
5. Het ontwikkelen van een valide betrouwbare set van kwaliteitsindicatoren voor het monitoren van HPP-zorg en welke gebaseerd is op de HPP richtlijn, MOET-instructies en internationale literatuur;
6. Het verkrijgen van inzicht in de kwaliteit van de huidige HPP-zorg door middel van de bovengenoemde kwaliteitsindicatoren;
7. Het verkennen van de factoren die volgens patiënten en zorgverleners het leveren van optimale HPP-zorg, zoals beschreven in de HPP-richtlijn, MOET-principes, beïnvloeden;
8. Het ontwikkelen van een op maat gemaakte verbeterstrategie aan de hand van de resultaten gevonden in hoofdstuk 4, 5, 6 en 7.

Hoofdstuk 3: Het ontwikkelen van kwaliteitsindicatoren voor HPP-zorg

Hoofdstuk 3 geeft de ontwikkeling van een set van kwaliteitsindicatoren weer, op basis van de landelijke richtlijn en de MOET-principes. Hiermee kan de naleving van de richtlijn in de dagelijkse zorgpraktijk worden gemeten. De kwaliteitsindicatoren zijn volgens de gemodificeerde Rand-Delphi procedure systematisch ontwikkeld, in vijf rondes; 1. Selectie van de potentiële kwaliteitsindicatoren (n=69); 2. Schriftelijke beoordeling door een panel van experts op het gebied van HPP en MOET op het belang voor verbetering van de zorg en van de efficiëntie; 3. Een consensus ronde voor definitieve selectie van de indicatoren; 4. De vertaling van de indicatoren naar een haalbare meetinstrument.; 5. Laatste schriftelijke ronde onder alle leden van het expertpanel ter goedkeuring van de uiteindelijke set van indicatoren. De definitief geselecteerde set bestaat uit 22 kwaliteitsindicatoren rond professioneel functioneren (n=17) en organisatie van HPP-zorg (n=5). De 17 indicatoren met betrekking tot professioneel functioneren bestaan uit indicatoren voor preventie (n=2) en management van HPP (n=15). De management indicatoren betreffen communicatie en beleidsdocumentatie, herkennen en voorkomen van shock, gebruik van bloedproducten en de mogelijke therapeutische opties. De indicatoren met betrekking tot de organisatie van HPP-zorg bestaan uit de aanwezigheid van protocollen en afspraken, regelmatig uitvoeren van audits en complicatiebesprekingen, de toegankelijkheid van zorg en documentatie van complicaties. Deze set kwaliteitsindicatoren kan gebruikt worden om het gehele zorgproces van preventie, management en organisatie van HPP te meten.

Hoofdstuk 4: De kwaliteit van de locale protocollen voor HPP

De kwaliteit van HPP-protocollen in Nederlandse ziekenhuizen worden in hoofdstuk 4 geëvalueerd op zowel structuur als inhoud door middel van het zgn. Appraisal of Guidelines for Research and Evaluation (AGREE-II) Instrument en de set kwaliteitsindicatoren uit hoofdstuk 3. HPP-protocollen zijn verzameld uit 18 Nederlandse ziekenhuizen waaronder drie universitaire ziekenhuizen (UZ), 8 opleidingsziekenhuizen (OZ) en 7 niet-opleidingsziekenhuizen (NOZ). Er is een
een groot kwaliteitsverschil tussen de HPP-protocollen van de verschillende ziekenhuizen gevonden, met voldoende ruimte voor verbetering. Op de verschillende onderdelen van het AGREE-II Instrument scoorden de protocollen over het algemeen laag (8 uit 10 onderdelen scoorden < 4 op een schaal van 1-7). Van de inhoud van de richtlijn was 46 % terug te vinden in de protocollen. Deze studie geeft aan dat de kwaliteit van de HPP-protocollen suboptimaal is, hetgeen naleving van de richtlijn en de MOET-principes bemoeilijkt.

Hoofdstuk 5: Naleving van de richtlijn in de huidige HPP-zorg

Een prospectief onderzoek is verricht naar de huidige HPP-zorg in zestien Nederlandse ziekenhuizen (4 universitaire-, opleidings-, en 3 niet-opleidings-) door gebruik te maken van onze set kwaliteitsindicatoren. Gegevens uit medische statussen van 398 hoogrisico patiënten zijn verzameld en aangevuld met video opnames van de derde fase van de bevalling. De videogegevens lieten zien dat er een onderrapportage van de zorg is in de medische statussen. In 20-50% werd de zorg verricht volgens de kwaliteitsindicatoren. Daarnaast werden veel handelingen niet op het juiste moment verricht. Vooral op de kwaliteitsindicatoren voor het management van meer dan 1000 cc bloedverlies werd laag gescoord. De organisatie van HPP-zorg scoorde goed, met name het aanwezig zijn van teamtrainingen, complicatiebesprekingen en audits. Er is echter ruimte voor verbetering in bijvoorbeeld het aantal trainingen en complicatiebesprekingen per jaar. Aanvullende video observaties bleken waardevol om concreet aan te kunnen tonen op welk niveau verbetering van zorg nodig is. De resultaten kunnen gebruikt gaan worden om een passende verbeterstrategie te ontwikkelen en zo de kwaliteit van de Nederlandse HPP-zorg te verbeteren.

Hoofdstuk 6: Niet-technische vaardigheden in HPP-zorg

Klinisch functioneren oftewel technische vaardigheden en de niet-technische vaardigheden zoals teamcommunicatie en leiderschap van obstetrische teams zijn onmisbaar om goede kwaliteit HPP-zorg te kunnen verlenen. In Hoofdstuk 6 hebben we de niet-technische vaardigheden van obstetrische teams tijdens huidige HPP-zorg beoordeeld en de invloed ervan op het klinisch functioneren en uitkomsten van zorg geëvalueerd. Er waren video opnames van 57 bevallingen met >700 ml bloedverlies in de post partum fase bruikbaar voor beoordeling. Deze videos waren afkomstig uit twaalf verschillende Nederlandse ziekenhuizen. De niet-technische vaardigheden van de obstetrische teams zijn beoordeeld aan de hand van de Clinical-Teamwork-Scale. De teamleiders zijn beoordeeld aan de
hand van de Ottawa Crisis-Resource-Management-global-rating-scale. Het klinisch functioneren is gemeten aan de hand van de eerder genoemde kwaliteitsindicatoren. De klinische uitkomst is gemeten aan de hand van de totale hoeveelheid bloedverlies van elke patiënte. Dit onderzoek laat zien dat in de huidige HPP-zorg de niet-technische vaardigheden van obstetrische teams verbetering behoeven op het gebied van communicatie, situatie overzicht verkrijgen en het probleemoplossend vermogen. Situatie overzicht verkrijgen en het probleemoplossende vermogen van de teamleiders lijken belangrijk te zijn voor de HPP-zorg aangezien deze factoren een significante associatie laten zien met het klinisch functioneren en de hoeveelheid bloedverlies.

Hoofdstuk 7: Beïnvloedende factoren op hoog kwalitatief HPP-zorg
In Hoofdstuk 7 is kwalitatief onderzoek beschreven naar factoren die van invloed zijn op het verlenen van HPP-zorg van goede kwaliteit. Door middel van individuele interviews met HPP-patiënten, en focusgroep interviews met de zorgverleners, werkzaam op de verloskamer, zijn factoren die van invloed zijn op de kwaliteit van HPP-zorg geselecteerd. Om het gewicht te kunnen bepalen van deze verschillende factoren zijn deze gekwantificeerd in een online vragenlijst. De classificatie van de gevonden factoren voor optimale HPP-zorg zijn door middel van de theoretische kaders van Grol en Cabana verricht (factoren horend bij de richtlijn, bij professionals, bij patiënten, bij de sociale omgeving en bij de organisatie). Patiënten hebben aangegeven dat het gebrek aan informatie aan de patiënt en partner voor, tijdens en na het ontstaan van HPP verbetering behoeft. Een informatieve patiëntenwebsite, een patiëntenfolder en een extra polibezoek zouden behulpzaam kunnen zijn. De grootste belemmeringen genoemd door de zorgverleners waren: gebrek aan duidelijkheid van de richtlijn, gebrek aan kennis over HPP-zorg en falende teamcommunicatie. Teamtraining en checklists/flowcharts werden genoemd als potentiële hulpmiddelen. Deze gegevens kunnen gebruikt worden om een gerichte strategie te ontwikkelen om de richtlijn en MOET-principes beter te implementeren en zo de HPP-zorg te verbeteren.

Hoofdstuk 8: De ontwikkeling van een op maat gemaakte verbeterstrategie
Om het gat tussen de huidige zorg en de zorg zoals beschreven in de richtlijn en MOET-principes te overbruggen is in Hoofdstuk 8 een verbeterstrategie ontwikkeld. Deze maakt gebruik van de eerder gevonden hiaten in de huidige zorg en de gevonden factoren van invloed op het uitvoeren van HPP-zorg van goede
kwaliteit. Er is een plan van aanpak met bijbehorende instrumenten ontwikkeld en de strategie is door deskundigen en patiënten geëvalueerd. Deze strategie bestrijkt het verbeteren van de zorg vanaf het derde trimester van de zwangerschap tot en met het einde van de derde fase van de barings. Voor de professionals bestaat deze strategie uit een checklist om hoog-risico vrouwen te identificeren, een checklist voor de preventie en voor de behandeling van HPP. Als ondersteuning van de patiënt zijn een patiënten paspoort, een informatieve website over HPP en een instrument voor het berekenen van hun risico op HPP ontwikkeld. De beoordeling door een vakkundig panel van zorgverleners gaf aan dat allen tevreden waren over de inhoud en gebruiksvriendelijkheid van de instrumenten. De patiënten waren van mening dat de informatie die zij met behulp van de instrumenten zouden verkrijgen nog steeds onvolledig was waarop de instrumenten zijn aangepast. Wij zijn erin geslaagd een op maat gemaakte strategie te ontwikkelen om de HPP-richtlijn en MOET principes beter toe te passen. De volgende stap is de evaluatie van deze strategie in de praktijk.

Hoofdstuk 9: Algemene beschouwing
In dit hoofdstuk wordt teruggekeken naar de onderzoeksvragen uit het inleidende hoofdstuk, trekken we conclusies en bespreken we onze bevindingen in het licht van beschikbare literatuur, rekening houdend met de methodologische beperkingen. Er worden aanbevelingen gedaan voor toekomstig onderzoek naar verdere verbetering van de naleving van richtlijn. Het testen van de effectiviteit en efficiëntie van de implementatiestrategie is een logische volgende stap. Gezien de toekomstige ontwikkelingen in de verloskundige zorg, zoals het creëren van geïntegreerde zorgtamsen, kan onderzoek gedaan worden naar de toepassing van risico inschatting, verbetering van team communicatie en verbetering van de toepassing van de richtlijn. Daarnaast worden in dit laatste hoofdstuk praktijk- en beleidsimplicaties voor zowel zorgverleners en patiënten benoemd. Zo wordt gesteld dat naast uitkomstindicatoren, als hoeveelheid bloedverlies, ook een beoordeling van de zorg aan de hand van proces- en structuur indicatoren bevorderd moet worden. Dit kan bewerkstelligd worden door deze indicatoren op te nemen in de nationale kwaliteitsregistratie. Dit maakt een solide beoordeling mogelijk van minder vaak voorkomende afwijkingen en complicaties. Tot slot dient de grote inspanning die in het algemeen gedaan wordt voor richtlijnontwikkeling, gevolgd te worden door inspanningen voor implementatie en onderzoek.
Publications and presentations
Dankwoord
Curriculum vitae
PUBLICATIONS AND PRESENTATIONS

Fluxim study


2. **Woiski M**, Scheepers H, Hermens R. Hoe verbeteren we de kwaliteit van zorg omtrent haemorrhagia post partum in Nederland (ingezonden brief) NTOG 2010; 123.


20. Interview Radio Nederland 1 2010: Bloedverlies na de bevalling

21. Interview Radio BNR 2010: Bloedverlies na de bevalling

Other Publications


## PHD PORTFOLIO

**Name PhD student:** Mallory Woiski  
**Department:** Obstetrics and Gynaecology  
**Graduate School:** Radboud Institute for Health Sciences  
**PhD period:** 01-01-2008-02 02-2016  
**Promotors:** Prof. dr. R. Grol, Prof. dr. F.K. Lotgering  
**Co-promotors:** Dr. R. Hermens, Dr. H. Scheepers

### TRAINING ACTIVITIES

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<td>2012</td>
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<td>2014</td>
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<td>2015</td>
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<table>
<thead>
<tr>
<th>c) Symposia &amp; congresses</th>
<th>Year(s)</th>
<th>ECTS</th>
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</thead>
<tbody>
<tr>
<td>Gynaecongres (poster presentation)</td>
<td>2011</td>
<td>0,25</td>
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<tr>
<td>Society of maternal fetal medicine San Francisco (poster presentation)</td>
<td>2012</td>
<td>1,25</td>
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<tr>
<td>Guidelines International Network, Berlin (oral presentation, poster presentation)</td>
<td>2012</td>
<td>1,25</td>
</tr>
<tr>
<td>Society of maternal fetal medicine New Orleans (2 poster presentations)</td>
<td>2014</td>
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<tr>
<td>SGI Florence (poster presentation)</td>
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<tr>
<td>European intra partum care, Porto (2 oral presentation, 3 poster presentations)</td>
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<table>
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<tr>
<th>d) Other</th>
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<tr>
<td>Journal club obstetrics</td>
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<tr>
<td>2008-2016</td>
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### TEACHING ACTIVITIES

<table>
<thead>
<tr>
<th>e) Lecturing</th>
<th>Year(s)</th>
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<tbody>
<tr>
<td>Reference meeting Obstetrics Nijmegen, oral presentation</td>
<td>2012</td>
<td>0,25</td>
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<tr>
<td>Reference meeting Obstetrics Boxmeer, oral presentation</td>
<td>2013</td>
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<tr>
<td>Reference meeting Obstetrics Ede, oral presentation</td>
<td>2013</td>
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<table>
<thead>
<tr>
<th>f) Supervision of internships / other</th>
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<th>ECTS</th>
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<tbody>
<tr>
<td>5 students internship coaching</td>
<td>2011-2015</td>
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</tbody>
</table>

| g) TOTAL | | 27,5 |

---

**Publications and presentations**

**Institute for Health Sciences**

**Radboud University**

**Radboudumc**

---

187
BEDANKT

Dankj.
Lief XXX bedankt
Super Thank U
teamgenoot
Janine
M Heres J Roelofsen
N Schuitemaker D Moonen
P Pernet A Huisjes J Molkenboer

Patienten & partners
C van Meir S de Wit
R Rijnders J Loeffen
Verpleegkundigen Verloskundigen
Gynaecologen Arts Maya Research
Participerende assistenten medewerkers
Ziekenhuizen Raden v Bestuur Expertpanel indicatoren
Martina Anneke Consortium Focus groepen
Rosella Projectgroep FLUXIM
RadboudUMC FLUXIM Fred Annemiek
Ben Willem Martijn
IQ Liesbeth Richard
Mirelle Alex Hilda Didi Frank
Joris Suzan Evelien Nelleke ZonMw
Maatjes Marc Q10 Loes & Marije
Mireille Alex Hilda Didi Frank
Paranimfen Marije & Hilda
Researchstudenten Roy Femke
Paranimfen Marije & Hilda
Communication Translations Van Vliet
Dankwoord

ARUBA
Familie Bilderbeek
Woiski Croes Lampe

MAMA & PAPA
Onvoorwaardelijk Jimmy Charisma Sabina Miki
Gerard Francien Gwen Julia Isabel
Frederique Juliette Cathelijne

Steun Wine & Oyster Club
Marije LOL Thee Vriendinnen Gaby

WIJN Nijmegen Crew HH
Blauw Naftali Hilda Anita
Petra Team

FRANK

OPVANG Schoolmoeders Buren
Wilma Phoebe Jerremiah Nora
Buurtmoeders Jhennial

Love U All thanx 4 ever

Rosella Bedankt

❤
Mallory Woiski was born on the 31st of July, 1968, in Oranjestad, Aruba. She is the second of three children born of Dorinda Croes and Harry James Woiski. She first went to secondary school at Colegio Arubano in Aruba and then accompanied her older sister to the Netherlands, where she graduated Atheneum from Knippenberg College in Helmond, after which she started Medical School at Leiden University.

Mallory worked as a research student on Cobalamin deficiency in the elderly at the department of internal medicine under the supervision of prof. dr. Paul Peter Tak. She became inspired by performing clinical research and concluded her student research program with a review on cobalamin deficiency in the elderly, which was published in Age Ageing in 1995. She did her internship gynecology at the Bronovo Hospital in The Hague under the supervision of Maddy Smeets, who enthused her for the specialization Obstetrics and Gynecology.

After obtaining her medical degree in 1997, Mallory worked as a junior doctor in Obstetrics and Gynecology in several hospitals (Bronovo Hospital in The Hague, OLVG in Amsterdam and the Jeroen Bosch Hospital in Den Bosch). In the year 2000, she started her residency Obstetrics and Gynecology at the Cluster Nijmegen. She pursued her training at the Jeroen Bosch Hospital (dr. Herman Oosterbaan), the Radboud University Medical Center (the late prof. dr. Henk Boonstra and prof. dr. Didi Braat) and at the Canisius Wilhelmina Hospital (dr. Jan Sporken). In 2005, after finishing her residency, she did a fellowship Perinatology at the Radboudumc (prof. dr. Fred Lotgering). She is currently working as a member of the medical staff at the department of obstetrics in the Radboudumc, with a special interest in Prenatal Diagnosis and Obstetric Emergencies. In combination with her work as a Perinatologist she started her PhD research in the quality of care: The Fluxim Study in 2009 (prof. dr. Richard Grol, prof. dr. Fred Lotgering, dr. Rosella Hermens and dr. Liesbeth Scheepers), which was granted by ZonMw and was performed within the Dutch Consortium for research in women’s health.

Mallory lives together with her partner Frank van den Assem, and they are the proud parents of their precious gift, Karina, who is currently 8 years old.
Quality of Postpartum Hemorrhage Care

The need for standardization

Mallory Woiski