

REPORT AND RECOMMENDATIONS

THE NEW JERSEY GOVERNOR'S

TASK FORCE ON

WOMEN AND BLEEDING DISORDERS

**Submitted by:
Parvin Saidi, MD Chairperson
June, 2006**

BACKGROUND

The Governor's Task Force on Women with Bleeding Disorders was established by Governor James E. McGreevy as Executive Order # 51 on March 7, 2003. The membership of the Task Force were appointed by the Governor in August of 2004 and included:

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Dr. Parvin Saidi was appointed as the Chair of this Task Force on August 11, 2004. This Task Force was directed to:

- a. Review current information and data describing the problem of bleeding disorders in women.
- b. Define the need for appropriate testing and access to diagnosis and treatment options for women with bleeding disorders.
- c. Make recommendations designed to address identified problems and concerns related to bleeding disorders including, but not limited to, education of targeted medical and consumer communities.

The Task Force held its first meeting on November 16, 2004. It has met every 4-6 weeks since with an agenda as established on its first meeting to include:

- Defining the problem: Women with Bleeding Disorders - The larger picture.
- Scope of the problem.
- Approaches to identify extent of the problem in New Jersey.
- Summation.
- Recommendations.

EXECUTIVE SUMMARY

Bleeding disorders in women is a common, but hitherto neglected problem with substantial medical, psycho-social and financial implications for affected women and public health impact for the State of New Jersey. Excessive menstrual bleeding (**menorrhagia**) is the most common clinical manifestation of bleeding disorders in women which in an estimated 15% of menstruating girls and women results in iron deficiency states or iron deficiency anemia with significant detrimental effect on their health and well-being. Additionally, bleeding disorders cause other reproductive tract problems as well as serious complications, including death, during childbirth, major surgeries and injuries. Despite the scope and magnitude of health problems related to bleeding disorders, it has hitherto received limited appropriate and commensurate attention from the medical profession or the public at large. The underlying reasons relate to lack of information – among women about normal vs. excessive menstrual blood loss, and in the medical community, the prevalence of bleeding disorders in women and the presence of menorrhagia as a possible indicator of an underlying bleeding disorder. In order to address the problem, there must be, in tandem, plans to educate the public and the medical community on the existence of the problem as well as strategies to develop practical clinical criteria for clinicians to identify those women who may have an underlying bleeding disorder and guidelines for access to diagnosis and treatment options. The specific steps in addressing the problem include:

- Development of clinically practical criteria for determining excessive menstrual blood loss.
- Education of the medical community about the prevalence of bleeding disorders among women.
- Education of the medical community about the high probability of bleeding disorders as causes of menorrhagia.
- Development of practical clinical screening instruments to identify women likely to have a bleeding disorder.
- Development of guidelines on laboratory diagnosis of bleeding disorders.
- Development of guidelines for referrals to specified laboratories equipped to handle time sensitive blood specimens for tests of hemostasis.
- Development of guidelines for referrals to hematologists knowledgeable in the diagnosis and management of bleeding disorders.
- Development of guidelines on treatment options.
- Education of young girls and women about normal and abnormal menstrual cycles and the prevalence of bleeding disorders as causes of abnormal menstrual cycles.

I. DEFINING THE PROBLEM: WOMEN WITH BLEEDING DISORDERS – THE LARGER PICTURE

Based on the National Health and Nutrition Examination Surveys (NHANES II and III) for the periods 1976-1980 and 1988-1994^{1,2}, anemia for the United States population has been defined as hemoglobin of less than 13.2g/dl in men and 11.7g/dl in women and it has been estimated that 5.9% of girls and young women suffer from anemia (less than 95% of normal hemoglobin) compared to 2.6% of men in the same age group; and iron deficiency is the most common identifiable cause of the anemia¹. Globally nutritional iron deficiency affects some 500 million people.³ By contrast, in the United States (and other developed countries) iron deficiency, with rare exceptions, is always due to blood loss. Iron is an essential nutrient for nearly all living organisms. It is involved in facilitating oxygen transport to all body tissues and transferring energy within individual cells. In humans about 65% of the total body iron is in the form of hemoglobin in red blood cells, 25-30% as storage iron and the remaining 5-10% as myoglobin (muscle pigment iron), the respiratory enzyme (cytochromes) within cells and as minute traces in other forms. With blood loss the storage iron (25-30% of total body iron) is depleted first followed by a decrease in synthesis of hemoglobin and production of red blood cells, i.e. **anemia**. Again, in surveys of the United States population, 9-11% of menstruating girls and women (ages 12-50) have iron deficiency reflecting depletion of iron storage compared to only 1% of boys and men in the same age group.² Anemia, regardless of the cause, deprives tissues of oxygen and compromises all normal functions. If severe enough it can cause death. Iron deficiency without anemia, i.e. depletion of storage iron also impacts on energy transfer in individual cells with many negative effects on health including changes in immune function, cognitive development, temperature regulation, energy metabolism and work performance. It is apparent, therefore, that some 15% of the female population of the U.S. ages 12 to 50 suffer from iron deficiency and iron deficiency anemia with significant negative consequences on their health which at the very least compromises the quality of their lives, but more often impacts on their health and may cause serious medical problems. The high prevalence of iron deficiency and iron deficiency anemia in women, although recognized for many decades, has just begun to receive focused attention from the medical profession.

Prolonged menstrual cycle and/or excessive menstrual flow (**menorrhagia**) has been understood to be the cause of blood loss, depletion of storage iron and eventually iron deficiency anemia in women. Until recently menorrhagia has not received much attention from the public or the medical profession. The explanation for such neglect is in part related to the traditional social ‘taboo’ against open discussion about the bleeding associated with menstruation. Furthermore, although there have been a number of studies quantifying the average ‘normal’ volume of blood lost during a menstrual cycle⁴, the laboratory methodology for quantifying such menstrual blood loss is investigational, cumbersome, and not available to clinicians. The medical profession as yet does not have clinically practical and universally accepted criteria for quantifying the normal versus abnormal bleeding of a menstrual cycle by either history, physical evaluation or laboratory assessment. Women, in general, have no idea how to determine if the amount of bleeding they experience during menses is or is not normal – relying at best on comparison with their immediate female relatives or close friends, but more often avoiding discussion of it altogether. Those who have menorrhagia suffer the ‘inconvenience’ and ‘embarrassment’ of heavy menstrual bleeding which often results in fatigue and/or lost days from school or work. Ultimately, as anemia and its clinical manifestations develop they may take the initiative to seek medical attention or (more likely) are found to be severely anemic when seen by a physician for other reasons. In such cases pharmacologic therapy (usually with oral contraceptive pills) and/or invasive procedures including D&C, hysteroscopy, endometrial ablation, myomectomy or uterine artery embolization are offered empirically; and if not effective, a hysterectomy is performed in an attempt to remove the obvious site of blood loss even when uterine pathology is not the cause of menstrual hemorrhage. It is estimated that in the United States approximately 500,000 hysterectomies are performed annually – of which 20% (100,000) are for menorrhagia without significant organic pathology of the uterus (**Dysfunctional Uterine Bleeding**).^{5,6} Hysterectomy is a major surgical procedure with attendant 4-6% morbidity⁷, and high cost (estimated to be in excess of \$5 billion per year).⁸ For women with menorrhagia who have not undergone hysterectomy, prolonged and heavy menstrual cycles impact negatively on the quality of their lives and eventually lead to the medical consequences of iron deficiency and iron deficiency anemia. During the past 10 years, the medical profession and especially

hematologists have started to address and investigate the possible causes of menorrhagia when there is no organic pathology of the uterus.⁹⁻¹⁴ The evidence gathered to date indicate that in the majority of women with menorrhagia, in the absence of significant organic pathology of the uterus, a **bleeding disorder** is usually the cause.

Bleeding disorders comprise a large spectrum of congenital or acquired abnormalities of specific blood proteins (promoting or inhibiting clot formation), platelets (specific blood cell fragments essential for initiation and formation of a blood clot) and lining cells of blood vessels. Clinically, the bleeding disorders have been characterized – regardless of the specific etiology - as severe, moderate or mild. In the severe condition, external or internal bleeding episodes may develop without known antecedent cause. In the moderate condition, bleeding usually follows minimal injury or surgery, not affecting individuals without bleeding disorders; and in the mild condition prolonged and excessive bleeding is noted only after significant injury or major surgery. The most common severe bleeding disorders are the hemophilias (clotting Factor VIII and IX deficiencies) which are transmitted as genetic defects by the female but exhibited, with rare exceptions, by the male only. Even as recent as the mid 1970's when the United States Congress enacted legislation providing line item funding for the establishment of Comprehensive Hemophilia Treatment Centers, it was with the implicit understanding that it would be for the diagnosis and management of males (children and adults) with hemophilia. Classic hemophilia has relatively low prevalence affecting 1 out of 7,500 males.¹⁵ In contrast, other bleeding disorders affect males and females equally with disorders such as von Willebrand's Disease or platelet dysfunction having a prevalence of approximately 1-2% in the general population.¹⁶ The critical difference between the hemophilias and the other bleeding disorders is that in the latter the vast majority of affected individuals have clinically mild disorders and only bleed following major injuries or with surgical procedures, thus usually escaping clinical suspicion and detection. In menstruating girls and women, however, the cyclic shedding of the uterine lining during menstruation exposes a bleeding surface which, in the absence of normal hemostasis (clot formation), results in heavy and prolonged uterine bleeding i.e. **menorrhagia**. In menstruating women, menorrhagia is the most common clinical manifestation of an underlying bleeding disorder.¹⁷ Furthermore, it is well documented that

although excessive and prolonged menstrual bleeding may be the most common clinical manifestation of a bleeding disorder, it is not the only reproductive tract abnormality caused by the bleeding disorder.¹⁷ Beyond and in addition to excessive uterine bleeding during menses, a bleeding disorder in a woman can and often does cause serious complications including death during childbirth, major surgeries (including hysterectomies) and major injuries. Clearly bleeding disorders carry significant medical, psychosocial and financial implications for the affected women, and because of their prevalence have substantial public health impact.

As yet, the lay and professional public are by and large neither fully informed about the prevalence nor the medical and public health implications of bleeding disorders in women. Recognition of the existence of this problem is obviously essential before appropriate measures for detection, specific diagnosis and management can be implemented. Above and beyond the need for educating the lay public and the medical community on menorrhagia and bleeding disorders, there remain the essential and obvious needs for defining practical clinical parameters in determining normal menstrual flow, developing appropriate clinical screening tools for identifying women who may have a bleeding disorder, guidelines for selecting appropriate laboratory tests for confirming a bleeding disorder, and finally, optimal treatment options for women with bleeding disorders. The New Jersey Governor's Task Force on Women with Bleeding Disorders is the first State initiative to address this topic. The Task Force's recommendations are basic, but we believe far reaching in their potential impact for the State of New Jersey and possibly as blueprints for similar initiatives across the country.

SCOPE OF THE PROBLEM

There are many studies (including those reported by physician members of the Task Force) that document prevalence of **anemia** related to blood loss among women, high incidence of **menorrhagia** in women who have a bleeding disorder, high probability of a **bleeding disorder** as the cause of menorrhagia, and an extraordinarily high number of hysterectomies performed annually for menorrhagia despite the absence of significant organic uterine pathology. By contrast, there are only limited number of studies on the level of information and understanding about bleeding disorders in women; nevertheless, these studies show a dearth of information in the medical community as well as the lay public about normal vs. abnormal menstrual bleeding, prevalence of bleeding disorders in women and bleeding disorders as causes of menorrhagia. The national scope of the problem can be summarized as follows:

- 30% of women complain of menorrhagia.¹⁸⁻²⁰
- In 50% of cases of menorrhagia, no significant organic pathology is found (**Dysfunctional Uterine Bleeding**).²¹
- Menorrhagia is the presenting symptom in the majority of over 500,000 hysterectomies performed annually in the US.^{5,9}
- 20% of hysterectomies (100,000) are performed for “**dysfunctional uterine bleeding**” without significant organic pathology.⁶
- More than 25% of the US female population undergoes hysterectomies by age 60.⁵
- In a series of diagnostic testing of women with menorrhagia, up to 76% were found to have a hemostatic abnormality – indicative of a potential bleeding disorder.¹⁴
- In studies of women with an established diagnosis of bleeding disorder, menorrhagia was found in 57-74%.²²
- Mail surveys of obstetricians/gynecologists in at least one state reported a lack of understanding of bleeding disorder as a possible cause of menorrhagia.²³
- Annual cost of hysterectomies in the United States is estimated at more than \$5 billion.⁸

APPROACHES TO IDENTIFY EXTENT OF THE PROBLEM IN NEW JERSEY

Rather than duplicating the national studies, the Governor’s Task Force on Women with Bleeding Disorders decided to focus on gathering information on four broad areas in order to validate the national data and/or determine the magnitude of the problem in the State of New Jersey.

1. PREVALENCE OF ANEMIA AND IRON DEFICIENCY IN WOMEN AGES 13 TO 50 IN ONE HOSPITAL IN NEW JERSEY.

All unduplicated laboratory results for a one month period of Complete Blood Counts (CBC), serum iron, total iron binding capacity (TIBC), % iron saturation, and ferritin levels performed by the Central Diagnostic Laboratory of a major University Hospital in the State of New Jersey were analyzed - selected for gender (female), age (13-50), significant anemia (hemoglobin less than 10g/dl), microcytic indices (MCV < 80 μm^3), low serum iron (serum iron <30 $\mu\text{g}/\text{dl}$), high Total Iron Binding Capacity (TIBC >390 $\mu\text{g}/\text{dl}$), low iron saturation (<15%), and low serum ferritin (<20 $\mu\text{g}/\text{ml}$). Clearly patients tested by the general laboratory of a major hospital can be assumed to have had other medical problems (mild to severe) associated in some with anemia related to their primary medical condition. Nevertheless, our objective was to determine what percentage of the tests indicated microcytic anemia usually reflecting chronic iron deficiency of blood loss; and in those individuals in whom iron parameters were tested, what percentage showed low saturation of serum iron together with a high total iron binding capacity – again, typical of chronic iron deficiency of blood loss. Iron deficiency with or without anemia is rarely the reason for hospital admission, and therefore, its presence can be assumed to be incidental to the medical reason for admission.

Results (among hospitalized women):

Hemoglobin and Mean Corpuscular Volume (MCV) of Red Blood Cells

1,338 unduplicated records showed:

235 with Hemoglobin <10g/dl	(Normal 11.7-14g/dl)	17%
300 with MCV <80 μm^3	(Normal 80-98 μm^3)	22%
42 with Hemoglobin <10/gdl and MCV <80 μm^3		3%

Iron, Ferritin, % Iron Saturation

62 unduplicated records showed:

15 Ferritin <20µg/dl	(Normal 20-120µg/dl)	24%
24 Saturation <15%	(Normal 20-55%)	39%
10 Saturation <15% and TIBC >390µg/dl		16%

Above findings indicate **16%** of the women ages 13-50 had parameters consistent with iron deficiency and **3%** had significant microcytic anemia. These findings, although a retrospective and random analysis, is impressively close to a large study of prevalence of iron deficiency in the United States which showed 9-11% of women ages 12-49 having low iron saturation, and 2-5% of these showing anemia.²

2. PREVALENCE OF MENORRHAGIA

Clearly a systematic survey of incidents/prevalence of menorrhagia among women in New Jersey was beyond the time and resources available to the Task Force. Nevertheless, we attempted to arrive at the same information by analyzing the percentage of sanitary napkins sold that are of extra absorbent/super-size category. The information obtained is based on annual sales, nationally, of all major brands by four national discount department store chains. Assuming a normal menstrual cycle to last for seven days with the first two days heavier than the next five, and that most women use regular size pads, even for the first two days, we predicted that at most **14-28%** of sanitary pads sold would be of the super-size variety (1-2 days out of 7). The findings were as follows:

Percentage of Super Long, Overnight, and Long Sanitary Pads Sold

2002	52.06%
2003	46.27%
2005	48.02%

The above indices indicate that the number of super-size napkins sold exceeded the expected 14-28% by an average of 25-31% which is remarkably consistent with the national estimate of 30% of women complaining of menorrhagia, as cited in reference #18.

3. HYSTERECTOMIES PERFORMED FOR UTERINE BLEEDING WITHOUT ORGANIC PATHOLOGY

The following data reflects information obtained from 2003 New Jersey hospital discharge files on reported hysterectomy procedures and bleeding disorders. For this analysis of the hysterectomy data we are indebted to Dr. Lakota Kruse, Medical Director, Family Health Services, New Jersey State Department of Health and Senior Services.

HOSPITALIZATIONS FOR BLEEDING DISORDERS AND TYPE OF HYSTERECTOMY PROCEDURE: NJ 2003

BLEEDING DISORDER (ICD-9 Code)	Subtotal Hysterectomy (68.3)	Total Hysterectomy (68.4)	Vaginal Hysterectomy (68.5)	All Hysterectomy Procedures
Coagulation defects (286)	15	32	4	51
Excess or frequent menstruation (626.2)	654	1940	300	2894
Metrorrhagia (626.6)	12	33	6	51
Other disorders of menstruation (626.8)	124	396	79	599
Unspecified disorders of menstruation (626.9)	8	18	2	28
Premenopausal menorrhagia (627.0)	5	12	2	19
Postmenopausal bleeding (627.1)	25	279	32	336
More than one disorder	5	21	5	31
No bleeding disorder	1363	5885	1712	8960
SUM	2211	8616	2142	12969

Source: 2003 New Jersey Hospital Discharge File

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The above information in summary indicates that a total of 12,969 hysterectomies were performed in New Jersey in 2003. Of these, 3978 (30%) were coded for excessive bleeding (coagulation defect, excess or frequent menstruation, menorrhagia, disorders of menstruation, pre-menopausal menorrhagia or post-menopausal bleeding). Nationally it is estimated that 20% of hysterectomies are for menorrhagia. The New Jersey data of 30% is substantially more than the national numbers. However, it is possible that in some of the hysterectomies

coded only with coagulation defect or excessive menstrual bleeding the uterus may have had leiomyomas (fibroids) or other lesions which were not reflected in the discharge coding. In any event, even correcting for such possibility, the total number remains substantially higher than the national estimates.

4. HIGH SCHOOL STUDENTS AWARENESS OF ABNORMAL MENSTRUAL BLEEDING, AND BLEEDING DISORDERS

The Governor's Task Force decided to focus on information/level of understanding of high school students (girls and boys) because all middle schools and high schools provide a core curriculum on Health Education and therefore, high school students' knowledge/information on abnormal/excessive blood loss or bleeding disorders would reasonably reflect the education that they may have received on these topics and, by extrapolation, the public awareness of these topics. The Task Force members met with ten student representatives (girls and boys) from four high schools in Middlesex County. The students first met as a group, given an overview about the purpose of the meeting and basic explanations on normal vs. abnormal menstrual flow, bleeding disorders and association of bleeding disorders and abnormal menstrual cycle. The students were then divided into two groups, separating the boys and the girls. A set of prepared questions was discussed with each of the groups separately before the students were again brought together for a final overall discussion. Based on the responses to the questions it can be concluded that:

- A. Although high school students receive information during Health Education classes on female and male anatomy, reproduction, pregnancy prevention and sexually transmitted diseases; they do **not** receive any information on normal vs. abnormal menstrual cycle and causes of excessive menstrual flow.
- B. The girls stated that some of their friends had complained of excessive menstrual flow, but generally do not take any specific action. They usually did not consider the school nurse as a resource and often used other medical excuses (headache, nausea) for going home.
- C. Neither the girls nor the boys had any information on bleeding disorders.

- D. Both girls and boys (separately and together) expressed interest in knowing more about normal and abnormal menstruation; the girls, so that they could make the correct decision on when to seek medical attention, and the boys so that they could support their female friends.

In an effort to determine practices within Emergency Department's, the physicians on the Task Force individually and informally sample questioned Emergency Department nurses and pharmacists. These medical professionals admitted to lack of information on normal vs. abnormal menstrual cycle and stated that they would refer every woman who asked them for advice on menstruation or excessive flow to see a gynecologist.

RECOMMENDATIONS

RECOMMENDATION – I

- Educational guidelines should be developed by the Medical/Scientific Sub-Committee (as described in recommendation IV), based on current medical information, that provide reasonable and acceptable criteria that can be easily used to clinically define normal menstrual flow, and by extrapolation, clinically determine abnormally heavy or prolonged menstrual flow (menorrhagia). These criteria will be in tandem with national/federal criteria should they become available.
- A clinically useful screening instrument for menorrhagia should be developed by the Medical/Scientific Sub-Committee (as described in recommendation IV), based on current medical information/evidence. This screening instrument, consisting of a brief list of reasonable and acceptable criteria which may include specific items of medical history, family history, physical (including pelvic) examination and appropriate laboratory tests may be used by health care providers to clinically determine whether a bleeding disorder should be considered.
- Guidelines should be developed by the Medical/Scientific Sub-Committee (as described in recommendation IV) for laboratories which perform tests of hemostasis regarding technical requirements for obtaining and transporting blood samples essential for the performance of these tests.

- An Advisory Recommendations Statement should be developed by the Medical/Scientific Sub-Committee (as described in recommendation IV) to be distributed by DHSS to all primary care physicians, internists, pediatricians, obstetricians/gynecologists, and women's health clinicians in the State of New Jersey. This Advisory Recommendation Statement will include:
 - Clinically useful definition of normal and excessive menstrual flow.
 - Screening instrument to assist internists, primary care physicians, obstetricians/gynecologists, pediatricians, and nurse practitioners in the identification of girls and women at risk for having a bleeding disorder.
 - Guidelines for appropriate evaluation and referral to hematologists for clinicians to use for women identified at risk with a possible bleeding disorder.

RECOMMENDATION – II

- Education, based on best practices, should be provided to girls in middle and high school on normal and abnormal menstruation through:
 - Inclusion of information and instruction on normal and abnormal menses in the Core Curriculum of Health Education.
 - Inclusion of normal and abnormal menses in the master list of discussed disorders and disabilities.
 - Education Core Curriculum of Standards geared towards specific outcomes expected by specific age/grade level.
- Education should be provided to relevant school personnel including, but not limited to school nurses and physical education instructors through facilitating the development of:
 - After class seminars
 - Video conferences
 - Specific training sessions
 - Annual professional organization meetings/conventions.

RECOMMENDATION – III

- A public awareness campaign, targeted to women, should be launched to educate the general public about normal and abnormal menses and bleeding disorders as possible cause of menstrual cycles with excessive bleeding.

RECOMMENDATION – IV

- In order to implement Recommendations I, II, and III, it is proposed that the Governor’s Task Force on Women with Bleeding Disorders be sustained for a period of an additional 18 months and directed to establish the following sub-committees to address the specific recommendations. These include:
 - **Medical/Scientific Sub-Committee** that may include two hematologists, one obstetrician/gynecologist, one family practitioner, Assistant Commissioner of Family Health Services, Director of the Office on Women’s Health and a member of the consumer organization Hemophilia Association of New Jersey (HANJ). This Sub-Committee will be charged in implementing **Recommendation I**. The Sub-Committee will present to the Governor’s Task Force its progress and final report at intervals and timeframe to be determined by the Governor’s Task Force.
 - **Education Sub-Committee** that may include Assistant Commissioner of Family Health Services, Director of the Office on Women’s Health, two senior members from the Department of Education, a hematologist, an obstetrician/gynecologist, a family practitioner, a member of the Consumer Organization (HANJ), and a school nurse and high school and college student representatives. The Sub-Committee is charged with developing plans on implementation of **Recommendation II** by the Department of Education including timetable and an oversight process by that Department. This Sub-Committee will present its progress and final report to the Governor’s Task Force at intervals and timeframe to be determined by the Governor’s Task Force.
 - **Public Awareness Committee** that may include Executive Director and two other members of the Consumer Organization (HANJ), Director of Office on Women’s Health, hematologists, obstetrician/gynecologists, family practitioners, high school and college student representatives. This Sub-Committee will be charged with developing plans for implementing **Recommendation III**. This Committee will present its progress and final report to the Governor’s Task Force at intervals and timeframe to be determined by the Governor’s Task Force.

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