

## Bundle for quantifying vaginal blood loss after childbirth

*Bundle para quantificação de perda sanguínea pós-parto vaginal**Bundle para la cuantificación de pérdida sanguínea posparto vaginal*Mariana Torreglosa Ruiz<sup>1</sup>  <https://orcid.org/0000-0002-5199-7328>Nayara Freitas Azevedo<sup>1</sup>  <https://orcid.org/0000-0001-7748-4777>Cynthia Viana de Resende<sup>1</sup>  <https://orcid.org/0000-0003-1203-2504>Maria Paula Custódio Silva<sup>1</sup>  <https://orcid.org/0000-0001-8694-1589>Divanice Contim<sup>1</sup>  <https://orcid.org/0000-0001-5213-1465>Luciano Marques dos Santos<sup>2</sup>  <https://orcid.org/0000-0001-7866-6353>Monika Wernet<sup>3</sup>  <https://orcid.org/0000-0002-1194-3261>Ana Maria Linares<sup>4</sup>  <https://orcid.org/0000-0002-8883-5197>**How to cite:**

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**Abstract**

**Objective:** To construct and validate the content of a bundle to quantify vaginal blood loss after childbirth.

**Methods:** This is a methodological study developed from February to August 2022, divided into bibliographic survey, instrument construction and content validity, by 14 experts. The instrument for validity consisted of 11 items selected from a systematic review. For each item in the bundle, a Likert scale was applied, and to check agreement among experts, the Concordance Index was calculated. Items with agreement above 80% were considered valid. Content validity was carried out in a single round of assessment.

**Results:** The final version of the bundle consisted of nine items. The proposed care is related to direct quantification of postpartum bleeding and its recording, observation of postpartum women, use of institutional protocols in cases of postpartum hemorrhage as well as team training.

**Conclusion:** The study allowed constructing and validating a bundle for quantifying vaginal blood loss after childbirth, with a view to improving postpartum hemorrhage diagnosis.

**Resumo**

**Objetivo:** Construir e validar o conteúdo de um *bundle* para quantificação da perda sanguínea pós-parto vaginal.

**Métodos:** Estudo metodológico desenvolvido de fevereiro a agosto de 2022, em três etapas: levantamento bibliográfico, construção do instrumento e validação de conteúdo por 14 *experts*. O instrumento para validação foi composto por 11 itens selecionados a partir de revisão sistemática. Para cada item do *bundle* aplicou-se escala Likert e para verificar a concordância entre experts, calculou-se o Índice de Concordância. Consideraram-se válidos os itens com concordância acima de 80%. A validação de conteúdo foi realizada em uma única rodada de avaliação.

**Resultados:** A versão final do *bundle* foi composta por nove itens. Os cuidados propostos estão relacionados à quantificação direta do sangramento pós-parto e seu registro, observação da puérpera, a utilização de protocolos institucionais em casos de hemorragia pós-parto, assim como a capacitação da equipe.

**Conclusão:** O estudo permitiu construir e validar *bundle* para quantificação da perda sanguínea pós-parto vaginal, com vistas à melhora do diagnóstico de hemorragia pós-parto.

**Resumen**

**Objetivo:** Elaborar y validar el contenido de un *bundle* para la cuantificación de pérdida sanguínea posparto vaginal.

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**Conflict of interest:** nothing to declare.

**Métodos:** Estudio metodológico, llevado a cabo de febrero a agosto de 2022, en tres etapas: análisis bibliográfico, construcción del instrumento y validación de contenido por 14 expertos. El instrumento para validación consistió en 11 ítems seleccionados a partir de revisión sistemática. Se aplicó la escala Likert para cada ítem del *bundle*; y para verificar la concordancia entre expertos, se calculó el Índice de Concordancia. Se consideraron válidos los ítems con concordancia superior a 80 %. La validación de contenido se realizó en una única ronda de evaluación.

**Resultados:** La versión final del *bundle* consistió en nueve ítems. Los cuidados propuestos están relacionados con la cuantificación directa del sangrado posparto y su registro, la observación de la puerpera, la utilización de protocolos institucionales en casos de hemorragia posparto, así como también la capacitación del equipo.

**Conclusión:** El estudio permitió elaborar y validar un *bundle* para la cuantificación de pérdida sanguínea posparto vaginal, con el fin de mejorar el diagnóstico de hemorragia posparto.

## Introduction

Postpartum hemorrhage (PPH) is a cause of maternal death that deserves attention,<sup>(1-4)</sup> as it accounts for approximately 27% of deaths related to obstetric causes.<sup>(1-3)</sup> One case occurs for every ten childbirths of PPH and, within this statistic, there is at least one death due to PPH for every 190 childbirths.<sup>(1-4)</sup>

On the national scene, data from the Brazilian Health System Department of Informatics (DATASUS - *Departamento de Informática do Sistema Único de Saúde*) indicate that, of maternal deaths occurring between 1996 and 2020, 69% of cases were due to direct obstetric causes and, of these causes, 17.3% (5,056) resulted in deaths due to PPH.<sup>(5)</sup>

PPH diagnosis is defined as blood loss of more than 500 ml after vaginal childbirth, or more than 1,000 ml during cesarean section in the first 24 hours, or any blood loss after childbirth capable of causing hemodynamic instability or requiring blood transfusion for control.<sup>(1,2,6)</sup> It is a complex diagnosis that involves the volume of blood lost, the tolerability and clinical response to blood loss, women's overall health status, the speed of loss, variation in hemoglobin levels throughout pregnancy and the appropriate functioning of the coagulation system.<sup>(6-8)</sup>

Measuring postpartum blood loss is extremely important to improve quality of care as well as to prevent maternal death from PPH. In 2015, the World Health Organization (WHO) published the Before birth: WHO safe childbirth checklist, an instrument in the form of a checklist that aims to promote greater safety for the dyad. The checklist must be applied upon admission, at birth, immediately after birth and before hospital discharge. Given the magnitude of PPH, the document recommends

assessing maternal bleeding in the first hour after birth, instituting measures for its treatment in cases where an increase is detected, in addition to reinforcing the need for assessment before hospital discharge.<sup>(9)</sup>

The prevalent diagnostic method adopted to quantify blood loss is visual estimation. It is subjective and has a chance of underestimation in around 30 to 50% of cases.<sup>(6,10)</sup> Other commonly used strategies are gravimetry via weighing of compresses and surgical drapes used to assist with childbirth, laboratory and/or clinical parameters, shock index.<sup>(1,2,6)</sup>

Quantifying blood loss is recommended for diagnosing PPH in all childbirth types, enabling timely care, reducing uterotonic administration and unnecessary transfusions, with reduced costs.<sup>(11)</sup>

Given the above, the establishment of protocols and bundles denotes a pertinent contribution, especially if associated with team training for implementation and use.<sup>(11,12)</sup> A bundle is defined as a set of interventions with specific care that, when grouped together, provide improvements in care practices, with a view to promoting greater safety for patients. When selecting items to make up the bundle, one must consider costs, ease of implementation and adherence to proposed actions. Success is related to the completion of all items, without fragmentation of any stage.<sup>(13-15)</sup>

In this regard, studies have shown the effectiveness of bundles for safe care. A review on bundle implementation to reduce bloodstream infections related to central venous catheter use in critically ill patients showed a reduction between 26 and 100% after their adoption, showing a positive impact.<sup>(13)</sup> Aiming for the same result in the neonatal population, a care bundle was designed for peripherally inserted central venous access catheters.<sup>(15)</sup> A methodological study validated a bundle for the care of

newborns born to mothers with a suspected or confirmed diagnosis of COVID-19 in the birth room and rooming-in during the pandemic.<sup>(14)</sup> Thus, the results emphasize using bundles for specific care and contexts.

In the area of obstetric nursing, bundles are still in their infancy; however, it is noted that production has been growing over time, but many still focus on describing consensus for their elaboration and not exactly their validity or implementation results. Similar to previous descriptions, bundles aimed at the obstetric population have shown effective results. A bundle aimed at preventing PPH showed a reduction in cases, greater uterotonic use and a greater patient safety climate for obstetric nurses.<sup>(16)</sup> A bundle aimed at risk stratification for PPH identified that its implementation enabled an improvement in 90% of assessments, when compared to the previous period.<sup>(17)</sup>

Given the magnitude of PPH and the relevance of quantifying blood loss for care procedures in this context, constructing a bundle is justified. Its innovation consists of focusing on postpartum bleeding assessment, which can favor prompt recognition of PPH cases, greater resolution of them, consequently guaranteeing safer care, with a possible impact on reduction of maternal deaths due to PPH. Therefore, the study aimed to build and validate the content of a bundle to quantify vaginal blood loss after childbirth.

## Methods

This is a methodological study, developed in three stages: survey of scientific production on the topic, bundle construction with guidelines containing care for postpartum blood quantification and content validity carried out by experts. The research report was carried out in accordance with Standards for Quality Improvement Reporting Excellence (SQUIRE) recommendations.<sup>(18)</sup>

In the theoretical stage, the results of a systematic review<sup>(19)</sup> with 14 articles were used, which served as the basis for constructing the bundle.

After the review, it was decided to build a bundle to quantify vaginal blood loss, given its low cost. It is noteworthy that the American College of Obstetricians and Gynecologists and the Association of Women's Health, Obstetric and Neonatal Nurses<sup>(11,12)</sup> consensus and guidelines supported all proposed items.

The validity instrument was built using the Hyper Text Markup Language (HTML) standard in Google Forms<sup>®</sup>. Part I involved expert characterization data. Part II was responsible for composing the bundle, assessed based on a Likert scale containing the options "totally disagree", "disagree", "agree" and "totally agree". In all items, experts had a blank field for free records. It should be noted that in guidelines for filling out the form, the need to assess each item was mentioned based on the requirements as follows: usefulness/pertinence; consistency; clarity; objectivity; simplicity; feasibility; updating; accuracy; instructional sequence of topics; and form of presentation of the protocol.<sup>(21)</sup> In addition to these precautions at the end, experts gave their opinion on the bundle usefulness in practice, with a blank field for comments.

Experts were selected in May 2022 and, in this group, researchers in obstetric nursing with scientific publications on the subject were included, and this information was checked in the *Curriculum Lattes*. An invitation was sent by email to 23 experts and, of these, 14 agreed to participate.

Thus, the sample was composed of 14 experts, following recommendations from the literature, which recommends six to twenty validators and a minimum of three individuals when representing a professional group.<sup>(22)</sup> Expert selection followed the adapted Fehring<sup>(23)</sup> criteria: postdoctoral title (five points); PhD degree (four points); master's degree (three points); publication in an indexed journal on the thematic areas of interest of study (two points); specialization in the thematic areas of interest of study, such as pediatrics, neonatology and obstetrics; simulation (two points); care practice of at least two years in thematic areas of interest of study (two points); and participation in a scientific event in the last two years in thematic areas of interest of study (two points). To be selected, experts must obtain a

minimum of five points and have at least a master's degree.

The validity questionnaire was sent followed by a term clarifying the objectives of the study and a document describing the activities requested of them. The consent form and the validity questionnaire were sent online, using an electronic form on Google Forms<sup>®</sup>. The consent form clarified the objectives of the study and provided instructions for filling it out and, at the end of the home page, participants could tick the options: 1 – I have read and agree to participate; 2 – I have read and do not accept to participate. Participants were redirected to the validity questionnaire only if they clicked on option 1 – I read and agree to participate. Experts who did not return the instrument within 15 days of receipt were not included. Incomplete item responses were also an exclusion criterion. No participants were excluded.

Data were imported from Google Forms<sup>®</sup> into a database in Excel<sup>®</sup> format. Content validity data were presented in percentage and absolute frequencies. In this study, the Concordance Index (CI) was adopted, in which the number of times there is agreement (total, partial or just agreement) is divided by the total number of assessments, varying between 0 and 100%. For assessment to be adequate or excellent, a minimum CI of 80% agreement must be obtained.<sup>(24)</sup> CI calculation was the result of applying the formula:  $CI = \text{sum of number of agreement responses} / \text{number of total responses} \times 100$ .<sup>(24)</sup>

The study was approved by the Research Ethics Committee, under Opinion 5.539.782 of July 22, 2022 (CAAE (*Certificado de Apresentação para Apreciação Ética* - Certificate of Presentation for Ethical Consideration) 58880822.3.0000.5154) and followed all ethical precepts provided for by Resolution 466/2012. It is noteworthy that, as this is a remote collection, the Informed Consent Form was prepared in accordance with the Guidelines for Procedures in Research with any Stage in a Virtual Environment, from the Brazilian National Research Ethics Commission (CONEP - *Comissão Nacional de Ética em Pesquisa*), published on February 25, 2021.

## Results

Experts' mean age was  $49.2 \pm 13.5$  years, with a minimum age of 30 and a maximum of 76 years. Most were female (13 – 92.9%) and had a PhD degree (eight – 57.2%). Three (21.4%) experts had master's degree and three (21.4%) had postdoctoral degrees. The mean length of training was  $26.6 \pm 13.8$  years, with a minimum of seven and a maximum of 54 years. All were nurses, specializing in obstetric nursing and working in the area, and the majority (12 – 85.8%) worked in teaching and two (14.2%) in care/management. The mean length of experience was  $20.6 \pm 12.5$  years, with a minimum of five and a maximum of 41 years. Experts worked in the states of São Paulo (five -35.8%), Rio de Janeiro (two -14.2%), Santa Catarina (two - 14.2%), Federal District (two - 14.2%), with one (7.1%) representative each, Minas Gerais, Bahia and Portugal. Most (12 - 85.7%) worked in universities, seven (58.3%) state and five (41.7%) federal. Applying the criteria adapted from Fehring (1987), selected experts had a mean of 15.4 points, with the minimum being eleven and the maximum obtained and possible score being 20 points. Table 1 presents expert characteristics.

Of the 11 items proposed for quantifying vaginal blood loss after childbirth, nine were validated by experts with high levels of agreement, considered adequate or excellent. Items 5 and 6 were excluded from the bundle because they had a CI of 79% (less than 80%), as shown in Table 2.

Eight comments/suggestions from experts were recorded. One asked about quantification given the limitation of mixing blood with amniotic fluid, urine and/or feces. This expert also described that weighing the materials before and after birth could make their implementation in practice unfeasible/difficult. Another comment considered the importance of surveillance, theorization and adoption of preventive measures for PPH, and registered believing in bundle use application for specific situations such as women with anemia, multiparous women, coagulation disorders, third trimester bleeding and in cases that bleeding is increased by visual estimation. A third comment suggested the inclusion of

**Table 1.** Characterization of experts who validated the bundle

Characteristics	n(%)	
Sex		
Female	13(92.9)	
Male	1(7.1)	
Degree		
Postdoctoral	3(21.4)	
PhD	8(57.2)	
Master's	3(21.4)	
Activity		
Teaching	12(85.8)	
Care/management	2(14.2)	
State of operation		
São Paulo	5(35.8)	
Rio de Janeiro	2(14.2)	
Santa Catarina	2(14.2)	
Federal District	2(14.2)	
Minas Gerais	1(7.1)	
Bahia	1(7.1)	
Portugal	1(7.1)	
Professors – institution		
State	7(58.3)	
Federal	5(41.7)	
Variable (years)	Mean and standard deviation	Minimum and maximum
Age	49.2 ± 13.5	30 – 76
Length of training	26.6 ± 13.8	7 - 54
Length of experience	20.6 ± 12.5	5 - 41
Criteria adapted from Fehring	15.2 ± 3.19	11 - 20

**Table 2.** Description of items for quantifying vaginal blood loss after childbirth for prevention, prompt recognition and treatment of cases of postpartum hemorrhage

Item	Description	CI (%)
1	Conduct annual training using simulation for the entire obstetric team on quantifying postpartum blood loss	93
2	Institute a protocol for quantifying postpartum blood loss	93
3	Weigh all the drapes and compresses that will be used in the birth beforehand (Material Center)	86
4	Add weighted cards to the outer surface of birth packages	86
5	After removing postpartum women from the surgical table, weigh all fields in direct contact with her and soaked in blood on a calibrated scale	79
6	Weigh all items soaked in blood used at birth (compresses and gauze)	79
7	If clots come out, weigh them	86
8	At the end, subtract wet weight (drapes, compresses, gauze, clots) from dry weight (drapes weighed previously)	86
9	Record blood loss quantification	93
10	If postpartum hemorrhage is detected (loss of more than 500 ml), assess patients and initiate interventions, according to protocol	93
11	If available at the institution, carry out an assessment of hemoglobin and hematocrit levels upon admission (before birth) and 24 hours after birth	86

CI – Concordance Index

an item with shock index calculation in the bundle. The fourth comment suggested qualification of the writing of item 1: training/improvement should be carried out every semester and/or whenever there are changes in many team members, instead of the annual proposition. This same expert questioned

whether the stretcher sheet would also be weighed in item 5 and about the possibility of inserting a PPH management protocol in item 10. Another expert made contributions regarding the agreement for the plural of an item that had a spelling error, which was accepted in the final version. Finally, the last comment suggested weighing the materials in the Surgical Center to standardize the scale and asked about mixing blood with other fluids. However, the comment highlighted the importance of bundle and quantification as a low-cost and viable strategy for detection of cases and PPH. The final version of the bundle consisted of nine items after adjustments following suggestions from evaluators (Chart 1). Regarding its usefulness in practice, 12 (86%) experts indicated that it is useful and applicable.

**Chart 1.** Nursing care in the final version of the bundle to quantify vaginal blood loss after childbirth

Item	Description
1	Conduct training at least annually, preferably every six months or when there are important changes in the team, using simulation, for the entire obstetric team on postpartum blood loss quantification
2	Institute a protocol for quantifying vaginal blood loss after childbirth
3	Weigh all drapes and compresses that will be used during birth in advance at the Material Center or during Surgical Center assembly, on a calibrated scale
4	Add weighted cards to the outer surface of birth packages
5	If clots come out, weigh them
6	At the end, subtract wet weight (drapes, compresses, gauze, clots) from dry weight (drapes weighed previously)
7	Record blood loss quantification
8	If postpartum hemorrhage is detected (loss of more than 500 ml), assess patients and initiate interventions, according to the institution's PPH protocol
9	If available at the institution, carry out an assessment of hemoglobin and hematocrit levels upon admission (before birth) and 24 hours after birth

## Discussion

The quantification proposed by the bundle is intended to be a resource to improve the assessment of blood loss after vaginal childbirth.

Vaginal childbirth is a route with greater challenges for measuring blood loss, as it is not possible to control the variables related to other secretions present during labor and immediately post-birth, such as amniotic fluid and urine,<sup>(12)</sup> requiring further studies on the topic.

Quantifying blood loss by visual estimation is a prevalent method.<sup>(25)</sup> It is considered subjective, under the influence of several variables, including the professional who assesses it. Failures are common,

with a tendency to overestimate large losses and underestimate smaller losses.<sup>(11,25-27)</sup>

Like the experts, the literature points out limits to the effective quantification and qualification of blood loss, closely related to the mixing of blood with amniotic fluid or diuresis at birth and the immediate postpartum period, the volume of blood retained in the surgical fields and the differentiation blood loss resulting from episiotomy and/or lacerations.<sup>(6,10)</sup>

Despite the limitations, the comparison between visual estimation versus quantification indicates that quantitative methods are more inclined to more accurate detection of PPH,<sup>(11,12, 28)</sup> with a recommendation for practice. Gravimetry reveals significant differences for PPH diagnosis,<sup>(28,29)</sup> and low cost should be considered in clinical practice.

A bundle evaluator highlighted that, due to the complexity of the technique, it should only be used in specific cases. However, the American College of Obstetricians and Gynecologists and the Association of Women's Health, Obstetric and Neonatal Nurses recommend to quantify bleeding for PPH diagnosis in all childbirth types, applied to low- and high-risk postpartum women.<sup>(11,12)</sup> Furthermore, the creation of protocols and bundles associated with team training for their adoption stands out in the literature.<sup>(11,12)</sup>

In this study, the bundle items that showed the highest agreement (93%) among experts were related to periodic team training, institution of protocols, records of quantification carried out and early intervention in cases of PPH.

Studies indicate that the more the care team is trained in the methods of quantifying postpartum volume loss, the fewer divergences and the more reliable the quantifications are, bringing significant care improvements, reinforcing item 1 of the bundle developed.<sup>(27,30,31)</sup> To this end, using active methodologies is encouraged, with simulation being highly recommended as a strategy. Studies based on simulation show improvement in the recognition of PPH cases after simulated team training.<sup>(27,30,31)</sup> It should be noted that with positive results, there is an exponential increase in using realistic simulation in preparing professionals for emergencies,

more specifically in obstetric emergencies, including PPH.<sup>(31)</sup>

According to the literature, learning, mainly through simulated scenarios for training the multidisciplinary obstetric team, associated with care protocol and/or care bundle implementation, generates a reduction in the cost of diagnostic, therapeutic and emergency identification resources.<sup>(30,32)</sup> They are highly recommended strategies for PPH diagnosis, prompt recognition and treatment. Institutional protocol implementation was one of the items with the highest agreement score.

Another item that obtained a high level of agreement was related to recording blood quantification. Clinical records or documentation are powerful communication tools among health professionals, identifying professionals' performance in the care provided.<sup>(33)</sup> However, when assessing records, a study showed that the outpatient, diagnostic support, Surgical Center and Obstetric Center sectors are those with the highest proportions of missing records in patients' medical records.<sup>(34)</sup> Thus, it is possible to note the relevance of reinforcing the registry, being an extremely important item in the bundle.

In cases of detection of high volumes of blood loss, the bundle recommends the institution of treatment protocols for PPH, which achieved high agreement among experts.

Only training for diagnoses in a timely manner does not guarantee the best results. There is a need to strengthen health services in training professionals to deal with a picture of PPH, which requires changes in institutional philosophy in addition to guaranteeing availability of resources (pharmacological and non-pharmacological) for the clinical management of PPH.<sup>(27,35)</sup> All associated measures are capable of associating better maternal health outcomes.

The clinical response to postpartum blood loss is variable and can be influenced by several factors, such as the volume of blood lost, tolerability to blood loss, general health status, speed of loss, variation in hemoglobin levels throughout pregnancy and the adequate functioning of the coagulation system.<sup>(6,7)</sup> The impact and symptoms of the loss

and evolution of the picture depend on all factors listed.<sup>(27)</sup> Therefore, clinical examination based on women's response to blood loss as the only diagnostic tool is insufficient for detecting PPH, although we cannot fail to value its practice, associated with other strategies.

The association of strategies, such as shock index calculation (result of dividing the heart rate by the systolic blood pressure of postpartum women),<sup>(1,2)</sup> accurate clinical examination, looking for signs of lipothymia and mucous membrane discoloration during the immediate postpartum period, and measurement of hemoglobin and/or hematocrit levels before and after birth,<sup>(6)</sup> which appears in the last item of this bundle to be followed depending on each institutional reality, contributes to early and more assertive identification.<sup>(23-25, 27)</sup> It is also important to highlight that accurate diagnostic methods to quantify postpartum bleeding are effective not only to identify but also to avoid and/or minimize a bad prognosis in cases of already established hemorrhage.<sup>(27)</sup>

Most experts indicated that the constructed bundle is useful and applicable. Two experts cited its non-clinical usefulness/applicability. The issue of long-term applicability was mentioned, since new routines require major changes, including one attitude, and that implementing bundles aiming at treating PPH should be prioritized as well as the recognition of signs of shock, but strongly suggested their use in cases of higher risk for PPH. The second expert pointed out non-agreement of weighing as an assessment measure.

It is recommended to use this bundle in its final version as printed material, easy to view, posted in Obstetric Centers. However, for its effective implementation, it may be made available on health institutions' platforms and intranets. Furthermore, the need for team training and continued education is reinforced for their adherence.

The limitation of this study is the method used, as it is specifically a validity. Other investigations are necessary to verify the applicability of the items listed. However, this bundle is considered valid in terms of content, theme and best level of evidence of care.

## Conclusion

This study made it possible to build and validate a bundle that includes nursing care to quantify vaginal blood loss after childbirth, with a view to prevention, prompt recognition and treatment of PPH cases based on scientific evidence. Care includes team training, establishing protocols, quantifying/measuring bleeding, recording quantification for clinical documentation, recognizing and managing PPH cases, in addition to laboratory quantification of hemoglobin/hematocrit levels, depending on the institutional reality. It is recommended to use this bundle in its final version as printed material, easy to view, posted in Obstetric Centers. However, for its effective implementation, it may be made available on health institutions' platforms and intranets. Furthermore, the need for team training and continued education to raise awareness and promote adherence is reinforced. Furthermore, it is suggested that new studies be carried out on the subject, highlighting results regarding bundle implementation.

## Collaborations

Ruiz MT, Azevedo NF, Resende CV, Silva MPC, Contim D, Santos LM, Wernet M and Linares AM contributed to study design, data analysis and interpretation, article writing, relevant critical review of intellectual content and approval of the final version to be published.

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