

Background and Brief Description

Up to 2 million women in the United States may have an inherited bleeding disorder and not know it. Many women learn to live with the problems their bleeding causes, such as heavy periods, and do not realize that they may have a bleeding disorder. Other women may have more serious bleeding problems such as hemorrhages after childbirth or surgery, and some have hysterectomies to end their heavy periods. With proper diagnosis, women with bleeding disorders could avoid these complications and surgeries. Management of bleeding in these women can decrease heavy periods and can improve quality of life.

The most common bleeding disorder is called Von Willebrand disease (VWD). VWD is caused by a deficiency or defect in the body's ability to make a protein, Von Willebrand factor, which helps blood clot. The symptoms of VWD can range in severity; however, 90 percent of people who have this disease have the mild form. VWD occurs in men and women equally, but women are more likely to notice the symptoms of VWD due to heavy or abnormal bleeding during their menstrual periods and after childbirth. There are many gynecological and physical causes for heavy periods, such as endometriosis, thyroid problems and cancer; however, the cause is not identified in half the cases. A CDC-Emory University survey

found that gynecologists rarely considered bleeding disorders as a cause of heavy menstrual bleeding. However, recent research from Europe and CDC has shown that 15–20% of women with heavy periods have inherited bleeding disorders. Women with VWD interviewed by CDC reported an average of 16 years between the onset of bleeding symptoms and diagnosis of a bleeding disorder. CDC and the National Hemophilia Foundation have been working to encourage gynecologists to consider bleeding disorders in women who have heavy menstrual bleeding, also called menorrhagia. As a result, the American College of Obstetricians and Gynecologists has recently recommended screening for VWD in these women.

An important part of increasing the awareness among physicians and their patients with heavy periods who may have an underlying bleeding disorder is referral for appropriate diagnosis. Federally funded Hemophilia Treatment Centers (HTCs) are thought to be the best source for appropriate laboratory diagnosis, however, the following concerns have been raised: (1) Anecdotal reports from HTC providers describe reduced capacity of in-house laboratory support and access to specialty coagulation laboratory tests that are essential for appropriate diagnosis of bleeding disorders; (2) A CDC Public Health Practice Program

Office (PHPPO) study demonstrated reduced capacity to perform specific coagulation tests through their survey of hospital laboratories; but it is impossible to know if HTCs have higher capacity than the hospitals studied; (3) HTCs report that changes in third party payer policies, especially health maintenance organizations, are dictating the source of laboratory testing requiring shipment of laboratory specimens to sites away from the hospital that reduce the quality of the sample and affect the reliability of the results. It is important to assess the HTCs and determine their capabilities and barriers to delivering comprehensive care to patients with bleeding disorders.

The setting for the proposed study is the 135 federally funded HTCs, and the Directors and Lab Directors of these 135 HTCs will be the potential respondents. A survey will be distributed to the above personnel to ascertain their perceptions of lab capabilities and procedures.

The data received from this survey will allow CDC to evaluate the functional status of HTC labs, describe the services available, and make programmatic decisions that will best serve the medical needs of this population.

There will be no cost to the respondents other than their time. The total estimated annualized burden hours are 90.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondents	Number of respondents	Response per respondent	Burden per response (in hours)
HTC Directors	135	1	20/60
Lab Directors	135	1	20/60

Dated: January 11, 2006.

Betsey S. Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-06-0213]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under

review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-4766 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

National Vital Statistics Report Forms—Extension—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Vital Statistics Report Forms project (0920-0213) is an approved collection and compilation of national vital statistics. This collection dates back to the beginning of the 20th century and has been conducted since 1960 by the Division of Vital Statistics of the National Center for Health Statistics, CDC. The collection of the data is authorized by 42 U.S.C. 242k. The National Vital Statistics Report forms provide counts of monthly occurrences of births, deaths, infant deaths, marriages, and divorces. Similar data have been published since 1937 and are the sole source of these data at the national level. The data are used by the Department of Health and Human Services and by other government,

academic, and private research and commercial organizations in tracking changes in trends of vital events.

Respondents for the National Vital Statistics Report form (CDC 64.146) are registration officials in each State and Territory, the District of Columbia, and New York City. In addition, 33 local (county) officials in New Mexico who record marriages occurring in each county of New Mexico will use this form. The data are routinely available in each reporting office as a by-product of ongoing activities. This form is designed to collect counts of monthly occurrences of births, deaths, infant deaths, marriages, and divorces immediately following the month of occurrence.

The Annual Marriage and Divorce Occurrence Report form (CDC 64.147) collects final annual counts of marriages and divorces by month for the United States and for each State. The statistical counts requested on this form differ from provisional estimates obtained on the National Vital Statistics Report form in that they represent complete and final counts of marriages, divorces, and annulments occurring during the months of the prior year. These final counts are usually available from State or county officials about eight months after the end of the data year. The data are widely used by government, academic, private research, and

commercial organizations in tracking changes in trends of family formation and dissolution.

Respondents for the Annual Marriage and Divorce Occurrence Report form are registration officials in each State, the District of Columbia, New York City, Guam, Puerto Rico, Virgin Islands, Northern Marianas, and American Samoa. The data are routinely available in each reporting office as a by-product of ongoing activities.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 208.

ESTIMATED ANNUALIZED BURDEN TABLE

Respondents	No. of respondents	No. of responses per respondent	Average burden per response (in hours)
CDC64.146: State and Territory registration officials	58	12	12/60
CDC64.146: New Mexico County marriage registrars	33	12	6/60
CDC64.147: State/Territory/City registration officials	58	1	30/60

Dated: January 11, 2006.

Betsey S. Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Clinical Laboratory Improvement Advisory Committee (CLIAC).

Times and Dates: 8:30 a.m.-5 p.m., February 8, 2006; 8:30 a.m.-3 p.m., February 9, 2006.

Place: Doubletree Hotel (Atlanta/Buckhead), 3342 Peachtree Road NE., Atlanta, Georgia 30326, Telephone: (404) 231-1234.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This Committee is charged with providing scientific and technical advice and guidance to the Secretary, Department of Health and Human Services; the Assistant Secretary for Health; and the Director, CDC, regarding the need for, and the nature of, revisions to the standards under which

clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances.

Matters To Be Discussed: The agenda will include updates from the Food and Drug Administration, the Centers for Medicare & Medicaid Services, and CDC; reports on national cytology proficiency testing status and Coordinating Council on the Clinical Laboratory Workforce activities addressing laboratory personnel shortages; and the role of the public health laboratory, including scope of services, customers, connectivity, and preparedness.

Agenda items are subject to change as priorities dictate.

Providing Oral or Written Comments: It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments whenever possible. *Oral Comments:* In general, each individual or group requesting to make an oral presentation will be limited to a total time of five minutes (unless otherwise indicated). Speakers must also submit their comments in writing for inclusion in the meeting's Summary Report. To assure adequate time is scheduled for public comments, individuals or groups planning to make an oral presentation should, when possible, notify the contact person below at least one week prior to the meeting date. *Written Comments:* For individuals or groups unable to attend the meeting, CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, the comments should be received at least one week prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments, one hard copy with original signature, should be

provided to the contact person below. Written comments will be included in the meeting(s) Summary Report.

Contact Person for Additional Information: Devery Howerton, Acting Chief, Laboratory Practice Standards Branch, Division Public Health Partnerships—Laboratory Systems, National Center for Health Marketing, Coordinating Center for Health Information and Service, CDC, 4770 Buford Highway NE., Mailstop G-23, Atlanta, Georgia 30341-3717; telephone (770) 488-8155; fax (770) 488-8279; or via e-mail at DHowerton@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: January 10, 2006.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease