ORIGINAL RESEARCH

# Who is at risk? The development of a tool to predict and prevent postpartum hemorrhage

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## ABSTRACT

**Background:** Postpartum hemorrhage remains the main cause of maternal mortality in Low and Middle Income Countries. There is a need to advocate for extra vigilance to recognize women at a greater risk and implement early intervention for Postpartum hemorrhage prevention. The purpose of the present study is to develop a content validated risk assessment tool for the prediction and prevention of Postpartum hemorrhage among childbearing women.

**Methods:** This study is drawn from a larger mixed method sequential exploratory study. Factors influencing the prevention of Postpartum hemorrhage were identified from a scoping review and qualitative descriptive studies previously conducted. To establish content validity Index of the instrument, content experts assessed each item of the tool for comprehensiveness, relevance, and face validity. The tool was pilot tested to assess its clinical utility by fifteen (15) health care providers purposively selected from one district hospital based on a minimum of one-year experience in maternity. Ethical considerations were observed.

**Results:** The Risk Assessment Tool went through three rounds of assessment for its content validity. The final round of quantification of the content validity demonstrates that 4 items out of 46 had an Item Content Validity Index (I-CVI) of 0.85 while 42 had the maximum I-CVI of 1. The overall Scale Content Validity Index/ Average (S-CVI/Ave) was 0.98, and the universal approach of Scale Content Validity Index/Universal Agreement (S-CVI/UA) was 0.91. The assessment of clinical utility of Risk Assessment Tool for the Prediction and Prevention of Postpartum hemorrhage among Childbearing women (RATP) demonstrates that its format allows easy recording of findings and using the tool can be an added value for prevention of PPH.

**Conclusions:** The risk assessment tool for the prediction and prevention of Postpartum hemorrhage is intended to be used by health care providers in Rwanda to identify mothers at risk of developing PPH and implement timely prevention strategies. The clinical use of the tool can be vital in the development of accurate preventive approaches by key policy makers in Rwanda in particular and in other developing countries.

**Key Words:** Risk assessment, Tool development, Content validation, Prediction, Prevention, Postpartum hemorrhage

## 1. BACKGROUND

Postpartum hemorrhage (PPH) is the foremost cause of maternal mortality in low- and Middle-income countries and the principal cause of around one quarter of all maternal deaths worldwide.[1] According to Rwanda demographic and health survey- Key indicators,[2] maternal mortality ratio for the period 2014-2015 to 2019-2020 is 203/100,000 live births. Further, according to Sayinzoga, Bijlmakers, van Dillen et al.[3] 70% of maternal deaths were due to direct causes, of which PPH was the leading one at 22.7% of all reported cases. Consequently, PPH has received increasing attention as a quality indicator for obstetric care not only globally[4,5]

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but also nationally in Rwanda.[6] Further, the review of maternal mortality have demonstrated that most of maternal deaths due to obstetric hemorrhage are preventable.[7,8] Advancing the understanding of risk factors associated with PPH during the antenatal, intrapartum and early postpartum periods is of primary importance among researchers and health practitioners in obstetrics.

The consequences of PPH are widely known and the importance of early assessment of PPH risk factors has been discussed in the literature. Briley, Seed, Tydeman et al.[9] in their study which aimed to measure reported errors, assess incidence of PPH and define risk factors for PPH; concluded that identification of risk factors is important because predisposing risk can underlie factors that impact later the outcome of childbearing period, even including subsequent pregnancies. The identification of PPH risk factors requires clinicians to remain vigilant, to identify and respond to women's accumulating risks, such as recognizing abnormal bleeding for timely intervention. The World Health Organization (WHO),[1,10] recommends the use of injectable oxytocin as the medication of choice to prevent PPH for all births. However, a study conducted in Uganda[11] concluded that the incidence of Postpartum hemorrhage remains high even though many women receive uterotonic medications to manage the third stage of labor.

Numerous factors contributing to high PPH morbidity and mortality rates have been identified both in developed and developing countries. In our previous two studies,[12,13] we conducted a scoping review and a qualitative descriptive study to identify salient factors associated with PPH, which concluded that it is important to set up strategies and approaches for early recognition of women at higher risk of developing PPH. Prata, Bell and Weidert[14] argue that structural barriers are further complicated by difficulties in predicting who will develop PPH. In the same vein Halle-Ekane, Emade, Bechem et al.,[15] highlight that a woman's risk of dying after childbirth is not only associated with the amount of blood loss at delivery but also with a woman's general health status, poverty, life style, and nutritional status. A host of literature[15–17] noted that PPH risk factors may occur at the antenatal, intrapartum and in some circumstances postpartum stages. Antenatal factors associated with PPH include being obese women, Asian ethnicity, PPH in previous pregnancies, pregnancy with more than one fetus, anemia in pregnancy, maternal age greater than 40 and placenta praevia. The intrapartum risk factors include induced labor, prolonged active phase of labor, intrapartum fever, episiotomy, placental abruption, instrumental vaginal delivery, retained placental tissues, and caesarean birth. Andrikopoulou and D'Alton[16] highlight that risk assessments should be undertaken during prenatal consultation, on admission to labor and delivery, when woman is in labor and during postpartum period, as PPH risk factors may change or develop over time.

Various quality improvement initiatives, have been advanced to decrease maternal risk for PPH by improving birth preparedness for recognition of and responses to maternal postpartum blood loss.[18] An integrative review conducted by Hancock, Weeks and Lavender[19] to evaluate the various methods of assessing maternal blood loss during childbirth revealed that most studies attempting to improve recognition and response to PPH have focused on improving estimates of the volume of blood lost. Nevertheless, the review concluded that it should not be assumed that because PPH is defined according to the volume of blood loss, PPH diagnosis should be based on volume estimates. According to Andrikopoulou and D'Alton[16] both estimated and measured blood loss can be inaccurate and cannot predict or reduce the risk of PPH. Therefore, early identification of risk factors for PPH can lead to both awareness and preparedness for high blood loss.

The literature advocates for extra vigilance during the antenatal and intrapartum periods to identify women at risk and implement early intervention to prevent PPH.[20] PPH prevention lies also in the identification of the associated risk factors and proper management of the third stage of labor.[15] The continuum of care from antenatal to postnatal periods was found to be an important consideration as health interventions in prevention of PPH in isolation will likely not be enough to prevent morbidity and mortality associated with PPH.[14] According to Owili, Muga, Chou et al.;[21] antenatal care, childbirth, and post-natal care are regarded as crucial components of maternal health services for improving maternal and new born outcomes and focusing on these areas ensure early detection and management of complication like PPH.[22]

Therefore, optimal care during obstetric hemorrhage remains an area of active research and it has been reported that individual patients need to undergo risk assessment starting in the antenatal period and this assessment need to be optimized as much as possible.[20] Additionally, it is suggested that policy and research should address potentially modifiable risk factors of PPH.[9] Guidelines, strategies and checklists are found in the literature[16,23–25] and are in use in developed countries to assist health care providers in detection of women at risk of developing PPH. To the best of our knowledge, little attention has been devoted in developing countries such as Rwanda especially, for development of instruments to assess risk factors that are likely to lead to PPH. Although numerous factors were found to be associated with PPH prevention, prevention strategies based on early identification of PPH

risk factors were limited and focused primarily on developed countries.[16,24,25] To address this gap we developed a risk assessment tool for the prediction and prevention of PPH (RATP). When a new instrument is designed its content validity is of fundamental importance.[26] Therefore, the purpose of this study is to develop a content validated risk assessment tool for the prediction and prevention of PPH among childbearing women (RATP). The developed tool will be later used for a case control study to identify those risk factors among women in postpartum period.

## 2. METHODS

During a two-stage process (design-judgment),[27] the RATP was developed as illustrated by Figure 1. Ethical considerations were respected such as receiving approval from the Institution Review Board at the College of Medicine and Health Sciences, University of Rwanda (approval No 439/CMHS IRB/2019). The permission from the administration of the selected district hospital was granted and informed consent from women who participated in the pilot testing of the tool was also obtained. Content experts were invited by email while women in postpartum who were not yet discharged from the hospital were given a verbal invitation for the assessment of the clinical utility of the tool. All study participants were explained the purpose of the study and agreed freely to participate.

### 2.1 Stage one: Design

The first stage of designing the RATP was achieved through three steps: to determine the content domain, to sample from content (item generation) and to construct instrument.[27,28] Step 1 was to determine the content domain of a construct that the instrument is designed to measure. According to Haynes, Richard and Kubany[29] cited in Boateng, Neilands, Frongillo et al.,[30] a domain or construct refers to the concept, attribute, or unobserved behavior that is the target of the study. The content domain or construct is identified by literature review, content analysis, and/or by conducting interviews with the respondents or focused groups.[31] For the present study, a scoping review and qualitative descriptive study[12,13] were conducted to determine the content domain. This first step helped the researcher to identify an agreed definition of the domain of study and generate items at a preliminary stage. Consultation with the research team was also used for the conceptual definition of the domain which is "factors associated with PPH prevention" and its boundaries in relation to different levels of the social-ecological model guiding the present study: individual, interpersonal, community, organizational, and policy/enabling environment.[32] At this step Boateng et al.[30] suggest that the researcher confirm that there are no existing instruments that will adequately serve the same purpose. To this end, we conducted a scoping review[12] which confirmed that no such tool has been developed for use in low- and middle-income countries.

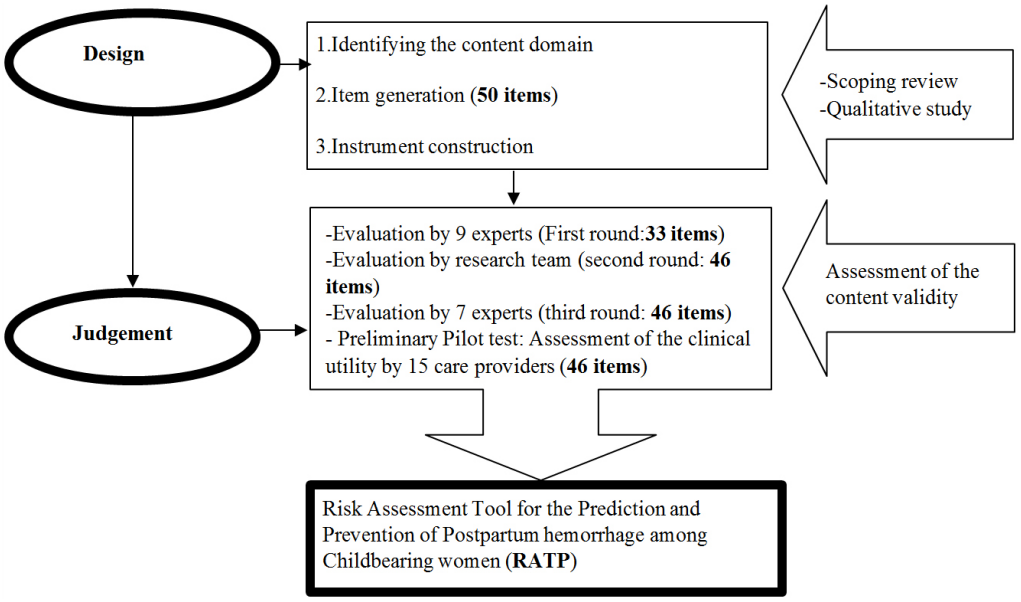


**Figure 1.** Steps used for development of the RATP

Step 2 was to generate items which is also called question development.[30] After delineating the domain, the Principal Investigator proceeded to produce a pool of items and combine both deductive and inductive methods to both define the domain and identify the questions to assess it, as reported by Zamanzadeh et al.[28] and Boateng et al.[30] The tool was

basically developed in English as the items were generated from scholarly activities carried out in English language. The item generation was conducted in the previous phases of the larger study through a scoping review (deductive method) followed by a qualitative study (inductive method) to enrich what had been identified in the literature. The items identified from the scoping review were mapped with those from the qualitative study in a table of specification for further steps. These items are presented in Table 3 under the section of results. The initial list was long, with a view to eliminate unnecessary items at the later stages of tool development. In addition, we referred regularly to the research questions to ensure that the instrument items were relevant.

Step 3 of instrument design was to construct the instrument. At this step, the items were refined and organized in a usable format and sequence, to be reserved for instrument judgement in the second stage of instrument development. At this level, the form of the items, the wording of the items, and the types of responses that the question is designed to induce were taken into account by the researchers.[30] At this stage, the RATP consisted of 50 items with 3 content domains arranged as subsections of the tool: Section A: Social demographic characteristics (15 items), Section B: Newborn and maternal anthropometry and hemoglobin measurements (5 items), and Section C: Pregnancy, obstetric, intrapartum and immediate postpartum factors (30 items). The response format was a pre-coded list of response options for some questions and written responses for other questions.

### 2.2 Stage Two: Judgement

The second stage of judgment involved confirming the items by a specific number of experts for sense-check of the RATP shaped in the design stage. According to Shrotryia and Dhanda,[31] the second stage of judgment involves confirming the items by specific number of experts to ensure content validity of the instrument. Boateng et al.[30] mention that expert judges are used to evaluate each of the item of the instrument to determine whether they represent the domain of interest. To select these individuals, the researchers considered the relevant training, experience, and qualifications of content experts. We selected eight people formally trained as midwives and one medical doctor specialized in obstetrics and gynecology. All Content experts had extensive experience of more than 5 years working in maternal health services including PPH prevention. Zamanzadeh et al.[28] suggest that the adequate number of experts for determining content validity of instruments is between 5-10 people. Participants to be part of expert team were recruited using email and telephone messages. All correspondences to potential participants were in Kinyarwanda. Characteristics of content experts are depicted in Table 1.

**Table 1.** Characteristics of content experts

| S/N | Expert | Education Level | Field ,Working place | Year of experience |
|---|---|---|---|---|
| 1 | Midwife | Masters | Midwifery, Nursing Education, Leadership and Management: High teaching Institution | 30 |
| 2 | Midwife | Bachelor | Midwifery: Association of Midwives & Clinical setting | 8 |
| 3 | Midwife | Bachelor | Midwifery & public health: Association of Midwives | 16 |
| 4 | Midwife | Masters | Midwifery, Nursing Education, Leadership and Management: Society of Obstetricians and Gynecologists | 19 |
| 5 | Midwife | Masters | Midwifery, Academia and research: High teaching Institution | 19 |
| 6 | Midwife | Masters | Midwifery: Maternity, district hospital | 28 |
| 7 | Midwife | Masters | Academia and research: Midwifery education | 19 |
| 8 | Midwife | Masters | Midwifery & Administration: University teaching hospital | 34 |
| 9 | Obstetrician/gynecologist | Masters | Gynecology and obstetrics unit at referral hospital, academia and research | 20 |

The nine content experts included: 1 obstetrician/gynecologist with clinical and research experience, 4 midwives practicing in clinical setting, 2 midwives working within midwives' and obstetricians' professional associations, and 2 midwives working in academia. In addition to this team of experts in the field of PPH prevention, we consulted a statistician to review the tool.

The judgement of the RATP involved three rounds. The first round was held in a meeting with nine content experts to review the format and to quantitatively assess the content validity of the initial RATP with 50 items. The content experts in the first round were explained the purpose of the study and the process to validate the tool. They all consented to be part of the expert team. The aim of the first round was to

combine some items, refine others and remove the items that were not directly relevant to the domain and context of study. Based on the experts' review, the RATP was amended so that it contained 33 items, in the same three domains (sections). The deleted items were judged to be the causes of PPH rather than risk factors (tears: episiotomy, perineal tear, vaginal wall tear, cervical tear and uterine rupture; and uterine atony which might be associated to uterine inversion). The content validity was assessed on relevance, clarity and simplicity of items.

The second round was the meeting with two research team members and one statistician. For items like age, anthropometry and hemoglobin measurements, suggestions were made to collect data in actual numbers (e.g. age: 32 years old,..) rather than by choosing a category (e.g. age: 30-39,. . . ), to allow a more accurate data analysis. The item order was revised to make a more logical sequence. An additional 13 items associated with the four common causes of PPH were suggested at the second round to be added (items associated with uterine atony, trauma of genital organs, retained tissues and problems of blood coagulation were added) as far as the continuity of care for the prevention of PPH is concerned in the present study. The RATP was refined to assess PPH risk factors from the antenatal, intrapartum to early postpartum periods. Based on the results from the second round the RATP was again amended to produce a more comprehensive RATP with 46 items.

With the third round, the revised version of RATP with 46 items was resubmitted to 7 experts from the original team of 9 (three with academic and research expertise and four with childbirth expertise as clinical midwives) to assess again the content validity using a 3-point Likert scale on relevance, clarity and simplicity. The two experts from the original team were not available for the third round to assess the content validity of the RATP. At this level, no further changes were made to the tool.

In addition to the assessment of the content validity, the final format of the RATP with 3 content domains through 46 items was pilot tested in January 2020 for clinical utility to describe the relevance and usefulness of the tool in one selected clinical setting. A group of 15 health care providers from a district hospital (4 nurses, 9 midwives, 2 medical doctors) in Rwanda with a minimum clinical experience of one year were selected to assess the extent to which the instrument is user-friendly and efficient.[33–36] A questionnaire on the clinical utility was developed to assess the level of agreement and was administered to the 15 health care providers who used the RATP to assess clients in childbearing period. Each health care provider used the RATP to assess 3-5 childbearing women to be familiar with the tool. After using the tool, health care providers determined the clinical utility of the tool using a Likert scale by assessing how the RATP was user-friendly, its format and efficiency (strongly disagree, disagree, agree and strongly agree), then time used (not reasonable, somewhat reasonable and reasonable). The selected health care professionals also described their level of agreement with the RATP in relation to the following items: The RATP is easy to use, the format allowed easy recording of findings, the language is clear, the time used to complete the tool is reasonable, the RATP is an added value for PPH prevention, the RATP measure the continuity of care for PPH prevention then lastly health care professionals were free to make comments on a provided space.

### 2.3 Data analysis

The content validity of the RATP was determined using the qualitative and quantitative viewpoints of the panel of experts. Comments provided by participants about the format of the RATP were reviewed. Changes for the numbering, the wording of items and the types of responses that the question is designed to elicit were made based on content experts' recommendations.[30] Then after including 46 items in the final form, the results from assessment of the content validity were captured in Excel sheet, analysed quantitatively and the content validity index (CVI) was set for the whole tool. The quantitative content validity assessment was conducted twice: (1) during the first round of the judgement stage, then (2) during the third round of the judgement stage. For our study we reported the CVI as it is the most widely reported approach in nursing for content validity.[28]

The quantification of content validity involved giving marks to each item on the basis of relevance, clarity and simplicity by members of the expert team.[26,28] Therefore, the calculation of the CVI for all individual items, Item-CVI (I-CVI) was performed as well as the overall scale-CVI (S-CVI). For CVI, we requested the panel of experts to rate each scale item in terms of its relevance in relation to the principal construct which is prevention of PPH. To avoid a neutral point, a 4-point scale was used.[31] The used criteria are presented in Table 2. An item's clarity refers to how clearly the item was worded, the relevance looks to how relevant the item was to the construct and the simplicity considers how easily the item can be understood by the tool user.[26]

Content validity of the final form of the RATP was assessed quantitatively by the seven expert team members who were asked to state their rating of the relevance, clarity and simplicity of each item using the four point Likert-scales. The I-CVI was computed for each item as a proportion, where the numerator was the number of experts giving a score of

three or four (Number of agreements referred as NA) and the denominator was the total number of experts,[31] i.e. 0.77. Thus, the maximum I-CVI was 1. Shrotryia and Dhanda[31] indicate that a scale with high content validity could have an I-CVI over 0.78 while items with lower I-CVI should be re-examined and changed according to the suggestions of experts.[28]

**Table 2.** Criteria for quantification of content validity

| Relevance | Clarity | Simplicity |
|---|---|---|
| 1 = Not relevant | 1 = Not clear | 1 = Not simple |
| 2 = Item needs revision | 2 = Item needs revision | 2 = Item needs revision |
| 3 = Relevant but needs minor revision | 3 = Clear but needs minor revision | 3 = Simple but needs minor revision |
| 4 = Very relevant | 4 = Very clear | 4 = Very simple |

The RATP has been pilot tested and a rating scale was used to measure clinical utility based on the following criteria: ease administration of the tool, clear language, time, format and efficiency. Statistical analysis was performed using IBM SPSS software version 22 and the percentage mean level of agreement was set.

## 3. RESULTS

### 3.1 Findings from assessment and quantification of content validity

At the first round, nine content experts assessed the CVI and the instrument initially with 33 items met the standards for the average approach of Scale Content Validity Index (S-CVI/Ave) which was 0.94, and the universal approach of Scale Content Validity Index (S-CVI/UA) of 0.84. However, three items scored below the acceptable I-CVI of 0.78. The item on retained tissues scored 0.33, trauma of genital organs scored 0.44; uterine atony scored 0.77. Content experts in this round suggested to remove from the tool the items relating to retained tissues and trauma of genital organs as they were thought to be causes of PPH but not risk factors to PPH. The item of uterine atony was suggested to be revised.

After consultation of the literature on PPH risk factors, the conclusion from the second round was to keep all items from the first round as the team was of the view that all items could be PPH risk factors from antenatal, intrapartum and postpartum periods. The RATP was then shaped with 46 items in three content domains (sections) on the tool: Section A, Social demographic characteristics of the woman (Items 1-10); Section B, Newborn and mother anthropometry and hemoglobin measurements (Items 11-14); Section C, Pregnancy, obstetric, intrapartum and immediate postpartum factors (Items 15-46). The items are listed in Table 3. The second round after refining the RATP, suggested another assessment of the content validity by a team of experts.

The final quantification of content validity of the RATP conducted by seven experts in the third round demonstrated that 4 items had an Item Content Validity Index (I-CVI) of 0.85 while 42 had the maximum I-CVI of 1. The overall S-CVI/Ave was 0.98, and the S-CVI/UA was 0.91. The findings from the final quantification of the content validity are reported in Table 3.

### 3.2 Findings from assessment of the clinical utility

Twelve participants out of fifteen agreed (agree and strongly agree) that the tool was easy to administer. From 15 participants, 9 responded that it took them 5 minutes or less to complete the tool and twelve participants indicated that the time needed to complete the tool was reasonable. Almost all participants (14) agreed that the tool's format allowed for easy recording of findings. Fourteen participants out of fifteen agreed (agree and strongly agree) that using the tool would be an added value for PPH prevention. The majority of participants (13) agreed that the tool measured the continuity of care for PPH prevention. Then participants suggested that the tool needs to be available in three languages including French, English and Kinyarwanda to reduce language barriers as it was developed only in English.

## 4. DISCUSSION

In this study, we developed a content validated risk assessment tool for the prediction and prevention of PPH among childbearing women (RATP). To design the RATP, the items were generated from previous phases of this study which are published elsewhere: a scoping review[12] to describe the research output on factors affecting the prevention of PPH in low and middle income countries and a qualitative descriptive study[13] to explore the influencing factors for early detection and prevention of PPH as perceived by beneficiaries and health workers in the Northern Province of Rwanda. Our process to generate items is in agreement with Zamanzadeh et al.[28] in a study focusing on the process used to assess content validity. The authors affirm that items can be identified by literature review on the topic being measured and interviewing with the respondents and focus groups discussions.

**Table 3.** Content validity of the risk assessment tool for the prediction and prevention of PPH among childbearing women (RATP)

| Items | Exp 1 | Exp 2 | Exp 3 | Exp 4 | Exp 5 | Exp 6 | Exp 7 | NA | I-CVI |
|---|---|---|---|---|---|---|---|---|---|
| 1. Age | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 7 | 1 |
| 2. Marital status | 3 | 4 | 4 | 4 | 3 | 4 | 3 | 7 | 1 |
| 3. Level of education | 4 | 4 | 4 | 3 | 4 | 3 | 3 | 7 | 1 |
| 4. Area of residence | 3 | 4 | 4 | 4 | 3 | 3 | 3 | 7 | 1 |
| 5. Accessibility to nearest health facility | 3 | 4 | 4 | 4 | 3 | 3 | 2 | 7 | 1 |
| 6. Use of medical insurance | 3 | 4 | 4 | 4 | 3 | 3 | 4 | 6 | 1 |
| 7. Use of Family Planning methods outside pregnancy | 4 | 4 | 3 | 4 | 3 | 3 | 3 | 7 | 1 |
| 8. Health facility where delivery took place | 3 | 3 | 3 | 4 | 4 | 4 | 4 | 7 | 1 |
| 9. Socio economic status | 3 | 4 | 2 | 3 | 4 | 4 | 3 | 6 | 0.85 |
| 10. Woman religion | 3 | 3 | 4 | 3 | 4 | 4 | 3 | 7 | 1 |
| 11. Newborn weight | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 7 | 1 |
| 12. Woman weight | 3 | 4 | 4 | 3 | 3 | 4 | 4 | 7 | 1 |
| 13. Woman Height | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 7 | 1 |
| 14. Woman Hemoglobin level | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 7 | 1 |
| 15. Primiparity | 3 | 3 | 3 | 4 | 3 | 3 | 2 | 6 | 0.85 |
| 16. Multiparity | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 7 | 1 |
| 17. Uterine anomaly | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 7 | 1 |
| 18. Uterine surgery (e.g. myomectomy) | 4 | 4 | 4 | 3 | 4 | 3 | 3 | 7 | 1 |
| 19. Previous Caesarean Section | 3 | 4 | 4 | 4 | 4 | 4 | 3 | 7 | 1 |
| 20. Previous PPH | 3 | 4 | 4 | 4 | 4 | 4 | 3 | 7 | 1 |
| 21. Antepartum hemorrhage | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 7 | 1 |
| 22. HIV Positive status | 3 | 3 | 3 | 3 | 3 | 3 | 2 | 6 | 0.85 |
| 23. Multiple pregnancy | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 7 | 1 |
| 24. Anemia | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 7 | 1 |
| 25. Gestational diabetes mellitus | 4 | 4 | 4 | 2 | 3 | 4 | 3 | 6 | 0.85 |
| 26. Polyhydramnios | 3 | 4 | 4 | 3 | 4 | 4 | 3 | 7 | 1 |
| 27. Anticoagulant medications in pregnancy | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 7 | 1 |
| 28. Severe pre-eclampsia | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 7 | 1 |
| 29. Intra uterine fetal death | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 7 | 1 |
| 30. Premature rupture of membranes | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 7 | 1 |
| 31. Prolonged labor | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 7 | 1 |
| 32. Spontaneous Vaginal delivery | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 7 | 1 |
| 33. Instrumental Vaginal delivery | 3 | 3 | 4 | 3 | 4 | 4 | 4 | 7 | 1 |
| 34. In labor Caesarean Section | 3 | 3 | 3 | 3 | 4 | 4 | 4 | 7 | 1 |
| 35. Repeat Caesarean delivery | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 7 | 1 |
| 36. Labour induction | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 7 | 1 |
| 37. Labour augmentation | 4 | 4 | 4 | 3 | 4 | 4 | 3 | 7 | 1 |
| 38. Administration of Oxytocin for active management of the third stage of labor | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 7 | 1 |
| 39. Episiotomy | 4 | 3 | 4 | 4 | 3 | 4 | 3 | 7 | 1 |
| 40. Perineal tear | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 7 | 1 |
| 41. Vaginal wall tear | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 7 | 1 |
| 42. Cervical tear | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 7 | 1 |
| 43. Uterine rupture | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 7 | 1 |
| 44. Retained tissues | 4 | 4 | 4 | 3 | 4 | 3 | 4 | 7 | 1 |
| 45. Uterine atony | 3 | 3 | 4 | 4 | 3 | 3 | 4 | 7 | 1 |
| 46. Uterine atony with Uterine inversion | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 7 | 1 |
| S-CVI/Ave | | | | | | | | | 0.98 |
| Total agreement | | | | | | | | | 46 |
| S-CVI/UA | | | | | | | | | 0.91 |

***Note***. Exp.: Expert; NA: Number of Agreements (number of experts giving a score of three or four); ICV-I = Item Content Validity Index

S-CVI/Ave: Scale Content Validity Index/Average

S-CVI/UA: Scale Content Validity Index/Universal Agreement; 2: Need revision; 3: relevant, clear and simple; 4: very relevant, very clear very simple

**Table 4.** Assessment of the clinical utility

| Criteria to the clinical utility assessment | N = 15 |
|---|---|
| The RATP is easy to use | |
| Agree and Strongly agree | 12 |
| Disagree | 3 |
| Time to complete to tool | |
| 1-5 minutes | 9 |
| 5-10 minutes | 6 |
| Time used was reasonable | 15 |
| Format allowed for easy recording of findings | |
| Agree and strongly agree | 14 |
| Disagree | 1 |
| Efficiency | |
| Agree and strongly agree that the tool's format allows for easy recording of findings | 14 |
| Disagree that the tool is an added value for PPH prevention | 1 |
| Agree and strongly agree that the tool assesses continuity of care for PPH prevention | 13 |
| Disagree that the tool assesses continuity of care for PPH prevention | 2 |
| Comment: Suggestion to have the RATP translated in English, French and Kinyarwanda | |
| To have the RATP translated | 10 |

### 4.1 Assessment of the content validity

The content experts, for this study were individuals judged to have characteristics as described by literature[28,30,31,37] to be highly knowledgeable about the domain of interest and/or scale development. Nine domain experts assessed the content validity for the first round and seven for the third round. A minimum of five people are believed to have sufficient control over chance agreement while a group bigger than ten people has the probability of decreased chance of agreement.[28]

To assess the content validity of the items generated, the RATP is designed in three content domains also called sections on the tool through 46 items depicted in Table 3. The identified content domains are also called sections: Section A, Social demographic characteristics of the woman (Items 1-10); Section B, New and mother anthropometry and hemoglobin measurements (Items 11-14); Section C, Pregnancy, obstetric, intrapartum and immediate postpartum factors (Items 15-46). The items or PPH risk factors on the RATP could be assessed in antenatal, labor and early postpartum period by health care providers for early identification of women who are at risk of developing PPH. This substantiates with findings in Boyd[25] where a structured checklist and a PPH risk assessment tool are introduced for a proactive prevention of PPH in a consultant-led maternity unit in Scotland. Andrikopoulou and D'Alton[16] suggest an obstetric hemorrhage risk assessment table shaped in two categories: Risk factors assessed on admission to labor & delivery and intrapartum risk factors. The clinical practice guideline developed by the Association of Ontario Midwives put these risk factors into three categories: Stronger, moderate and weaker risk factors. We did not find literature describing how the content validity of these tools have been assessed and validated.

The present study considered the qualitative and quantitative assessment of expert viewpoints for the content validity of the RATP. According to Zamanzadeh et al.,[28] the retention of an item depends on whether it was supported and agreed by a number of panel members who gave a score of three or four and the lowest Item Content Validity Index (I-CVI) should be 0.78. Additionally, literature suggests that researchers should consider I-CVI of 0.80 ( 80%) or higher among judges for new instruments; if it is between 70% and 79%, the item needs revision and when it is less than 70%, then it is eliminated.[31] In this regards, at the first round of assessment of the CVI of the RATP by nine experts, three items scored less than the acceptable level of agreement of the I-CVI. The item on retained tissues had scored 0.33, trauma of genital organs had scored 0.44 while uterine atony scored 0.77. Experts at this round of assessment had commented that these items are likely to be common causes of PPH rather than risk factors and were suggested to be eliminated. However, literature[24,25] included these items considered as common causes of PPH among PPH risk fac-

tors which led to producing a RATP with 46 risk factors to be assessed from antenatal, intrapartum and early postpartum periods. The last form of the RATP has been assessed and validated at the third round by seven content experts.

As illustrated in Table 3 of this study, all items scored highly on the I-CVI where the lowest I-CVI was 0.85 (85%). This led to the retention of all items. The Scale –Content Validity Index (S-CVI) was computed as well to ensure content validity of the overall scale.[31] We calculated the S-CVI/ UA (Universal agreement) to reflect the proportion of items on the RATP that achieved a rating of 3 or 4 by all the experts in the panel and this was 0.91. The S-CVI/Ave (Average) was calculated as well, to give interpretation of Scale Validity Index, and this average was 0.98. The literature indicates that a minimum S-CVI should be 0.8 to reflecting content validity[28,31] of a tool.

### 4.2 Assessment of the clinical utility

Our results from the clinical utility assessment align with previous literature. Bossuyt et al.[34] indicate that clinical utility tests contribute to health outcomes whereby results are used to guide clinical management, such as decisions to initiate, modify, stop, or withhold treatment. The RATP was perceived by participants as efficient to measure the continuity of care for PPH prevention, easy to administer without taking too much clinical time. A study conducted by Orlando et al.[36] to assess the clinical utility of a web-based, patient-facing risk-assessment and clinical decision support tool evaluated its impact on the risk-management care that an increased-risk patient receives. The researchers concluded that integration of the tool into primary-care practice can improve uptake of evidence-based risk assessment services and be a helpful tool for reducing disparities in preventive health care services. These previous findings support our results from the assessment of clinical utility of the RATP demonstrating that its format allows easy recording of the clinical data and using the tool can be an added value for prevention of PPH (93.3% of agreement).

One of the critical health care providers' remarks was to have the RATP available in three languages, Kinyarwanda, French and English as before it was in English and Kinyarwanda only. This is supported by Sibomana[38] in a study to explore the challenges and promises in the acquisition of English as a second/additional language in Rwanda. We agree that translating the tool would assist an extensive use of the tool by different health care providers, many of whom are more comfortable to work in French than in English. The RATP is warranted to be used later in a case control study the last phase of the mixed method study with the aim to investigate and model the risk factors of Primary PPH to predict the possibility of PPH for women admitted in maternity for labor and birth.

### 4.3 Strengths and limitations

This RATP was developed following a rigorous methodological protocol.[28,30,31] The initial list of domains and corresponding pool of items were derived from the scoping review and qualitative descriptive study. Findings from these previous studies are reported elsewhere.[12,13] We created new items to specifically evaluate PPH risk factors according to the results of our previous qualitative study. The generation of these items ensured that factors influencing PPH prevention in the context of Rwanda were not missed. Successive revisions were performed according to qualitative and quantitative assessments from a panel of content experts with extensive experience in PPH prevention. A pilot-test for clinical utility with 15 health care providers from a clinical setting was performed to maximize the content validity of the tool.

It is important to note some limitations pertaining to the present study which also are likely to happen to validity studies. As the feedback from the experts is subjective, our study is susceptible to possible bias among the experts. Additional potential limitation is that this type of study does not automatically describe content that might have been omitted. To minimize this limitation, experts were able to suggest other items based on their background and expertise as supported by Vermeulen et al.[37]

### 4.4 Implications and recommendations

The focus in this study is to use the RATP for improved prevention of PPH, a global maternal health issue by being proactive rather than being active. Furthermore, this tool can be of great value in improving the knowledge of health care providers especially nurses and midwives about the value of quality preventive care and maternity care in general. It also has the potential to enhance communication between the various levels of care provision. The RATP may improve research in the domain of maternity care, especially in preventive care. It can be used as both a research and a clinical instrument in its full version. A case control study using the RATP translated into three languages (Kinyarwanda, French and English) is warranted to evaluate the predictors to PPH for timely action and prevention. The upcoming case control study with diverse population will help to improve the reliability and validity of the RATP.

## 5. CONCLUSION

There is a cause to consider that all pregnant women are at risk of developing PPH. The RATP is a risk assessment

tool developed and validated to improve the prevention of PPH. It will be of special use in a field that has a scarcity of valid instruments to conduct an early assessment of PPH risk factors among childbearing women in Rwanda, in the region and other low- and middle-income countries.

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## CONFLICTS OF INTEREST DISCLOSURE

The authors declare that they have no competing interests.

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