

A Five-Year International Review Process Concerning Terminologies, Definitions, and Related Issues around Abnormal Uterine Bleeding

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ABSTRACT

Over the past decade there has been an increasing realization about the extent of confusion associated with the many terminologies used to describe abnormal uterine bleeding (AUB). This led to the organization of an international workshop of 35 experts from 15 countries in Washington, D.C., USA, in 2005, which addressed the confusions and controversies around AUB. The workshop comprehensively addressed anomalies in the terminologies, definitions, and causes of AUB. It also began to address broader issues including investigations, quality of life, the need for structured symptom questionnaires, cultural aspects, and future research needs. This workshop led to a series of recommendations and publications and to the establishment of the International Federation of Gynecology and Obstetrics (FIGO) Menstrual Disorders Working Group. Since then, a series of international presentations and small group workshops has resulted in a wide awareness of the program and a comprehensive series of recommendations and publications. A particularly influential large-scale interactive workshop with 600 attendees was held during the 2009 FIGO World Congress, which demonstrated the broad acceptability of the current recommendations. This article describes the process leading to the development of international recommendations on terminologies, definitions, and classification of causes of AUB and the establishment of the FIGO Menstrual Disorders Working Group.

KEYWORDS: Menorrhagia, dysfunctional uterine bleeding, terminology, definitions

Confusion concerning terminologies, definitions, and related issues around abnormal uterine bleeding (AUB) has led to difficulties in interpreting the results of clinical trials of both pharmacological inter-

ventions and surgical procedures. Further lack of consistency in use of terminology and definitions has confused understanding of studies investigating underlying mechanisms of both normal and abnormal uterine

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bleeding. Clinicians and the community use various terms to describe menstrual bleeding complaints. The terms in current common use encompass descriptive as well as diagnostic terms and phrases, and the same terms are used in various ways in different countries.^{1,2}

In 2005 this confusion was deemed sufficiently timely and important that a major international expert group was convened to develop an agreement process with the aim of recommending clear, simple terminologies and definitions that would have the potential for wide acceptance.^{3,4} Inherent in this initiative was the need for discussion to be an ongoing process. The importance of group processes for establishing consensus was highlighted by the World Health Organization Advisory Committee on Health Research.⁵ Publication of the details and outcome of the Washington meeting has met with positive support. For example, correspondence followed with recognition that an international standardization of terminologies used to describe AUB and of a definition that sets the boundaries of normal menstrual bleeding would be of benefit to clinicians and researchers.⁶

The initial workshop with international clinical and nonclinical representation took place in Washington, D.C., USA, in February 2005; several articles on the topic have been subsequently published,²⁻⁴ and the International Federation of Gynecology and Obstetrics (FIGO) 2009 meeting in Cape Town provided a forum to present, discuss, and receive feedback from the international gynecologic community.

Hence it is now timely to review the progress made if the overall aim remains to achieve good international agreement of terminologies and definitions to simplify the interpretation of clinical trials, treatment responses, and scientific studies of mechanisms.

THE PROCESS: THE WASHINGTON MEETING

A widespread consultation was undertaken with relevant international and national organizations, journal editors, and individuals, and a modified "Delphi process" (see later) was developed to determine current use of terminologies, followed by a structured face-to-face meeting of 35 experts in the field (mostly gynecologists) in Washington, D.C., in 2005. During the inaugural meeting in Washington, a multistage process was used to discern the level of then agreement on common terminology for menstrual disorders. The process is described in full in the initial two simultaneous publications,^{3,4} and the stages of this iterative process are summarized here.

In brief, it was *first* necessary to examine current use of terms pertaining to menstrual disorder. Next a review of a wide range of historical and recent published literature was required using three key terms commonly used to describe menstrual disorders: *menorrhagia*,

abnormal uterine bleeding, and *dysfunctional uterine bleeding*. The choice of terms selected reflected the three most commonly used terms to describe bleeding symptoms, signs, and potential etiology. The literature search included clinical trials, review articles, and well-read popular gynecologic textbooks. The intention at this stage was not to review the clinical literature on the topic exhaustively but rather to explore how common terms were defined and used. This rewarding exercise generated a review focusing on the confusion in current and historical terminology and definitions for disturbances of menstrual bleeding.² The review confirmed an absence of agreement concerning use of key terms to describe symptoms and signs of menstrual complaints.

The *second* stage was to implement a "Delphi process" using a modification of the validated RAND/UCLA panel method to determine disagreements. The Delphi process has been used for the past 50 years to study issues in business, public policy, science, and technology. The process was initially described in the 1950s. The Delphi approach is a nominal group process designed to determine opinion on a clearly defined topic.⁷ This approach has been used to develop guidelines on clinical topics including hysterectomy, coronary revascularization, and colonoscopy.⁸⁻¹⁰ Furthermore it is reported that clinical use of guidelines developed using a modified "Delphi process" may improve outcomes.¹¹

The goal of our international expert group was to develop an agreed terminology with utility for clinicians caring for women with menstrual complaints.

Members of the expert panel were identified to represent the international community of gynecologists and related clinicians and scientists (membership listed at the end of the article). Importantly the expert group included participants from the developing as well as developed nations. At this stage we recognized limitations of the proposed exercise because this initial process would inevitably not represent the whole wider medical and community views. Individual participants were identified if they held a track record for speaking and writing on issues relevant to disturbances of menstruation.

According to the Delphi process, our expert group was presented with a series of items that were independently and anonymously rated on a numerical scale. This Delphi process stage was executed by e-mail correspondence. Most of the items under consideration were rated on a 4-point scale (for discussion at the subsequent face-to-face meeting), and for these items, agreement was defined to mean either that >80% of respondents rated the item "agree" or "strongly agree" or that >80% rated it "disagree" or "strongly disagree." By way of example, if the rating scale was 1, strongly disagree; 2, disagree; 3, agree; and 4, strongly agree, the expert group was considered to be in agreement if >80% of respondents gave either a "disagree" answer (1 or 2) or an "agree" answer (3 or 4).

The aggregate ratings were thereafter shared when the expert group met in person for two and a half days in February 2005 in Washington, D.C. Following detailed discussion, the expert group then rerated each item. The process was facilitated by a team with extensive experience using the Delphi technique (M. Broder and the Partnership for Health Analytic Research, Beverly Hills, CA).

These extensive face-to-face discussions generated new survey questions to address areas of disagreement, and then modified surveys were administered to all participants with access to an electronic keypad voting system. The second round of ratings identified two levels of agreement. Expert group members were considered to have agreed on an item if ratings met the original criteria (>80% of answers either were 1 and 2 or were 3 and 4). Expert group members were considered to have unanimously agreed if all either rated an item 1 or 2 or rated it 3 or 4 (e.g., 100% of respondents selected either 4, "strongly agree" or 3, "agree").

Thus the outcome of the Washington 2005 meeting, where focused small group discussions led to plenary assessment of concepts and recommendations using an electronic keypad voting system, was close to universal agreement that poorly defined terms of classical origin should be discarded. It was agreed that simple, descriptive terms with clear definitions should be used instead. The choice of replacement terms should necessarily be understood by health professionals and patients alike, and importantly words used should be suitable for translation into most languages.^{3,4} The major recommendations were to replace the terms *menorrhagia*, *metrorrhagia*, *hypermenorrhea*, and *dysfunctional uterine bleeding*.

Crucial to the exercise was the agreement that there should be an ongoing process with international medical and community debate on this topic.¹² During the Washington 2005 meeting, the expert group also took the opportunity to discuss the development of a classification system with utility for diagnosis of disorders related to AUB. Thus similar documents are currently in preparation regarding classification of causes and investigations of AUB. These too will be part of an ongoing iterative process and are described in greater detail in other articles in this issue.^{13,14} The Washington 2005 meeting also provided an opportunity to engage in preliminary discussions concerning cultural and quality-of-life issues. These were topics planned for future focused workshop discussion and debate.

POST-WASHINGTON ACTIVITIES INCLUDING ESTABLISHMENT OF A MENSTRUAL DISORDERS WORKING GROUP

Following the very successful 3-day workshop of invited experts, "Terminologies, Definitions and Classifications

of Abnormal Uterine Bleeding (AUB)" held in Washington, D.C., in February 2005, the FIGO Menstrual Disorders Working Group (FMDG) was set up in early 2006. This initiative received approval from the FIGO officers at the time (under the presidency of Dr. Arnaldo Acosta). The FMDG was established in response to a clear need for an ongoing study group, and FIGO was identified as the most appropriate body to provide supervision and international credibility.

Several important publications resulted in the next 1 to 2 years. A small core group from the FMDG continued a range of activities and regular reports to FIGO officers and the executive board between 2006 and 2009. These activities involved a continuation of unfinished business from the Washington meeting, small face-to-face meetings of contributing experts, repeated presentations of various types at international meetings, informal discussions on difficult issues, and further publications. The activities also included planning for the further focused working group meeting in conjunction with the 2009 FIGO World Congress in Cape Town (a Pre-Congress Workshop) and a large symposium on AUB within the main scientific program of the 2009 FIGO Congress.

The following terms of reference have been developed for this Working Group to cover many ongoing areas of need and controversy around AUB:

1. To bring together a small group of experienced individuals to provide an international review and recommendation process around developing issues in the fields of menstruation and menstrual disorders.
2. To, initially, finalize and publish a document (or documents) setting out internationally agreed recommendations for terminologies and definitions around normal and abnormal menstruation.
3. To develop a program for introduction and review of proposed menstrual terminologies and definitions.
4. To publish a document, for international debate, with new directions for the classification of causes underlying AUB for use at family practitioner, specialist, and research levels.
5. To develop a structured menstrual history questionnaire for widespread clinical use.
6. To further define the issues that affect the burden of illness from menstrual disorders in different cultures.
7. To identify, investigate, and make recommendations on other matters relevant to menstrual disorders that require an international perspective.
8. To review any of these "living documents" on an approved, regular basis (nominally at the time of each FIGO World Congress).
9. To report to the FIGO officers and executive board on a biannual basis.

THE PROCESS: CAPE TOWN MEETING

The XIX World Congress of Gynecology and Obstetrics (FIGO), held in October 2009 in Cape Town, South Africa, provided a forum for a Pre-Congress Menstrual Disorders workshop and main-program session on AUB. The latter session, "Let's Talk about How We Can Improve Clinical Management through Clear Language and Disease Classification," provided a unique opportunity to canvass response, with the aid of an audience response system (ARS), to gauge international views on recommended terminologies, classifications, and management of AUB. With an audience of >800 FIGO congress participants from diverse cultural backgrounds (of whom nearly 250 had individual responder keypads), it was heartening to capture through the ARS the international support to move to simpler terminologies and definitions and for the implementation of a classification system to facilitate clinical care, teaching of health-care providers, and research design and interpretation. The detailed responses are presented in Munro et al in this issue.¹⁵

Outcomes from the Pre-Congress Menstrual Disorders workshop and main congress AUB session included support for discarding the terms *menorrhagia* and *dysfunctional uterine bleeding* (DUB). Neither of these terms has ever been well defined, and each is used by many as both a symptom and a diagnosis. Generally DUB has been used to describe AUB of uncertain cause ("absence of pathology"). In Washington 2005, a recommendation was made to abolish the term *DUB*, which was widely supported in Cape Town in 2009. The Cape Town Pre-Congress Workshop on Menstrual Disorders also reached agreement on the principles, structure, and content of a "discussion" document for "Classification of causes of abnormal uterine bleeding." This content was shared in the main-program session on AUB. Also discussed was the format and content of a proposed "Structured menstrual history" with widespread applicability.

SUBSEQUENT POST-CAPE TOWN DEVELOPMENTS: THE FIGO WORKING GROUP ON MENSTRUAL DISORDERS

Discussions following Cape Town have focused on the further identification of ongoing needs and issues and the preparation of a working plan. Further publications have been identified, and there will be a need for international debate around several of these issues, especially the proposals on terminology, definitions, and classifications. A particular focus is planned on consumer-based and cultural issues, and on the need for future research in the field.

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