




## ORIGINAL ARTICLE

# Quality of life in adolescents with heavy menstrual bleeding: Validation of the Adolescent Menstrual Bleeding Questionnaire (aMBQ)

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## Abstract

**Background/Objectives:** Heavy menstrual bleeding (HMB) affects 34% to 37% of adolescent girls. The Menstrual Bleeding Questionnaire (MBQ) is a validated measure of menstrual bleeding-specific health-related quality of life (HRQoL) for women aged  $\geq 18$  years. No similar measure existed for adolescents with HMB.

**Patients/Methods:** HMB was defined by the Pictorial Bleeding Assessment Chart (PBAC) score  $\geq 100$ . In Phase 1, a focus group of adolescents with HMB adapted the MBQ, to generate the Adolescent MBQ (aMBQ). In phase 2, participants with and without HMB were recruited from clinics and self-referral. Each participant completed 3 questionnaires (aMBQ, Pediatric Quality of Life module [PedsQL]<sup>®</sup>, PBAC) at two time points. Validity of the aMBQ was assessed by Pearson's correlation with the PedsQL<sup>®</sup>. Reliability was calculated using intra-class correlation (ICC) in those without HMB. The receiver operating characteristic curve assessed the aMBQ's ability to identify those with HMB.

**Results:** Phase 1 included five girls with a mean age of 17.1 (13-18) years. The aMBQ was adapted from the MBQ by substituting four words/phrases that altered 8 of the 20 questions and by adding 1 new question. The 21-item aMBQ has a score range of 0 to 77 (77 = worst HRQoL). Phase 2 included 52 participants: 20 with and 32 without HMB, with a mean age of 14.8 (11-17) years. The validity of the aMBQ was confirmed by a moderate correlation with PedsQL<sup>®</sup> ( $r = -0.63$ ;  $P < .001$ ). Test-retest reliability was substantial (ICC = 0.73;  $P = .04$ ). An aMBQ score of  $>30$  identified those with HMB with excellent discrimination (area under the curve = 0.82; sensitivity, 70.0%; specificity, 84.4%).

**Conclusions:** The aMBQ is a valid and reliable tool to assess HRQoL in adolescents with HMB.

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**KEYWORDS**

adolescent, heavy menstrual bleeding, menorrhagia, patient-reported outcome measures, surveys and questionnaires

**Essentials**

- A tool is needed to assess the impact of heavy periods on quality of life (QoL) in adolescents.
- This study took place in a pediatric hospital in Nova Scotia, Canada.
- The Adolescent Menstrual Bleeding Questionnaire (aMBQ) was established.
- The aMBQ measures the impact of heavy periods on adolescent QoL and may identify heavy periods.

## 1 | INTRODUCTION

Heavy menstrual bleeding (HMB), defined as excessive bleeding that interferes with social, emotional, physical, or material quality of life (QoL), is a common problem among adolescents, with a prevalence between 34% and 37%.<sup>1-5</sup> Many aspects of a young person's life may be affected by HMB, including school attendance and participation in social activities, but few studies formally evaluate this.<sup>1,6</sup> Understanding the impact of HMB on health-related quality of life (HRQoL) for adolescents is essential to shared decision making when selecting management that is appropriate for this population.<sup>4</sup> Adolescents with HMB are also at increased risk of developing both iron deficiency and anemia.<sup>7</sup> Twelve percent of adolescents with HMB have required hospital admission for management of anemia, with 5% of these patients requiring intensive care.<sup>3,4</sup>

Identifying HMB is clinically challenging as most women who menstruate are unable to measure their blood flow. The severity of menstrual blood loss is often quantified by unstructured questioning in a clinical encounter and objective measurements, such as by assessing hemoglobin or ferritin.<sup>7</sup> The Pictorial Bleeding Assessment Chart (PBAC) is an objective tool developed to visually correlate the amount of menstrual blood loss using saturation of sanitary products as a guide. A PBAC score  $\geq 100$  has a sensitivity of 86% and specificity of 89% for identifying HMB.<sup>8</sup>

Given the potential physical, emotional, and social consequences of HMB, its effect on well-being or HRQoL must be considered together with physical outcomes in its assessment. However, during a clinical encounter, estimating the effect of HMB on the HRQoL of an adolescent is a challenge. This challenge was identified by Matteson et al<sup>9</sup> in women aged  $>18$  years, which led to the development of the Menstrual Bleeding Questionnaire (MBQ). The MBQ was created using a literature review, a patient focus group, a national survey of gynecologists in the United States, and an expert review.<sup>9</sup> The content of the questions on the MBQ and the response options were generated on the basis of discussions with women in focus groups. Themes generated from the focus group sessions were incorporated into the MBQ, including pain, bleeding history, amount of bleeding, bleeding predictability, and bleeding-related QoL. The MBQ is a patient-reported outcome measure that is valid in adults (aged 18-55 years), with a Cronbach's alpha score of 0.87 to 0.94.<sup>10</sup> Its primary purpose is to measure HRQoL status. However, similar work

to develop and validate an HRQoL measure specific to adolescents aged  $<18$  years is currently lacking.

HRQoL instruments have been shown to have suboptimal performance for measuring the impact of bleeding on HRQoL because the symptom is intermittent and generally not life threatening.<sup>10</sup> Given this, bleeding-specific QoL instruments are needed for clinical care and research. The distinction between adult and pediatric measures is also important, as the components of QoL differ for these two groups.<sup>6</sup> To address this critical need for a measure of bleeding-specific QoL for adolescents, we used the validated MBQ as a foundation to adapt and validate the Adolescent MBQ (aMBQ) for an adolescent population with HMB.

The primary objective of this study was to adapt the MBQ for use in adolescents and to validate it as a tool to measure the impact of heavy menstrual bleeding on adolescent QoL (ie, a measure of status).

## 2 | METHODS

### 2.1 | Design

The study took place over 4 years (2016-2020) and consisted of two phases. Phase 1 examined the relevance of the MBQ to adolescents using a semistructured focus group with the goal of adapting the MBQ to form the aMBQ. Phase 2 evaluated the validity and reliability of the aMBQ. Approval from the institutional Research Ethics Board at the Izaak Walton Killam (IWK) Health Centre was obtained before initiation of the study (Research Ethics Board Number: 1022184). Written informed consent was obtained for all participants in both phases, including the focus group.

### 2.2 | Participants

Adolescent girls, aged  $\leq 18$  years, who were currently attending public/private school, who were able to read and understand English, and who had at least three cycles of menstruation were eligible to participate in this study. Those who had a history of one or more chronic diseases (cancer, asthma, cystic fibrosis, or diabetes) in the previous 12 months or who had 10 or more visits to a health care

provider for any chronic condition in the previous 12 months were excluded from participation in this study.

The minimum sample size required to show that the correlation is in the desired range ( $\alpha = 0.05$ ,  $\beta = 0.20$ ) was 47 total participants.

For the purpose of this study, HMB was defined as a PBAC score  $\geq 100$ .

### 2.3 | Phase 1: Adaptation of the MBQ using a focus group of adolescents with HMB

Two investigators (AC and VP, both experienced pediatric hematologist-oncologists) reviewed the MBQ and determined that it adequately captures the framework of HMB. Based on their clinical experience with adolescents, these investigators considered the language in the MBQ not entirely appropriate for adolescents. For example, critical contexts (eg, school) that are relevant to adolescents are not included in the MBQ. A provisional aMBQ was created on the basis of expert recommendations. (See Supplementary Material).

Female adolescents with HMB, followed by the pediatric hematology service at the IWK Health Centre, were invited to participate in a semistructured focus group. The focus group was held in person in the pediatric hematology clinic, consents were signed, and a confidentiality statement was agreed upon by all participants. HMB and HRQoL were described by the researchers. Participants were asked to independently write down five ways in which HMB impacts their HRQoL and then complete the provisional aMBQ. The group discussed whether any questions were unclear or difficult to understand and then reviewed the five ideas that were listed by each participant. The adolescents then determined whether their ideas were addressed by the provisional aMBQ. The focus group discussion included whether participants felt upset/embarrassed by the questions and whether these feelings would prevent them from answering the questions. At the conclusion of the focus group, the aMBQ was ready for use in phase 2.

### 2.4 | Phase 2: Validity and Reliability of the aMBQ

Phase 2 assessed the validity and reliability of the aMBQ. The aMBQ score is the sum of all responses, with high scores indicating the worst HRQoL. Validity was determined by administering the aMBQ together with the Pediatric Quality of Life Core Module (PedsQL)<sup>®</sup> to two cohorts of adolescents; those with a prior diagnosis of HMB and those without a known diagnosis of HMB (controls), with the a priori hypothesis that the correlation between these two measures would be in the range of  $-0.4$  to  $-0.6$ . The PedsQL<sup>®</sup> is a generic QoL measure with both child self- and parent-proxy report options scored on a scale of 0 to 100, with 100 representing the best QoL.<sup>11</sup> This tool was selected as the generic measure of HRQoL against which the aMBQ would be validated because it has been extensively tested and shown to have excellent reliability and validity. The PedsQL<sup>®</sup> takes <5 minutes to complete.<sup>11</sup>

Control subjects were recruited from the general pediatric and pediatric orthopedic surgery clinics, and via self-referral from participants' peers and family members. Adolescents with HMB were recruited from the pediatric hematology and gynecology clinics. All new referrals were assessed and, if eligible, patients were invited to participate.

The first page of the aMBQ collects demographic information (including age, grade, age of menarche). All participants completed the aMBQ, PBAC, and PedsQL<sup>®</sup> questionnaires at baseline. This was done in a private space in clinic or at home. Participants who completed the questionnaires at home were provided with a postage-paid envelope for return mail.

Controls were asked to complete the aMBQ, PBAC, and PedsQL<sup>®</sup> for a second time, at home, within 61 days, allowing for another menstrual cycle to evaluate test-retest reliability. The follow-up questionnaires were mailed to participants, including a postage-paid return envelope. Participants who consented to be contacted by email received an email notification/reminder from the research team to return their questionnaires.

If any participant had a PBAC score  $\geq 100$  (indicative of possible HMB), their consulting pediatrician was informed to determine if further investigation and management was required. If they were part of the control group, these participants were moved to the HMB group for analyses.

All study participants received a \$10 gift card.

### 2.5 | Analysis

Phase 1 analysis was completed primarily by the focus group facilitators (AC and VP) with the goal of generating a list of modifications required to improve the relevance of the MBQ for use in adolescents. To determine new items that should be added to the questionnaire, related ideas from the focus group were examined using content analysis, based on Charmaz's analysis methods.<sup>12</sup>

Phase 2 analyses included descriptive statistics to summarize the participants' characteristics and the distributions of the aMBQ and PedsQL<sup>®</sup> scores. The summary scores were calculated according to the guidelines for each measure.<sup>9,11</sup> PBAC scores of controls were compared to those with HMB using the Mann-Whitney *U* test. The validity of the aMBQ was assessed in the pooled sample of HMB and control cohorts by calculating Pearson's correlation coefficient with the PedsQL<sup>®</sup> at baseline, with the a priori hypothesis that the result would be in the range of  $-0.4$  to  $-0.6$ . A lower correlation indicates that the construct is no longer constituent with HRQoL and a correlation  $>0.8$  suggests that a bleeding-specific measure may not be required. Internal consistency of the aMBQ was assessed in the pooled sample by examining the Cronbach's alpha at baseline, which measures the average correlations between all of the scale items.<sup>13</sup> The aMBQ scores for controls were compared to those with HMB using a two-sample *t* test. Test-retest reliability of the aMBQ was assessed using a random-effects intraclass correlation (ICC) in the control cohort. ICC values between 0.4 and 0.75 indicate good

correlation.<sup>14</sup> The lower limit of a 90% confidence interval (CI) was computed.

The discriminatory power of the aMBQ was explored across various cutoff scores using multiple measures in the pooled cohort: sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and area under the curve (AUC) using a receiver operating characteristic (ROC). An ROC plots the false-positive rate (1-specificity) against the true-positive rate for a binary classification system; in this case, it illustrates the diagnostic ability of the aMBQ to distinguish between those with and without HMB. The AUC is equivalent to the probability that the aMBQ will discriminate heavy bleeders from controls. An AUC >0.7 indicates acceptable discrimination, with an AUC 0.8–0.9 indicating excellent discrimination.<sup>15</sup> CIs were estimated using the default 2000 stratified bootstrap replicates. Qualitative analyses were organized using Excel (Microsoft, Redmond, WA, USA).

Quantitative analyses were conducted using R version 4.0.1 (R Foundation for Statistical Computing, Vienna, Austria).<sup>16</sup> The “irr” package was used to calculate ICC and the “pROC” package was used to calculate the AUC.<sup>17,18</sup>

## 3 | RESULTS

### 3.1 | Phase 1: Adaptation of the MBQ using a focus group of adolescents with HMB

A total of 4 words/phrases in the MBQ were substituted, altering 8 of 20 questions (Table 1), to develop the provisional aMBQ for use in the focus group. Five female adolescents who experienced HMB, mean age 17.1 (13–18) years, participated in the focus group. With the provisional word/phrase substitutions made to the MBQ, the focus group participants agreed that the questions were relevant and confirmed their understanding of each question. A level of saturation of themes was reached, with the main themes identified as concern about breakthrough bleeding, school absenteeism, fatigue, and bullying. All of these themes were captured by the MBQ with the exception of bullying. The participants subsequently wrote a question stem that was added to the questionnaire: “Are you bullied or teased at school because of your menstrual period leaking through your outer clothes?”

All participants agreed that the aMBQ would be easy to complete in an office setting by any adolescent girl. Based on observation by the focus group facilitators (AC and VP), the aMBQ took ≈10 minutes to complete.

**TABLE 1** Substituted words in the aMBQ replace original words

Original word	Substituted word	Number of question(s) affected
Work	School	4
Sanitary product	Tampon/Pad	4
Incontinence brief	Adult diaper	2

The participants confirmed that none of the questions made them feel embarrassed or upset and endorsed that they were comfortable answering the questions.<sup>12</sup> The investigators noted there was a high level of engagement and interest by the participants of the focus group. The session went twice as long as the expected duration of 1 hour, as the participants wanted to share their experiences. The participants noted the focus group experience to be very therapeutic, helping them realize they are not alone in how HMB impacts their QoL. With the addition of one new question related to bullying, a 21-item aMBQ was established with a score range of 0 to 77, with 77 representing the worst HRQoL (Table 2). Responses to the aMBQ questions were categorical. This final version of the aMBQ was submitted to the IWK Research Ethics Board for approval.

### 3.2 | Phase 2: Validity of the aMBQ

Seventy-five adolescent females participated in the validation of the aMBQ. PBAC scores were received from 51 of the 75 participants (68%). We used the data from these 51 participants (20 with HMB and 31 controls) for validation of the aMBQ. Table 3 summarizes the demographics, clinical characteristics, and outcome scores for the study participants. A ceiling effect was found in the PedsQL<sup>®</sup> Physical domain, with 17.3% of participants scoring the highest possible score, while no ceiling/floor effects were observed in the aMBQ.

By definition, all participants in the HMB group had PBAC scores ≥100. A hemoglobin value was not routinely collected for participants. The mean (standard deviation [SD]) PBAC score for participants with HMB was 217.5 (108.1), which was significantly higher than the mean (SD) PBAC score for controls: 54.6 (25.7) ( $P < .001$ ; Table 3).

The mean (SD) of the aMBQ score for those with HMB was significantly higher at 29.8 (8.5) compared to a mean of 19.6 (7.6) among the control group ( $P < .001$ ; Table 3, Figure 1). Three participants in the control group and two participants in the HMB group submitted an incomplete aMBQ (missing a response to one question each). The missing questions were not consistent among these participants, and therefore it is unlikely that they were intentionally ignored. When the response to a question was missing, the mean value for that question was imputed from others in that group (ie, HMB or control group; Table 3).

The mean (SD) total PedsQL<sup>®</sup> score at baseline for those with HMB was 66.7 (15.3) compared to a mean of 80.8 (11.9) for participants in the control group (Table 3;  $P < .001$ ).

Although the correlation was slightly stronger than expected, the aMBQ fulfilled the expectation related to validity when compared to total PedsQL<sup>®</sup> score ( $r = -0.63$ ;  $P < .001$ ).

### 3.3 | Phase 2: Reliability of the aMBQ

The control group was used to assess test-retest reliability, as adolescents in this group were expected to experience no change in their menstrual bleeding. Of the 31 participants in the control cohort, 14 participants

**TABLE 2** Sample questions from the aMBQ

During your most recent period, on how many days do you think your <i>school</i> work suffered because you were bleeding?
During your most recent period, how many days of <i>school</i> did you miss because you were bleeding?
During your most recent period, on how many days did you plan your activities ( <i>school</i> , social, or family) based on whether or not there was a bathroom nearby?
During your most recent period, on how many days did you bring extra clothes with you (to <i>school</i> , out shopping) in case you had staining from your period?
During your most recent period, how often did you need to wear either an <i>adult diaper</i> or more than one product (either more than one <i>pad</i> , a <i>pad</i> or a <i>tampon</i> , more than one <i>tampon</i> ) at a time to contain your bleeding?
On your heaviest day of bleeding during your most recent period, how many <i>tampons</i> or <i>pads</i> did you soak (either completely or almost completely)?
During your most recent period, how many times did you need to get out of bed in the middle of the night to change your <i>pad/tampon</i> or <i>adult diaper</i> ?
<i>Are you bullied or teased at school because of your menstrual period leaking through your outer clothes?</i>

Note: These questions were adapted from the Menstrual Bleeding Questionnaire for use in adolescents. Substituted words are indicated in italics. The final question is unique to the Adolescent Menstrual Bleeding Questionnaire.

(45%) completed the aMBQ the second time at a median of 38.5 days (range, 32-61 days) from baseline. When analyzing these participants, the test-retest reliability for the aMBQ was substantial (ICC = 0.73; lower limit of 90% CI, 0.43;  $P = .04$ ).<sup>19</sup> The Cronbach's alpha for the aMBQ was 0.82 (95% CI, 0.76-0.89), indicating good internal consistency.<sup>17</sup>

### 3.4 | Discriminatory power

Using the PBAC and aMBQ scores at baseline for all 51 participants, the discriminatory power of the aMBQ was calculated as an AUC of 0.82 (95% CI, 0.70-0.94), indicating "excellent discrimination" (Figure 2).<sup>20</sup> Diagnostic characteristics were evaluated at each possible cutoff score, compared with the definition of HMB based on the PBAC. A cutoff aMBQ score of  $\geq 30$  achieved a sensitivity of 70.0%, specificity of 84.4%, PPV of 73.7%, and NPV of 81.8%.

## 4 | DISCUSSION

This study reports the adaptation of the MBQ to measure HRQoL in adolescents aged  $\leq 18$  years with HMB, the aMBQ. Our data show that it is a valid and reliable tool, with the ability to identify adolescents with HMB and measure its impact on HRQoL. The need for a bleeding-specific measure was reinforced by the finding of the ceiling effect in the PedsQL<sup>®</sup> and the moderate correlation found between the aMBQ and PedsQL<sup>®</sup>. Not surprisingly, the aMBQ scores

**TABLE 3** Demographics, clinical characteristics, aMBQ, and PedsQL<sup>®</sup> scores

	Control group	HMB group
Number of subjects (n = 51)	31	20
Age, y		
Mean (SD)	14.7 (1.6)	14.9 (1.5)
Grade: n (%)		
6-9	12/31 (39)	9/20 (45)
10-12	19/31 (61)	11/20 (55)
Age at menarche, y		
Mean (SD)	12.0 (1.5)	12.6 (1.2)
School days missed due to menstrual bleeding during last academic year		
Mean (SD)	1.1 (2.9)	2.1 (4.5)
PBAC		
Mean (SD)	54.6 (25.4)	217.5 (108.1)
Missing or incomplete, n (%)	0 (0)	0 (0)
aMBQ <sup>a</sup>		
Mean (SD)	19.6 (7.6)	29.8 (8.5)
Missing, n (%)	0 (0)	0 (0)
Incomplete, n (%)	3/31 (9)	2/20 (10)
PedsQL <sup>®</sup> (Total) <sup>b</sup>		
Mean (SD)	80.8 (11.9)	66.7 (15.3)
Missing or incomplete, n (%)	0 (0)	0 (0)

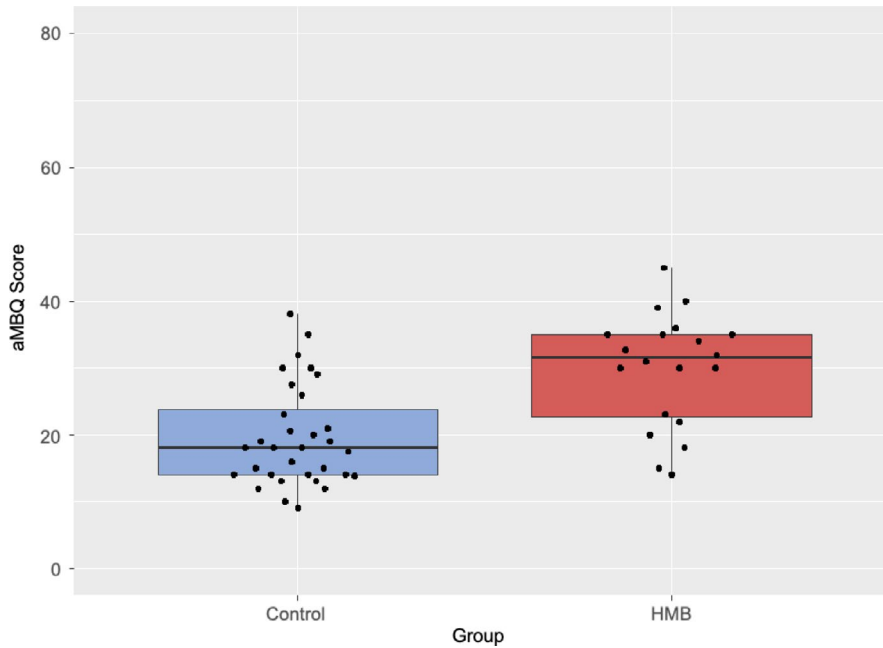
<sup>a</sup>Scale of the aMBQ is 0-77, where 77 indicates worst HRQoL.

<sup>b</sup>Scale of the PedsQL<sup>®</sup> total score is 0-100, where 100 indicates optimal HRQoL.

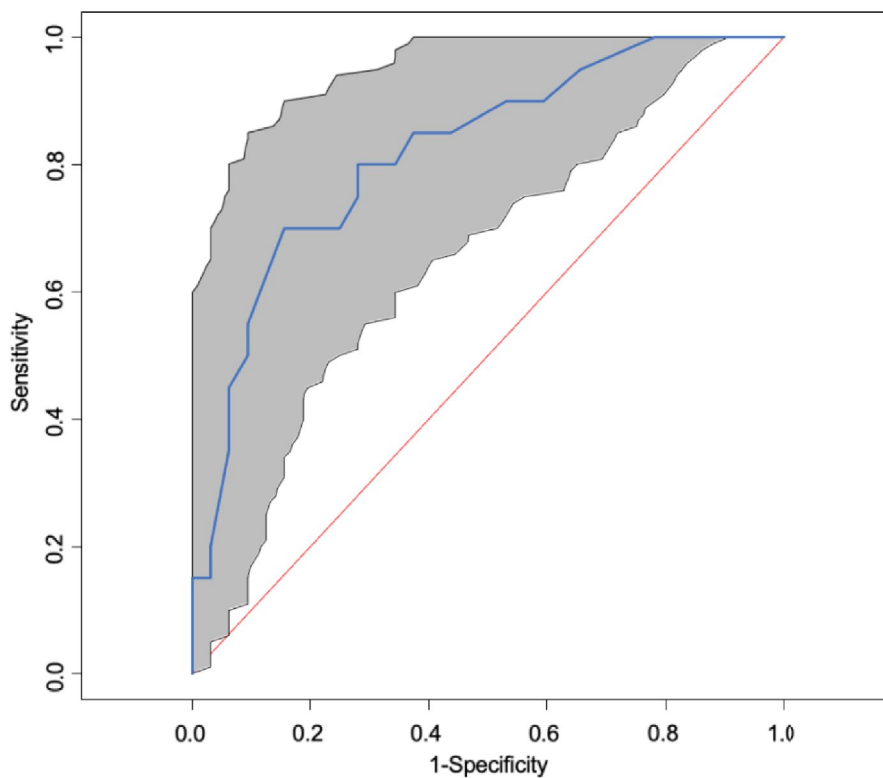
Abbreviations: aMBQ, Adolescent Menstrual Bleeding Questionnaire; HMB, heavy menstrual bleeding; HRQoL, health-related quality of life; PedsQL<sup>®</sup>, Pediatric Quality of Life inventory; PBAC, Pictorial Bleeding Assessment Chart; SD, standard deviation.

were significantly higher in the cohort with HMB compared to controls, denoting a worse HRQoL. This is in keeping with previous reports of adversely affected HRQoL due to HMB, manifesting as school absenteeism, fatigue, and limitations in participation in physical activities as well as socialization.<sup>1</sup> Readers who are interested in using the aMBQ in the clinical setting may contact Dr. Meghan Pike, Principal Investigator.

Adolescents may not inform their caregivers about their menses and may be unfamiliar with what is considered "normal."<sup>21</sup> In this study, six participants in the control group (without a previous diagnosis of HMB) had a PBAC score  $\geq 100$ . This may indicate a lack of recognition of HMB and/or hesitancy in reporting heavy bleeding (eg, due to shyness, embarrassment, or discomfort). Another explanation may be due to clinician discomfort and/or lack of knowledge discussing HMB with adolescents.<sup>21</sup> In this study, 24 adolescents did not return their PBACs, underscoring the challenge in recording use of sanitary products to quantify bleeding. The excellent discriminatory power of the aMBQ, together with the ability to administer it in a private setting without the need for counting menstrual products,



**FIGURE 1** Score for the Adolescent Menstrual Bleeding Questionnaire (aMBQ): controls (left) and participants with heavy menstrual bleeding (HMB) (right)



**FIGURE 2** Diagnostic characteristics of the Adolescent Menstrual Bleeding Questionnaire (aMBQ) using a receiver operating curve (ROC)

makes it an attractive tool to recognize adolescents with HMB. In a busy office setting, the aMBQ may serve to identify those adolescents who should undergo further investigation to identify a possible underlying cause for HMB. On a post hoc analysis, we found that a score of >30 on the aMBQ identified those with HMB with excellent discrimination and a sensitivity of 70.0%. Further study into the sensitivity of the aMBQ is required before its implementation as a screening tool for HMB. Further research will include factor

analyses to identify the most important questions to measure the impact of HMB on HRQoL, and the questions with the best predictive value for identifying HMB, which could be used as screening questions in a busy office setting.

There are several limitations to this study. Only 14 of 31 controls (45%) completed a second set of questionnaires within 61 days. This could be due to forgetfulness but also to the private nature of the topic being studied and the reluctance of adolescents to complete

paper-based questionnaires that may be visible to others in the household. Despite this, the authors believe the study data to be representative of the populations studied, as baseline data from all 51 participants were used to validate the aMBQ and reliability was calculated using only participants in the control group (ie, those expected to experience no change in their menstrual bleeding). The lack of return of paper-based questionnaires, together with the challenges to adapt to research execution within the COVID-19 pandemic, underscore the need for an alternate platform to administer the aMBQ, such as a mobile health application (mHealth app). While technology can assist adolescents in communicating menstrual patterns with health professionals, further research is required to evaluate the administration of the aMBQ using such technology to assist adolescents and clinicians in identifying HMB.<sup>22</sup>

A single focus group with only 5 participants was held to develop the aMBQ. However, all participants were unanimous in their review of the aMBQ in that it was relevant and addressed how HMB affects their HRQoL.

The aMBQ is currently available only in English. To address this, we plan to translate and cross-culturally validate the aMBQ into multiple languages to facilitate its use internationally.

## 5 | CONCLUSIONS

The aMBQ is a novel, valid, and reliable measurement tool to assess HRQoL in adolescents with HMB that is easily implemented in the office setting. Furthermore, it may assist clinicians in identifying those with HMB who may require further investigation for an underlying etiology and management of their bleeding. Further research will include assessment of the aMBQ's responsiveness to change due to interventions to determine its role in monitoring HMB, to determine the minimal clinically important difference in aMBQ scores, as well as translation and cross-cultural validation and development of an mHealth app to further explore its measurement properties.

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## RELATIONSHIP DISCLOSURE

MB is a member and consultant on the board of directors/advisory committees for Roche Canada and Takeda Canada. MB is a member on the board of directors/advisory committee for CSF Behring, Bayer Canada, and Novo Nordisk Canada. KM is a coinvestigator for Bayer Ensure and a member of the board of directors/advisory committee for Myovant, and has received honoraria from the American Board of Obstetricians and Gynecologists that is not related to this study. KU is currently employed at Syneos Health, and all relevant work in this manuscript was completed during his previous employment at the Hospital for Sick Children. The remaining authors on this study do not have any conflict of interests to disclose.

## AUTHOR CONTRIBUTIONS

MP collected data, provided material support, coordinated and supervised data collection, analyzed and interpreted data, drafted the initial manuscript, and reviewed and revised the manuscript. AC conceptualized and designed the study, obtained funding, designed the data collection instruments, collected data, drafted sections of the initial manuscript, and reviewed and revised the manuscript. NLY conceptualized and designed the study, analyzed data, reviewed and revised the manuscript, and critically reviewed the manuscript for important intellectual content. KU carried out data analysis, drafted sections of the initial manuscript, and reviewed and revised the manuscript. MB aided in conceptualization and design of the study, designed the data collection instruments, collected data, and reviewed and revised the manuscript. RM aided in conceptualization and design of the study, designed the data collection instruments, collected data, and reviewed and revised the manuscript. NVE aided in conceptualization and design of the study, designed the data collection instruments, and collected data. AB conceptualized and designed the study, obtained funding, provided administrative and material support, designed the data collection instruments, and collected data. KM conceptualized and designed the study, designed the data collection instruments, reviewed and revised the manuscript, and critically reviewed the manuscript for important intellectual content. VEP conceptualized and designed the study, obtained funding, designed the data collection instruments, collected data, coordinated and supervised data collection, analyzed and interpreted data, drafted sections of the initial manuscript, reviewed and revised the manuscript, and critically reviewed the manuscript for important intellectual content. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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## REFERENCES

1. Nur Azurah AG, Sancil L, Moore E, Grover S. The quality of life of adolescents with menstrual problems. *J Pediatr Adolesc Gynecol*. 2013;26:102-108.
2. Friberg B, Orno AK, Lindgren A, Lethagen S. Bleeding disorders among young women: a population-based prevalence study. *Acta Obstet Gynecol Scand*. 2006;85(2):200-206.
3. Borzutzky MD, Jaffray J. Diagnosis and management of heavy menstrual bleeding and bleeding disorders in adolescents. *JAMA Pediatr*. 2017;174(2):186-194.
4. O'Brien SH. Evaluation and management of heavy menstrual bleeding: the role of the hematologist. *Hematology*. 2018;2018(1):390-398.
5. National Institute for Health and Clinical Excellence. Clinical Guideline: Heavy menstrual bleeding. Available at: <https://pathways.nice.org.uk/pathways/heavy-menstrual-bleeding>. Accessed March 11, 2021

6. Parker M, Sneddon A, Arbon P. The menstrual disorder of teenagers (MDOT) study: determining typical menstrual patterns and menstrual disturbance in a large population-based study of Australian teenagers. *BJOG*. 2010;117:185-192.
7. Wang W, Bourgeois T, Klima J, Berlan ED, Fischer AN, O'Brien SH. Iron deficiency and fatigue in adolescent females with heavy menstrual bleeding. *Hemophilia*. 2013;19(2):225-230.
8. Sanchez J, Andrabi S, Bercaw JL, Dietrich JE. Quantifying the PBAC in a pediatric and adolescent gynecology population. *Pediatr Hematol Oncol*. 2012;29(5):479-484. doi:10.3109/08880018.2012.699165
9. Matteson KA, Scott DM, Raker CA, Clark MA. The menstrual bleeding questionnaire: development and validation of a comprehensive patient-reported outcome instrument for heavy menstrual bleeding. *BJOG*. 2015;122:681-689.
10. Rahn DD, Abed H, Sung VW, et al. Systematic review highlights difficulty interpreting diverse clinical outcomes in abnormal uterine bleeding trials. *J Clin Epidemiol*. 2011;64:293-300.
11. Varni JW, Seid M, Kurtin PS. PedsQL™ 4.0: reliability and validity of the pediatric quality of life inventory™ version 4.0 generic core scales in healthy and patient populations. *Med Care*. 2001;39:800-801.
12. Charmaz K, Denzin N, Lincoln Y. Grounded theory: Objectivist and constructivist methods. In *Strategies of Qualitative Inquiry*. New York: The Guilford Press; 2003; 249-291.
13. Cronbach LJ. Coefficient alpha and the internal structure of tests. *Psychometrika*. 1951;16:297-333.
14. Fleiss JL. *The Design and Analysis of Experiments*. John Wiley & Sons; 1986.
15. Nunnally JC, Bernstein IR. *Psychometric Theory*, 3rd edn. McGraw-Hill; 1994.
16. R Core Team. *R: A Language and Environment for Statistical Computing*. R Foundation for Statistical Computing; 2020. <https://www.R-project.org/>
17. Gamer M, Lemon J, Fellows I, Singh P. irr: various coefficients of interrater reliability and agreement. R package version 0.84.1. 2019. <https://CRAN.R-project.org/package=irr>
18. Robin X, Turck N, Hainard A, et al. pROC: an open-source package for R and S+ to analyze and compare ROC curves. *BMC Bioinformatics*. 2011;12(1):1-8.
19. Landis RJ, Koch GG. The measurement of observer agreement for categorical data. *Biometrics*. 1977;33:159-174.
20. Hosmer DW, Lemeshow S. *Applied Logistic Regression*. Wiley; 2013:177.
21. Committee on Adolescent Health Care. Menstruation in girls and adolescents: using the menstrual cycle as a vital sign. Committee opinion no. 651. American College of Obstetricians and Gynecologists. *Obstet Gynecol*. 2015;126:e143-e146.
22. Fowler LR, Gillard C, Morain S. Teenage use of smartphone applications for menstrual cycle tracking. *Pediatrics*. 2020;145(5):e20192954.

### SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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