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Hansen, Rasmus Sogaard; Vinholt, Pernille Just

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ORIGINAL ARTICLE

Prevalence of Bleeding Symptoms in Denmark Using the Patient-administered Bleeding Assessment Tool (self-BAT)

Rasmus Søgaard Hansen[1,2] | **Pernille Just Vinholt**[1,2]

[1]Dept. of Clinical Biochemistry, Odense University Hospital, Odense, Denmark

[2]OPEN, Open Patient data Explorative Network, Odense University Hospital, Odense, Denmark

Correspondence
Rasmus Søgaard Hansen, Dept. of Clinical Biochemistry, Odense University Hospital, J.B. Winsløws Vej 4, DK-5000 Odense C, Denmark.
Email: Rasmus.Sogaard.Hansen@rsyd.dk

Abstract

Introduction: The patient-administered bleeding assessment tool (self-BAT) is a screening tool developed to identify individuals in need of work-up for bleeding disorders. Nonetheless, large studies on self-BAT scores on healthy individuals according to gender and age are lacking.

Aim: Determine cut-offs for abnormal total score of self-BAT and investigate the prevalence of bleeding symptoms in blood donors and individuals representative of the general Danish population.

Methods: Blood donors, 15,600 children (<18 years) and 18,200 adults from the general Danish population, were invited to complete a Danish version of the self-BAT. To determine cut-offs for abnormal total self-BAT score, findings from healthy young children (0–11 years old), healthy adolescents (12–17 years old), healthy adult women and healthy adult men were used.

Results: Among healthy young children (244 girls, 260 boys), healthy adolescents (58 girls, 83 boys), healthy women ($n = 437$) and healthy men ($n = 278$) from the general population, along with healthy blood donors (116 women, 176 men), the 95th percentile for total score was two for young girls, three for young boys, four for adolescent girls, three for adolescent boys, eight for women and four for men.

Conclusion: Our findings indicate that the abnormal total self-BAT score is ≥3 for girls aged 0–11 years old, ≥4 for boys aged 0–11 years old, ≥5 for girls aged 12—17 years old, ≥4 for boys aged 12–17 years old, ≥9 for women and ≥5 for men. To establish the accuracy of these cut-offs for diagnosing bleeding disorders, further studies are needed.

KEYWORDS
bleeding, blood donor, children, general population, prevalence

1 | INTRODUCTION

To identify individuals with a potential bleeding disorder, a detailed bleeding history is central.[1,2] The International Society for Thrombosis and Hemostasis (ISTH) has developed a Bleeding Assessment Tool (ISTH-BAT) which has been amended into a patient-administered version (self-BAT).[3,4] The result of the self-BAT is a numerical score reflecting the patient's overall bleeding history.[4–6] If the self-BAT score

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is above a cut-off, a work-up for bleeding disorders is recommended.[4] A study from the 'Let's Talk Period!' project indicates that a large proportion of responders have self-BAT scores above the cut-off.[7] A reason could be that the existing self-BAT cut-offs were derived from 65 healthy individuals.[4] Another reason could be that the 'Lett's Talk Period!' project primarily included women in their reproductive years, focusing on menstrual bleeding.[7] Large studies on self-BAT scores for healthy individuals from the general population are lacking. Therefore, this study investigates the prevalence of bleeding symptoms in blood donors and individuals representative of the general Danish population. This is done to establish what normal bleeding is in Denmark and investigate cut-offs for self-BAT scores.

2 | METHODS

We performed an observational cohort study of blood donors and the general Danish population. Blood donors were invited to establish cut-offs for self-BAT scores in adults, whilst individuals representative of the general population were invited to validate the results of the blood donors and establish cut-offs for self-BAT scores in children.

2.1 | Self-BAT

In accordance with guidelines for cross-cultural adaption of self-reported measures, our research group translated the self-BAT from English to Danish.[8,9] Thereafter, the self-BAT was tested and validated in a Danish setting.[8] The questionnaire was computerised in Research Electronic Data Capture (REDCap) (Vanderbilt University, Nashville, Tennessee, United States).[10,11] Data were collected and managed using REDCap electronic data capture tools. The data were hosted at Odense University Hospital on an encrypted website which met the requirements for data protection at the time of study.

Due to local regulations at the time of study, we amended the patient information page to only include questions on gender, age, region of living, and the question (translated from Danish): 'Are there cases of bleeding in your family' (yes/no). To help determine if included blood donors and individuals from the general Danish population could be considered healthy, we included the following three questions (translated from Danish): (1) 'Do you take prescription medication (yes/no)', (2) 'Have you been hospitalised within the past five years (yes/no)', and (3) 'Have you attended hospital for ambulant check-up of a disease within the past five years (yes/no)'. The amended Danish self-BAT is disclosed in the Supplementary Material 1.

2.2 | Healthy

A healthy person was defined as an individual who: (1) did not use any prescription medications, (2) had not been admitted to hospital in the past 5 years, (3) had not attended ambulant check-ups at hospital in the past 5 years, and (4) was not pregnant at the time of answering the questionnaire.

2.3 | Cohort

Inclusion criteria and group constitutions are depicted in supplementary material 2.[12] We contacted all blood banks in Denmark and invited them to distribute paper flyers with information on the project in their waiting rooms. Between 25 March 2021 and 31 June 2021, individuals visiting blood banks for blood donation could access an encrypted website that forwarded them to self-BAT in REDCap where they could complete the questionnaire.

The Danish Health Data Authority formed a cohort of 33,800 individuals reflecting the general Danish population based on gender and age.[13] The cohort consisted of 2600 individuals per age interval (0–2, 3–5, 6–8, 9–11, 12–14, 15–17, 18–30, 31–40, 41–50, 51–60, 61–70, 71–80, and ≥81 years) with an equal gender distribution (1300 women/girls and 1300 men/boys). All individuals in the cohort were forwarded a letter of invitation using the national digital postbox e-Boks® (PostNord and Nets, Hellerup, Denmark). In the letter, the project was described, and a unique code was provided to the self-BAT on an encrypted website connected to REDCap. This met the requirements for data protection at the time of study. According to law, children (< 18 years old) were not allowed to be contacted directly. Instead, each child's mother was contacted. If no mother was cohabiting with the child, no mother was registered as parent, or the mother did not fulfil the criteria depicted in supplementary material 2, the father was contacted.

One month after invitation, we assessed the questionnaire answers. We excluded individuals without e-Boks®, individuals not completing the questionnaire and individuals reporting answers not physically possible (e.g., menorrhagia in newly born children).

Included individuals were categorised according to gender, self-reported age and whether they were considered 'healthy'. Three age categories was constituted: Young children (0–11 years old), adolescents (12–17 years old) and adults (≥18 years old).

2.4 | Statistics

Data for healthy individuals were evaluated to determine cut-offs for abnormal total self-BAT score using both a nonparametric and a parametric approach.[4,5,14] The nonparametric approach was like other self-BAT studies that exclude outliers outside the range of mean ± three standard deviations (SD).[4,5] This was followed by calculating the 95th percentile for the total score which was then used as cut-off for abnormal total score.[4,5] In the parametric approach, Box-Cox transformation was applied to the non-zero parts of the data. Under the assumption of normality of the transformed score, the information from the transformed non-zero data were combined with the proportion of zeros using the Law of Total Probability to yield a parametric estimate of the 95% percentile of the total score.[14] Subsequently, the cut-offs for healthy individuals were applied on the whole cohort of included individuals to determine the prevalence of abnormal self-BAT scores in the general population.

Self-BAT scoring was based on the scoring table used by the developers of the self-BAT.[4] A significant bleeding symptom was defined as

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a score of 1 or more.[3] The existing self-BAT cut-offs for total score are defined as ≥6 for women and ≥4 for men.[4] Self-BAT has not been used for addressing bleeding history in children before. Therefore, no existing cut-offs exist.

2.5 | Ethics

The study was conducted in agreement with the tenets of the Declaration of Helsinki and the principles of good clinical practice. The Danish Data Protection Agency approved the study (Journal number: 21/40051). Since it was a questionnaire study, local ethics committee permission was not required according to Danish law.[15]

3 | RESULTS

In total, 482 blood donors and 3924 individuals from the general Danish population completed self-BAT (Table 1).

3.1 | Healthy individuals

In total, 553 women, 454 men, 58 adolescent girls, 83 adolescent boys, 244 young girls and 260 young boys were considered healthy. Cut-offs for abnormal total self-BAT is presented in Table 1. The cut-off for abnormal total self-BAT score was higher in women than men, higher in adolescent girls than young girls, and higher in adults than children of the same gender.

Equal cut-offs for abnormal total self-BAT score were found in healthy blood donors and healthy adults from the general population. Combining data for healthy blood donors and healthy individuals in the general population ($n = 1007$) did not change the cut-offs for abnormal total self-BAT score of women nor men.

Distribution of total self-BAT scores according to gender and age is presented in Figure 1. In healthy adults, the most common bleeding symptom was menorrhagia and 'other bleedings', while epistaxis, cutaneous bleeding and bleeding from minor wounds were the most common bleeding symptoms in children (Figure 2).

3.2 | Prevalence of bleeding and distribution of total self-BAT scores in the general population

Overall, 14% of women and 32% of men had no significant bleeding symptom from any organ (Figure 3). When applying the existing cut-offs for abnormal score to the sample from the general population, 32% of women and 24% of men had abnormal scores. When applying the proposed cut-offs identified in healthy individuals using the non-parametric approach, 14% of women, 15% of men, 5% of adolescent girls, 5% of adolescent boys, 9% of young girls, and 4% of young boys had abnormal score. When applying the proposed cut-offs identified in healthy individuals using the parametric approach 10% of women, 10% of men, 5% of adolescent girls, 5% of adolescent boys, 9% of young girls, and 8% of young boys had abnormal score

In total, 203 individuals reported cases of bleeding in their family. Of individuals reporting cases of bleeding in their family, the mean ± SD for total self-BAT score was 5.1 ± 4.8 compared to 2.7 ± 3.2 in individuals reporting no cases of bleeding in their family.

4 | DISCUSSION

For healthy blood donors and individuals in the general population, we found the same cut-offs for abnormal score, indicating a robust questionnaire and findings.

4.1 | Discrepancy between the existing self-BAT cut-offs and our findings

Comparing self-BAT and ISTH-BAT should be done very cautiously as the self-BAT includes questions on abortion and bleeding in relation to intercourse which the ISTH-BAT does not.[3,4] Yet, the existing self-BAT cut-offs are equal to that of the ISTH-BAT.[3,4] The selection criteria in the existing self-BAT cut-off study differ from the present study as persons with known problems with bleeding or bruising were excluded in the existing self-BAT cut-off study.[4] This may lead to lower bleeding scores in the population compared to assessing a population where bleeding is not an exclusion criterion like in our study. Congruently, we found a high frequency of cutaneous bleeding (13%) and bleeding from minor wounds (20%) in adults considered healthy. This may to some extent explain the higher cut-offs for abnormal bleeding in the present study.

4.2 | Prevalence of abnormal total self-BAT score in the general population

Self-BAT is intended as a screening tool for identifying individuals needing work-up for bleeding disorders. Therefore, it is important to test how many individuals have an abnormal score. When applying the existing cut-offs on adults from our general population cohort, 32% of women and 24% of men had abnormal total score. In the 'Lett's Talk Period!' study, 45% had abnormal total score.[7] Considering that the estimated prevalence of von Willebrand disease in highly developed countries is .09% and Haemophilia A is around .01%, a self-BAT abnormal rate of 24%–45% is very high.[16,17] When applying our proposed cut-offs on the general population cohort, 14% of women and 15% of men had an abnormal score. This is still a high proportion. Consequently, further clarification of when to perform diagnostic work-up for bleeding disorders in individuals with abnormal self-BAT score is needed. Both the existing cut-offs and the proposed cut-offs contain a risk of overinvestigation. Therefore, further studies on the self-BAT scoring key are needed. The importance of anatomical location of the bleeding, the importance of disposition to bleeding, and the importance of number of organ specific bleedings could be relevant to investigate to determine the optimal use of the self-BAT. Therefore, decisions on whether to perform work-up for

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TABLE 1 Characteristics of respondents

Healthy individuals	(*n*)	Age	Total self-BAT score		Total self-BAT cut-offs			
			Mean ± SD	Max	P 95%	Abnormal score	NP 95th	Abnormal score
0–11 year old girls	244	6 ± 3	.5 ± .9	6	2	≥3	2	≥3
0–11 year old boys	260	5 ± 3	.7 ± 1.1	6	2	≥3	3	≥4
12–17 year old girls	58	14 ± 2	1.4 ± 1.3	4	4	≥5	4	≥5
12–17 year old boys	83	14 ± 2	1.0 ± 1.3	6	3	≥4	3	≥4
General population – Women	437	49 ± 15	3.3 ± 2.9	16	9	≥10	8	≥9
Blood donor – Women	116	41 ± 13	3.1 ± 2.8	14	9	≥10	8	≥9
General population – Men	278	53 ± 15	1.6 ± 1.8	9	5	≥6	4	≥5
Blood donor – Men	176	44 ± 14	1.6 ± 1.6	8	5	≥6	4	≥5
Women	553	47 ± 15	3.3 ± 2.9	16	9	≥10	8	≥9
Men	454	49 ± 16	1.6 ± 1.7	9	5	≥6	4	≥5

All individuals	(*n*)	Age	Total self-BAT score	
			Mean ± SD	Max
0–11 year old girls	360	6 ± 3	.6 ± 1.0	6
0–11 year old boys	394	5 ± 3	.8 ± 1.3	12
12–17 year old girls	116	14 ± 2	1.7 ± 1.6	7
12–17 year old boys	119	14 ± 2	1.2 ± 1.7	12
General population – Women	1716	52 ± 17	4.4 ± 3.8	24
Blood donor – Women	247	41 ± 14	3.4 ± 2.9	16
General population – Men	1219	63 ± 16	2.3 ± 2.7	32
Blood donor – Men	235	45 ± 14	1.7 ± 1.6	7
Women	1963	50 ± 17	4.3 ± 3.8	24
Men	1454	59 ± 17	2.2 ± 2.6	32

Age was reported in years as mean ± standard deviation (SD). Presented is the mean ± SD, the parametrically (P) calculated 95% percentile and nonparametrically (NP) calculated 95th percentile for total patient-administered bleeding assessment tool (self-BAT) score according to gender and age of individuals considered healthy. Presented is also the mean ± SD for total self-BAT score and age of all included individuals. In the parametric approach, Box-Cox transformation was applied to the non-zero parts of the data. Under the assumption of normality of the transformed score, the information from the transformed non-zero data were combined with the proportion of zeros using the Law of Total Probability to yield a parametric estimate of the 95% percentile of the total score (14). The nonparametric approach was like other self-BAT studies that exclude outliers outside the range of mean ± three standard deviations (SD) (4, 5). This was followed by calculating the 95th percentile for the total score which was then used as cut-off for abnormal total score (4, 5)

A healthy person was defined as an individual who: (1) did not use any prescription medications, (2) had not been admitted to hospital in the past 5 years, (3) had not attended ambulant check-ups at hospital in the past 5 years, and (4) was not pregnant at the time of answering the questionnaire. "Women" and "Men" constitute the combined cohort of blood donors and general population.

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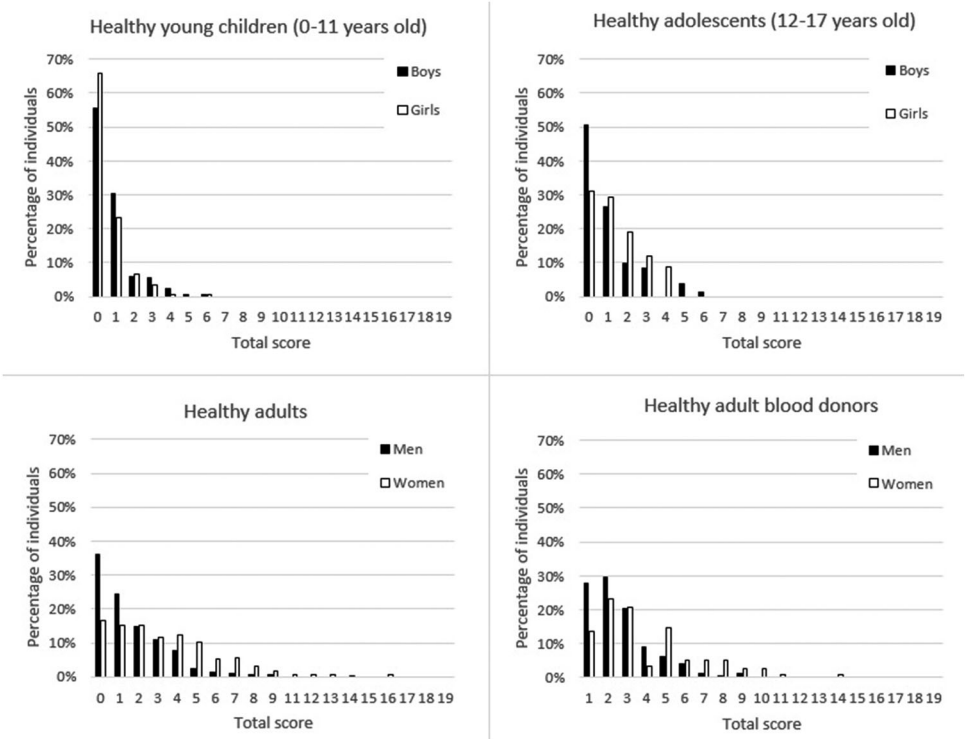

FIGURE 1 Distribution of total patient-administered bleeding assessment tool (self-BAT) scores for healthy young children (0–11 years old) ($n = 504$), healthy adolescents (12–17 years old) ($n = 141$), healthy adults from the general population ($n = 715$), and adult blood donors considered healthy ($n = 292$). A healthy person was defined as an individual who: (1) did not use any prescription medications, (2) had not been admitted to hospital in the past five years, (3) had not attended ambulant check-ups at hospital in the past five years, and (4) was not pregnant at the time of answering the questionnaire.

bleeding disorders or not should still be conducted by a haemostasis expert.

4.3 | Children and adolescents

We expected an increase in bleeding scores upon puberty due to menarche among females. Therefore, we divided children into young children and adolescents according to puberty age. We found that the cut-offs for abnormal total self-BAT score was ≥3 in girls aged 0–11 years old and ≥5 in girls aged 12–17. This indicates that menarche causes an increase in the total self-BAT score of females. Thus, females undergoing bleeding assessment should be evaluated according to puberty status.

4.4 | Strengths and limitations

The strengths of this study is the high number of included individuals from all ages and the inclusion of two populations of healthy individuals. We expect that our findings could be extrapolated to other high-income countries,[18,19] but our cut-offs should be verified before implementation.

According to guidelines, a nonparametric approach is preferred for determining reference intervals.[14] However, for the nonparametric approach, ≥120 samples are recommended. Therefore, a parametric approach could be considered for smaller sample sizes.[14] In the present study, we applied both a nonparametric and a parametric approach for determination of self-BAT cut-offs on all groups. The calculated cut-offs was lower when using the nonparametric instead of the parametric approach. The main reason behind this difference is the lack of outlier exclusion when using the parametric approach. Interestingly, in adolescents where the sample sizes were small, the nonparametric and parametric approach resulted in the same cut-offs.

This study also has limitations which needs to be addressed: The self-BAT is based on bleeding episodes throughout life, and is limited by a life-long recall period. In general, questionnaire research is limited by selection bias. However, the general population cohort was randomly sampled and included all ages, potentially reducing this bias. Still, 55% of included individuals were females, indicating a minor gender bias. The response rate was 9%–26% for adults, with the lowest response rate in young adults (18–30 years) and the highest in adults aged 61–70 years old. The response rate was 4%–9% for children. Taking our method into consideration, the response rate is acceptable. Based on the response rate, a broad spectrum of the Danish population is included, hopefully mimicking the general population. However, responders could be individuals with more bleeding symptoms than non-responders, causing the prevalence of bleeding to be overestimated.

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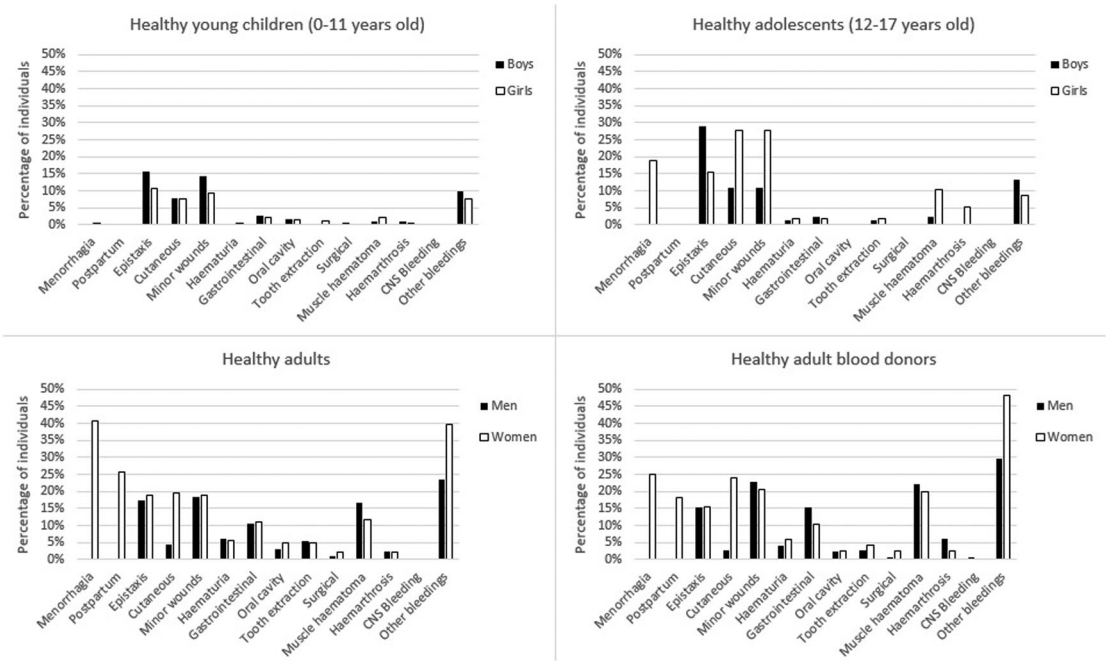

FIGURE 2 For healthy young children (0–11 years old) ($n = 504$), healthy adolescents (12–17 years old) (n = 141), healthy adults from the general population ($n = 715$), and adult blood donors considered healthy ($n = 292$), the percentage of individuals with a significant bleeding score (score equal to or above 1) stratified by anatomical location of the bleeding. A healthy person was defined as an individual who: (1) did not use any prescription medications, (2) had not been admitted to hospital in the past five years, (3) had not attended ambulant check-ups at hospital in the past five years, and (4) was not pregnant at the time of answering the questionnaire. Menorrhagia and postpartum bleeding was only assessed for women. CNS, Central nervous system.

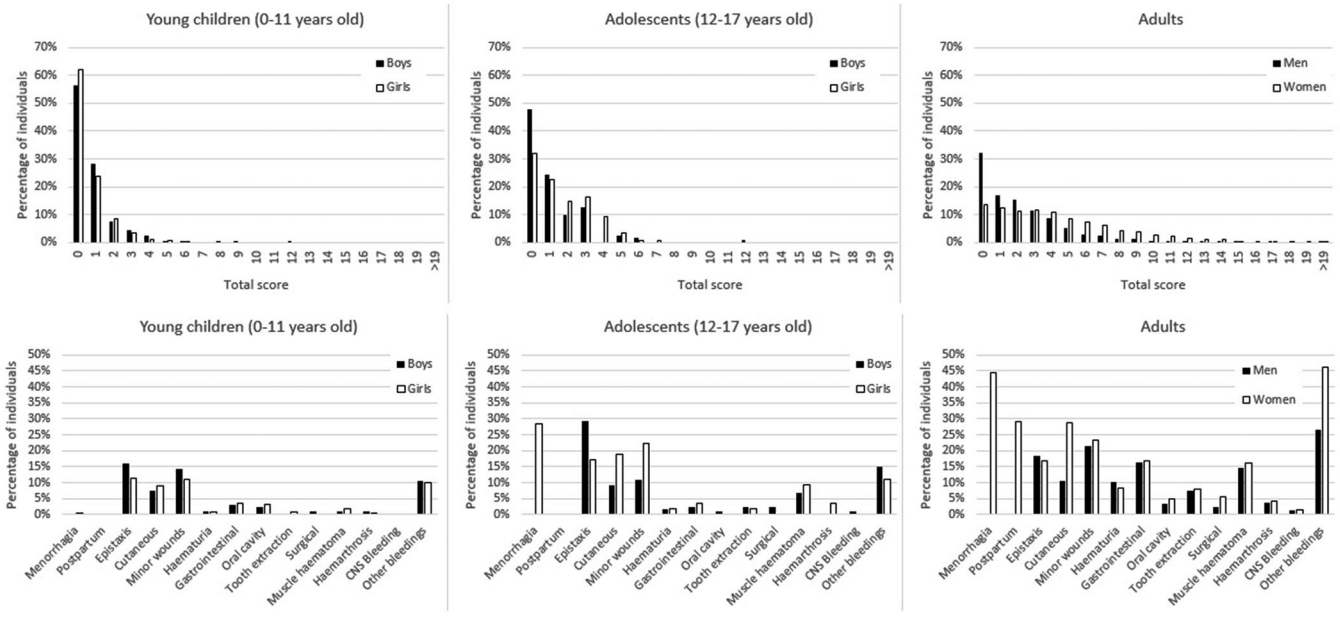

FIGURE 3 Distribution of total patient-administered bleeding assessment tool (self-BAT) scores and the percentage of individuals with a significant bleeding score (score equal to or above 1) stratified by anatomical location of the bleeding for individuals from the general Danish population (young children (0–11 years old) ($n = 754$), adolescents (12–17 years old) ($n = 235$), and adults ($n = 2935$)). Menorrhagia and postpartum bleeding was only assessed for women. CNS, Central nervous system.

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The findings in young children could be subjected to proxy response bias as the parents had to complete the self-BAT on their behalf. Lastly, individuals with unknown minor bleeding disorders could potentially be classified as healthy according to our criteria. However, in addition to our criteria, there are strict criteria for being a blood donor,[12,20] limiting the risk of including individuals with an unknown minor bleeding disorder. We found the same cut-offs in blood donors and healthy individuals in the general population, indicating that this limitation probably did not affect the findings. However, as diagnostic work-up on included individuals was not possible in this study, our findings need to be tested in a clinical setting with diagnostic work-up performed on all included individuals.

5 | CONCLUSION

Our findings indicate that the abnormal total self-BAT score is ≥3 for girls aged 0–11 years old, ≥4 for boys aged 0—11 years old, ≥5 for girls aged 12–17 years old, ≥4 for boys aged 12–17 years old, ≥9 for women and ≥5 for men. To establish the accuracy of these cut-offs for diagnosing bleeding disorders, further studies are needed.

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CONFLICT OF INTEREST

The authors stated that they had no interests which might be perceived as posing a conflict or bias.

ETHICS STATEMENT

The study was conducted in agreement with the tenets of the Declaration of Helsinki and the principles of good clinical practice. The Danish Data Protection Agency approved the study (Journal number: 21/40051). Since it was a questionnaire study, local ethics committee permission was not required according to Danish law.

DATA AVAILABILITY STATEMENT

Research data are not shared.

ORCID

Rasmus Søgaard Hansen https://orcid.org/0000-0002-5588-5489

Pernille Just Vinholt https://orcid.org/0000-0002-2035-0169

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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