Setting Standards for Appropriate and Necessary Care for Young Women with Heavy Menstrual Bleeding and Bleeding Disorders: An International Panel Survey

A joint project from: Women’s Issues in Thrombosis and Hemostasis and Pediatric and Neonatal Thrombosis Hemostasis Subcommittee

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Description

Abstract:
Heavy menstrual bleeding (HMB) at the time of menarche is common and historically attributed to immaturity of the hypothalamic-pituitary-ovarian axis. A decade of clinical experience and research has now established firmly that bleeding disorders (BDs) are common in adolescents with HMB. Guidelines for HMB and BD evaluation in adolescents suggest a variety of strategies for diagnosis and management, reflecting the lack of high-quality evidence demonstrating the superiority of any one approach. It is unclear whether clinicians and at times, even BD and HMB experts, agree on the diagnostic work-up and whether this impacts their decision-making and treatment approaches. Expert consensus is needed as a first step to define appropriate and necessary care for adolescents with HMB and BDs in the absence of randomized clinical trials.

This project aims to address the following question: Among adolescents with heavy menstrual bleeding (HMB) and bleeding disorders (BD), what constitutes “appropriate” and “necessary” standard of care for diagnosis and management?

Design and methodology (Data expected to collect, sample size and statistical analysis):
Cross-sectional appropriateness survey using RAND 1/ExpertLens survey methodology with blinded outcome ascertainment, consisting of 3-4 rounds of elicitation.

Participants/Panelists:
Consecutive sample of 50 international experts who meet eligibility criteria as identified by a pre-survey sent directly by the research team based on renown in the field.

Eligibility Criteria
1. ≥10 years of clinical experience in the fields of:
   a. Adult or pediatric hematology
   b. Adult or pediatric/adolescent gynecology
   c. Adolescent Medicine
2. Having specific expertise in the field of women and bleeding disorders, defined as “currently evaluates and treats at least 5 or more post-menarcheal females through age 21 per week, with heavy menstrual bleeding with or without bleeding disorders” and/or “is part of or leads a Hemophilia Treatment Center” and/or “is part of or leads a Women’s Hematology Program/Clinic.”
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3. Must have shown a willingness to participate and devote time to complete individual survey rounds within 4 weeks of receipt before survey initiation.

Study population (Inclusion, exclusion, eligibility) (patient population; recruitment of participating institutions/physicians and subjects; minimum number needed; expected number):

Not applicable for this project.

Expected timeline:

Determining the expert panel: 4 months
Developing RAND questionnaire and refinement of statements: 4 months
Completing 3-4 rounds of elicitation: 6 months (pending funding)
Manuscript writing: 4 months

Expected outcomes (i.e. publications):

A peer-reviewed manuscript.

Publication type (SSC Communication, Guidance document or original article):

Original article

Timeline: Completion of the project and manuscript: 2019

Description of project set/up and management, needed infrastructure and resources (summary): Most critical element will be obtaining funding to support costs of the online RAND survey platform. This will be an IRB exempt study, so once funding is procured, the project can start right away.

References: