GENERAL GYNECOLOGY

The FIGO systems for nomenclature and classification of causes of abnormal uterine bleeding in the reproductive years: who needs them?

Malcolm G. Munro, MD; Hilary O.D. Critchley, MD; Ian S. Fraser, MD

In November 2010, the International Federation of Gynecology and Obstetrics formally accepted a new classification system for causes of abnormal uterine bleeding in the reproductive years. The system, based on the acronym PALM-COEIN (polyps, adenomyosis, leiomyoma, malignancy and hyperplasia–coagulopathy, ovulatory disorders, endometrial causes, iatrogenic, not classified) was developed in response to concerns about the design and interpretation of basic science and clinical investigation that relates to the problem of abnormal uterine bleeding. A system of nomenclature for the description of normal uterine bleeding and the various symptoms that comprise abnormal bleeding has also been included. This article describes the rationale, the structured methods that involved stakeholders worldwide, and the suggested use of the International Federation of Gynecology and Obstetrics system for research, education, and clinical care. Investigators in the field are encouraged to use the system in the design of their abnormal uterine bleeding–related research because it is an approach that should improve our understanding and management of this often perplexing clinical condition.

Key words: abnormal uterine bleeding, classification system, FIGO, heavy menstrual bleeding, leiomyoma

In November 2010, the Fédération Internationale de Gynécologie et d'Obstétrique (International Federation of Gynecology and Obstetrics), more commonly known as FIGO, formally accepted a new classification system for causes of abnormal uterine bleeding (AUB) in the reproductive years that was e-published in February 2011 and print published in April of the same year.[1] The system, based on the acronym PALM-COEIN (polyps, adenomyosis, leiomyoma, malignancy and hyperplasia–coagulopathy, ovulatory disorders, endometrial causes, iatrogenic, not classified), was developed in response to concerns about the design and interpretation of basic science and clinical investigation that relates to the problem of AUB.[1,2]

So who needs this system? How was it developed? How should clinicians, educators, clinical investigators, and basic scientists use it when dealing with AUB in the reproductive years?

Background

When we try to evaluate studies that involve patients with AUB, a number of issues become readily apparent. First of all, there exists longstanding confusion concerning terminologies and definitions that are related to AUB. For example, what is "menorrhagia"? Is it a symptom? Is it a diagnosis? When 100 consecutive published research papers were reviewed for the use of the term, three-quarters of the papers considered it a symptom; the rest of the papers considered it a diagnosis. But even when it was used to describe a symptom, there was neither consistency regarding the menstrual pattern described nor consistency for the presence or absence of coexisting disease.[3] The same issues are apparent for terms such as metrorrhagia, menometrorrhagia, and dysfunctional uterine bleeding. This confusion has led to inconsistency in the design and interpretation of clinical trials and to miscommunication among health care providers, trainees, and patients.

Related to the issue of terminologies and definitions is the fact that there are a number of clinical entities that may cause or contribute to AUB, >1 of which may be present in any given woman. Furthermore, the contribution of adenomyosis, coagulopathies, and many leiomyomas and endometrial polyps is often in question, because many of these entities may be asymptomatic in a given individual.[1] Indeed, many clinical trials and even basic science studies are performed that do not even consider a number of potential diagnoses, which is a circumstance that brings into question the interpretation of the results and their appropriate application to clinical medicine.

From the Department of Obstetrics & Gynecology, David Geffen School of Medicine at UCLA, Kaiser Permanente, Southern California, Los Angeles, CA (Dr Munro); MRC Centre for Reproductive Health, The University of Edinburgh, The Queen's Medical Research Institute, Edinburgh, United Kingdom (Dr Critchley); Department of Obstetrics, Gynaecology and Neonatology, Queen Elizabeth II, Research Institute for Mothers and Infants, University of Sydney, Camperdown, Australia (Dr Fraser).

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TABLE 1
Terms abandoned in the FIGO nomenclature system

Dysfunctional uterine bleeding
Epimenorrhagia
Epimenorrhea
Functional uterine bleeding
Hypermenorrhea
Hypomenorrhea
Menometrorrhagia
Menorrhagia (all usages: essential menorrhagia, idiopathic menorrhagia, primary menorrhagia, functional menorrhagia, ovulatory menorrhagia, anovulatory menorrhagia)
Metrorrhagia
Metropathica hemorrhagica
Oligomenorrhea
Polymenorrhagia
Polymenorrhea
Uterine hemorrhage

FIGO, International Federation of Gynecology and Obstetrics.

Munro. FIGO system for abnormal uterine bleeding. Am J Obstet Gynecol 2012.

As a consequence of this unsatisfactory situation, an international working group was created under the aegis and responsibility of FIGO that is now known as the FIGO Menstrual Disorders Working Group. This group has developed a strategy of activities around outstanding issues that relate to AUB; the first products have been a new and flexible system of terminology and an equally flexible system for classification of causes of AUB in the reproductive years.[1,4-6]

The process of developing the systems

The process began with a rigorous peer evaluation of the terminology and definitions that are related to AUB in the reproductive years that served as a prelude to the design of a new, culturally sensitive and unambiguous system of terminology and classification of causes that could be translated easily into multiple languages.[4-6] It was recognized that such an endeavor would not be possible without funding, and not successful without the participation of a wide spectrum of relevant stakeholders.[1,6] Funding was obtained by means of unrestricted grants from pharmaceutical companies that were obtained and managed by a third-party health services organization, which allowed the organizers to function unencumbered by any corporate agenda or directives.

The process started in 2004 with the assembly of a multidisciplinary multinational set of gynecologists and hematologists, who were acknowledged experts in AUB, to participate in a face-to-face focused evaluation of the role and diagnosis of systemic disorders of hemostasis, commonly known as coagulopathies. The resulting articles were published simultaneously in *Fertility and Sterility* in 2005[7-11] and included a determination of the prevalence of disorders of hemostasis and their potential relationship with symptoms and, importantly, the appropriate screening techniques and laboratory procedures that would be required for diagnosis and consideration of options for management. This part of the process also helped to define context and the roles of primary care providers, gynecologists, and hematologists in the evaluation and treatment of women with these underdiagnosed systemic disorders.

The next steps were designed to rigorously evaluate definitions and to identify or develop new terminology that met the goals of simplicity, translatability, and acceptability to the wide spectrum of stakeholders. Another goal was to evaluate the need for a classification system and, if so confirmed, to implement a strategy that would be designed to culminate in a functional system that would be suitable for widespread use in research, teaching, and clinical care.[1,4-6] Identified stakeholders included a worldwide spectrum of clinical investigators and other experts in the topic of AUB and representatives from the Food and Drug Administration, the World Health Organization, professional societies, and specialty journals that published AUB-related research. Investigators were selected on the basis of their contributions to the literature, and every attempt was made to include participants from a wide spectrum of countries and health care systems. Collectively, these individuals and organizations participated in a rigorous process using the Delphi software system (Rand Corporation, Santa Monica, CA) that comprised months of remotely administered questions and revisions that served to determine a "baseline" that included areas of existing agreement and inconsistency.[4-6] Issues were resolved in 2005 during a 3-day meeting of all participants that was held in Washington, DC, with a structured process that was supported by an electronic voting system that preserved anonymity.

This introductory process resulted in a number of recommendations that included adoption of the term AUB as an overarching concept, recognition that the current terminology and definitions were generally unacceptable and irreparable, and the creation of a new set of terms for describing normal and AUB in the reproductive years. Poorly defined and confusing terminologies such as *menorrhagia*, *metrorrhagia*, and *dysfunctional uterine bleeding* were abandoned and replaced with a new recommended set of terms that were unambiguous and translatable into most other languages (Table 1).[4,5]

Work on the classification system was initiated during the Washington meeting and further developed over the next 24 months. The goals included support of the design and interpretation of clinical and even some basic science research and provision of a context for teaching students and residents/ trainees and for counseling patients. The abandoned term *dysfunctional uterine bleeding* was replaced with an evidence-based set of 3 categories that defined causes of AUB in women that were unrelated to structural abnormalities of the uterus.[1,2] These 3 groups of diagnoses (coagulopathies, ovulatory disturbances, and endometrial disorders) are sometimes referred to as "nonstructural" causes of AUB and will be described in detail later.[1]

Another important aspect of the classification system was clinician and patient access to the methods that would be required to evaluate adequately a patient's condition for cause regardless of country or health care system. It was determined that much of the categorization could take place with simple evaluations based on a structured history, readily available laboratory test results, and the use of ultrasound based tech-

niques and/or hysteroscopy for evaluation of uterine structure.[12] When the participants at the 2009 FIGO Congress were canvassed, it was apparent that the technical requirements for the system were available widely in all continents to a wide spectrum of clinicians.[13] Consequently, the system is designed with the anticipation that clinicians have access to transvaginal ultrasound equipment and 1 or a combination of contrast sonography and hysteroscopy.

The next general meeting of the group was held in conjunction with the 2009 FIGO Congress in Cape Town, South Africa. After final adjustments to the classification system from an extended group of stakeholders, the organizers had the opportunity to present the system to a large group of >600 gynecologists from the international gynecologic community, many of whom were able to use electronic response systems to provide instantaneous and anonymous feedback.[13] There were both general consensus from the Menstrual Disorders Working Group participants and overwhelming support from the multinational, multiethnic group that included both clinicians and members of the international academic community. The system was submitted to the FIGO Executive Board and was approved as a FIGO classification system in November 2010[1]; the nomenclature system was accepted by FIGO in early 2011.[4,5]

FIGO terminology system

Acute vs chronic AUB

Acute AUB is now defined as "an episode of bleeding in a woman of reproductive age, who is not pregnant, that, in the opinion of the provider, is of sufficient quantity to require immediate intervention to prevent further blood loss."[1,14] *Chronic AUB* is "bleeding from the uterine corpus that is abnormal in duration, volume, and/or frequency and has been present for the majority of the last 6 months."[1,14]

The nomenclature system: defining normal

The design of the nomenclature system is based around clear and simple terms that should be understood by both women and men in the general community and that can be translated easily into other languages (Table 2). Consequently, bleeding that can be defined as a "period" is described according to the following parameters: (1) regularity of onset, (2) frequency of onset, (3) duration of menstrual flow, and (4) heaviness (or volume) of menstrual flow.

Wherever appropriate, the definitions of *normal* have been based on statistics that were derived from large population studies that used medians and 5th and 95th percentiles.[15,16] Different population studies provide different data, and little really is known about cultural, ethnic, or geographic variations.[4,5] Also, there is an apparent large variation within the "normal" population in regularity and frequency of menstrual periods when 5th to 95th percentiles are used, because a variable proportion of women with ovulatory disturbances will be included. This circumstance may require that the definitions of normal be reconsidered in future versions of the terminology and classification systems.

AUB is the overarching term used to describe any departure from normal menstruation or from a normal menstrual cycle pattern and covers the full range of symptoms. When menstrual bleeding is absent during a 6-month reference period, the term *amenorrhea* was retained because there is little controversy in its definition or use.

TABLE 2
Suggested "normal" limits for menstrual parameters in the mid-reproductive years

Clinical dimensions of menstruation and menstrual cycle	Descriptive term	Normal limits (5th-95th percentiles)
Frequency of menses, d	Frequent	<24
	Normal	24-38
	Infrequent	>38
Regularity of menses: cycle-to-cycle variation over 12 months, d	Absent	No bleeding
	Regular	Variation ± 2-20
	Irregular	Variation >20
Duration of flow, d	Prolonged	>8.0
	Normal	4.5-8.0
	Shortened	<4.5
Volume of monthly blood loss, mL	Heavy	>80
	Normal	5-80
	Light	<5

Munro. FIGO system for abnormal uterine bleeding. Am J Obstet Gynecol 2012.

The nomenclature system: defining abnormal

Disturbances of menstrual frequency. Abnormal frequency of menses can be described as being either frequent or infrequent. Infrequent menses occur less frequently than every 35 days over a 6-month period of time; menses that occur more often than every 21 days are called frequent. It is understood that it may be difficult to discriminate between frequent menstruation and women who have intermenstrual bleeding.

Irregular menstrual bleeding. When the onset of menses is unpredictable, the woman may be said to have "irregular menstrual bleeding." The published data from several population studies provides a definition of cycle-to-cycle variation of >20 days in individual cycle lengths over a period of 1 year.[4,5] These data include women of varying ages with no known disease or hormonal therapy. The databases undoubtedly include women with any of a number of ovulatory disorders but with no formal diagnosis of polycystic ovary syndrome. Consequently, al-

though for the present, cycle variation of >20 days will define irregular menstrual bleeding, reevaluation of this definition is a priority for the FIGO Menstrual Disorders Working Group.

Abnormal duration of flow. The term *prolonged menstrual bleeding* is used to describe menstrual periods that exceed 8 days in duration on a regular basis. This phenomenon often, but not always, is associated with heavy menstrual bleeding (HMB). As a complaint, *shortened menstrual bleeding* is very uncommon and is defined as menstrual bleeding of <2 days in duration. The bleeding is also usually light in volume and is associated uncommonly with serious disease (such as intrauterine adhesions and endometrial tuberculosis).

HMB. The term *HMB* is used to describe the woman's perspective of increased menstrual volume, regardless of regularity, frequency, or duration. The entity of HMB has been well-defined in the United Kingdom's National Institute of Health and Clinical Excellence guidelines for the management of HMB[17]: "HMB should be defined as excessive menstrual blood loss which interferes with the woman's physical, emotional, social and material quality of life, and which can occur alone or in combination with other symptoms."

From a research perspective, *HMB* is defined more objectively with the measurement of actual blood loss per menstrual period, generally with the extraction of hemoglobin (alkaline hematin method) from menstrual products, which includes pads and tampons.[18-20]

Based on the description of the patient, when the volume of menstrual bleeding is reduced, it is termed *light menstrual bleeding*. Only rarely related to disease, it is usually a cultural complaint in those communities in which a heavy, "red" bleed is valued erroneously as a perceived sign of good health.[21]

Intermenstrual bleeding. When a woman experiences episodes of bleeding that occur between normally timed menstrual periods, the symptom is called *intermenstrual bleeding*. Such bleeding can be cyclic and predictable, such as that often associated with ovulation, or follow no particular pattern, which is a circumstance that typically is thought to be reflective of random bleeding from cervical lesions or endometrial polyps.

The FIGO classification system: causes of AUB in the reproductive years

The classification system is stratified into 9 basic categories that are arranged according to the acronym PALM-COEIN (*palm-koin*): polyp; adenomyosis; leiomyoma; malignancy and hyperplasia; coagulopathy; ovulatory disorders; endometrium; iatrogenic; and not classified (Figure 1). In general, the components of the PALM group are discrete (structural) entities that are measurable visually, with the use of imaging techniques, and/or with histopathologic findings, although the COEIN group comprises uteri that are structurally normal.[1,2] It is recognized that future developments and research findings will allow for the development of subcategories; therefore, the system was designed to facilitate such a process. Indeed, leiomyoma secondary and tertiary categories that were based in part on the work of Wamsteker et al[22] and that were used in the European Society of Human Reproduction and Embryology categorization are included in the initial classification system. The system was constructed with the recognition that any patient could have 1 or a spectrum of entities that could cause or contribute to the AUB and that definable entities such as adenomyosis, leiomyomas, and endocervical or endometrial polyps frequently may be asymptomatic and therefore not a contributor to the presenting symptoms.

Polyps (AUB-P)

Polyps may be present in either the endometrial cavity or the cervical canal and are categorized as either being present or absent as defined by 1 or a combination of contrast sonography and diagnostic hysteroscopy with or without histopathologic evidence. The entity sometimes characterized as "polypoid" endometrium is not considered to be a polyp per se. Although there is no currently recommended subcategorization of polyps, the size, number, and location of the polyps can be included within the category in any research design.[1]

Adenomyosis (AUB-A)

The role of adenomyosis in the genesis of AUB is extremely controversial. To date, the criteria for diagnosing adenomyosis have been based on histopathologic evaluation of the depth of "endometrial" tissue beneath the endometrial-myometrial interface from hysterectomy specimens. Not only do these histopathologic criteria vary substantially,[23] but also such an approach is not practicable in a clinical setting. Whereas magnetic resonance imaging was the first imaging modality to be demonstrated to be sensitive for the prediction of the histopathologic diagnoses of adenomyosis, it is not accessible readily to most clinicians worldwide. More recently, sonographic criteria for the diagnosis of adenomyosis have been found to be comparable with magnetic resonance imaging and, consequently, to comprise the minimum requirements for the assignment of diagnoses with the PALM-COEIN system.[1,24] As with polyps and leiomyomas, adenomyosis is a disorder that could benefit from its own subclassification system,[25] which would include standardization of methods of both imaging and ultimate histopathologic diagnosis.

Leiomyomas (AUB-L)

The FIGO Menstrual Disorders Working Group created the primary, secondary, and tertiary classification systems that are shown in Figure 1.[1] The primary system reflects only the presence or absence of ≥1 leiomyomas that were determined by sonographic examination, regardless of the location, number, and size. In the secondary system, the clinician is required to distinguish myomas that involve the endometrial cavity (submucous) from others because submucous lesions are more likely to contribute to the genesis of AUB. The distinction between submucous leiomyomas and other lesions should be made with either contrast sonography or hysteroscopy.[1] The root of the tertiary classification system is a previous design that originally was published by Wamsteker et al[22] in 1993 but was limited to those submucous leiomyomas that could be seen

with a hysteroscope. The PALM-COEIN subclassification adds categorization of intramural and subserous myomas and a category (type 8) that includes lesions that appear to be detached from the uterus, often called "parasitic" leiomyomas.

When a leiomyoma lies adjacent to or distorts both the endometrium and serosa, it is categorized first by the submucous categorization, then by the subserous location, with these 2 numbers separated by a hyphen.[1,2] Clinicians or investigators may also consider the size, number, and location within the uterus (eg, fundal, cervical), which currently are not included in the system but were included in another classification system that was proposed by Lasmar et al[26] in 2005.

Malignancy and premalignant conditions (AUB-M)

Endometrial hyperplasia or malignancy may occur because of an ovulatory disorder; however, when they are diagnosed histologically, the individual is categorized as AUB-M and then subclassified by the appropriate World Health Organization or FIGO system.[27,28]

Coagulopathies (AUB-C)

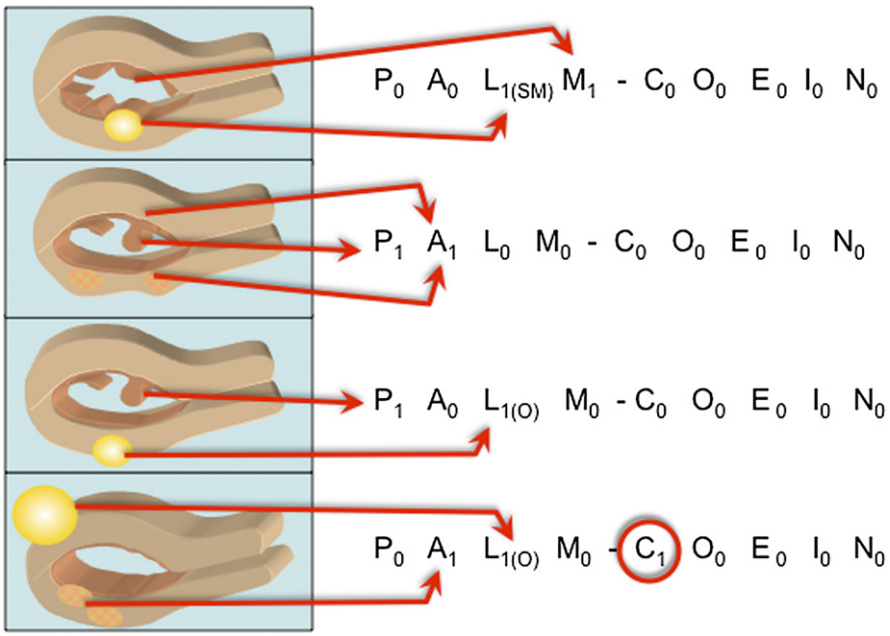
Although there exists a spectrum of systemic disorders of hemostasis (coagulopathies), the most common of these is von Willebrand disease, which is an entity that, in well-designed studies, has been identified in approximately 13% of women with HMB.[29] Approximately 90% of patients with these abnormalities can be identified by a structured history,[30] coupled with objective confirmation with testing for von Willebrand factor and ristocetin cofactor and other assays of coagulation function, as deemed appropriate.[9] It is not clear how often these abnormalities cause or contribute to the genesis of AUB and how often they are asymptomatic or minimally symptomatic biochemical abnormalities.

Ovulatory disorders (AUB-O)

Women with ovulatory dysfunction generally have some combination of irregular bleeding and a variable volume of menstrual flow, which in some cases includes HMB.[31] Most often the individual is either not ovulating, has infrequent ovulation, or, especially in the late reproductive years, has luteal out-of-phase events.[31] For the present at least, to be classified as having an ovulatory disorder, the individual should have a cycle length in the previous 6 months that varies by at least 21 days, although this definition is currently a subject of some debate.

FIGURE 1

FIGO classification system for causes of abnormal uterine bleeding in the reproductive years



The basic system (**top left** and **right panels**) comprises 4 categories that are defined by visually objective structural criteria (*PALM*: polyp; adenomyosis; leiomyoma; and malignancy and hyperplasia), by 4 criteria that are unrelated to structural anomalies (*COEI*: coagulopathy; ovulatory dysfunction; endometrial; iatrogenic), and by 1 criterion that is reserved for entities that are not yet classified (*N*). The leiomyoma category (*L*) is subdivided into patients with at least 1 submucous leiomyoma (L_{SM}) and patients with leiomyomas that do not impact the endometrial cavity (L_0). The tertiary classification of leiomyomas (**bottom 3 panels**) categorizes the submucous group according to the system of Wamsteker et al[22] and adds categories for intramural, subserous, and transmural lesions. Intracavitary lesions are attached to the endometrium by a narrow stalk and are classified as type 0, whereas types 1 and 2 require a portion of the lesion to be intramural, with type 1 being <50% and type 2 at least 50%. The type 3 lesions are totally extracavitary but abut the endometrium. Type 4 lesions are intramural leiomyomas that are entirely within the myometrium, with no extension to the endometrial surface or to the serosa. Subserous leiomyomas (types 5-7) represent the mirror image of the submucous leiomyomas, with type 5 being at least 50% intramural, type 6 being <50% intramural, and type 7 being attached to the serosa by a stalk. Classification of lesions that are transmural would be categorized by their relationship to both the endometrial and the serosal surfaces. The endometrial relationship would be noted first, with the serosal relationship second (eg, 2-3). An additional category, type 8, is reserved for leiomyomas that do not involve the myometrium at all and would include cervical lesions, lesions that exist in the round or broad ligaments without direct attachment to the uterus, and other so-called "parasitic" lesions.

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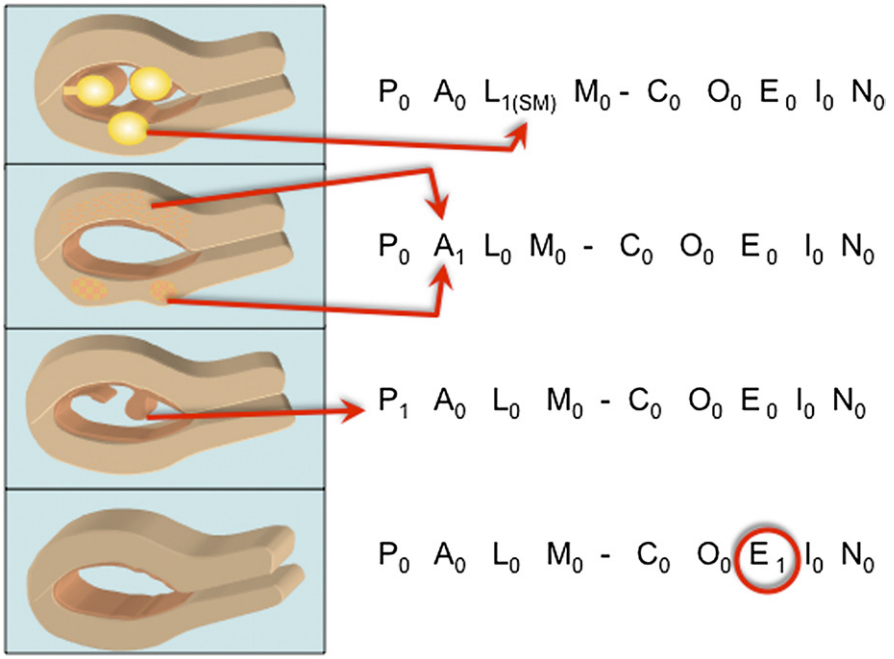
FIGO, International Federation of Gynecology and Obstetrics.

Munro. FIGO system for abnormal uterine bleeding. Am J Obstet Gynecol 2012.

Endometrial causes (AUB-E)

The cause of AUB that occurs in a normal endometrial cavity in the context of the predictable and cyclic menses that is suggestive of ovulatory function is thought to be the result of endometrial causes (AUB-E).[1] The cause of such

FIGURE 2
Notation for FIGO classification system



The status of each potential contributor to abnormal uterine bleeding (*AUB*) in a given patient is documented as being present (*1*) or absent (*0*). **A,** The panel shows examples with single positive findings; **B,** The panel shows examples with 2 or 3 positive findings. This approach may be most applicable to research settings. In clinical practices, the letters AUB followed by the identified entities can be used (eg, AUB-P, -0; or AUB-A, -LSM, -O).

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Munro. FIGO system for abnormal uterine bleeding. Am J Obstet Gynecol 2012.

bleeding is likely a primary disorder that resides in the endometrium; when the symptom is HMB, there are measurable disorders of a number of well-defined molecular mechanisms that regulate local endometrial hemostasis.[32-35] At the present time, there are no clinically available specific tests for these disorders; therefore, the diagnosis of AUB-E is probable if there are no other identifiable abnormalities.[2] Of course, it is also quite possible that women may have AUB-E while simultaneously having ≥1 of the frequently asymptomatic structural anomalies (such as polyps, adenomyosis, and leiomyomas). This circumstance begs the availability of assays for the known molecular disorders that contribute to AUB-E, thereby allowing a more definitive diagnosis.

Iatrogenic (AUB-I)

When unscheduled endometrial bleeding occurs during the use of gonadal steroid (eg, estrogens, progestogens, androgens) or gonadal steroid-related therapy (eg, gonadotropin-releasing hormone agonists, aromatase inhibitors, selective estrogen receptor modulators, or progesterone receptor modulators), the woman is categorized as having AUB-I.[1] By convention, when HMB occurs after the use of anticoagulants (such as warfarin or heparin), the patient's condition is categorized as AUB-C.[1]

Not classified (AUB-N)

There are a number of uterine or other entities that may or may not contribute to or cause AUB in a given individual but have not been identified or have been poorly defined, inadequately examined, and/or are extremely rare. Collectively, these entities (or future entities) have been placed in a category termed *not classified*.[1] As further evidence becomes available, they may be allocated a separate category or may be placed into one of the existing categories in the PALM-COEIN system.

How are these systems to be used in research, teaching, and clinical medicine?

After appropriate investigation has occurred, an individual may be found to have ≥1 potential causes of or contributors to her AUB symptoms. Consequently, the system has been designed to allow categorization and notation in a fashion that allows for this circumstance.[1] The formal approach follows the example of the World Health Organization TNM staging of malignant tumors, with each component addressed for all patients. Examples are provided in Figure 2. Recognizing that, in clinical practice, the full notation might be considered to be cumbersome, an abbreviation option has been developed.[1]

Comment

Establishment of the FIGO Menstrual Disorders Working Group has ensured that these publications and recommendations remain "living documents" that are open for international debate and accessible for triennial review at the time of each FIGO World Congress. This will allow greater precision to be built into the recommendations as new research clarifies areas of current uncertainty. However, practical testing of the terms, definitions, and classifications in different cultures and different languages will be an interesting challenge!

It is anticipated that widespread adoption of the recommended terms, definitions, and classification will allow for much more meaningful international communication, will clarify the populations that should be studied in clinical trials and published research, and will enhance communication with patients. Straightforward terms in the English language should be translated with relative ease into most other languages.

Wider acceptance of these recommended terms and definitions has opened up possibilities for the development of structured questionnaires for the improved assessment of the variability of symptoms and causes that are associated

with AUB.[36] Involvement of consumer groups and patients, which will be a vital next step in clearly determining the issues that most affect women, were highlighted effectively in the 2007 National Institute of Health and Clinical Excellence Guidelines from the United Kingdom: the corollary of a symptom that affects life and lifestyle "is that any interventions should aim to improve quality of life measures."[17] ■

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