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Acting Associate Direct for Policy Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-01-11]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995, the Center for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have

practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days.

Proposed Project: Vital Statistics Training Application Reinstatement—(OMB No. 0920-0217) National Center for Health Statistics (NCHS). In the United States, legal authority for the registration of vital events, *i.e.* births, deaths, marriages, divorces, fetal deaths, and induced terminations of pregnancy, resides individually with the States (as well as cities in the case of New York City and Washington, DC) and Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. These governmental entities are the full legal proprietors of vital records and the information contained therein. As a result of this State authority, the collection of registration-based vital statistics at the national level, referred to as the U.S. National Vital Statistics

System (NVSS), depends on a cooperative relationship between the States and the Federal government. This data collection, authorized by 42 U.S.C. 242k, has been carried out by NCHS since it was created in 1960.

To help in achieving the comparability needed for combining data from all States into national statistics, NCHS carries out a training program for State and local vital statistics staff to assist in developing expertise in all aspects of vital registration and vital statistics. The training offered under this program includes courses for registration staff, statisticians, and coding specialists, all designed to bring about a high degree of uniformity and quality in the data provided by the States. This training program is authorized by 42 U.S.C. 242b, section 304(a). In order to offer the types of training that would be most useful to vital registration staff members, NCHS requests information from State and local vital registration officials about their projected needs for training. NCHS also asks individual candidates for training to submit an application form containing name, address, occupation, work experience, education, and previous training. These data enable NCHS to determine those individuals whose needs can best be met through the available training resources. There is no cost to respondents in providing these data.

Respondents	Number of respondents	Responses/ respondents	Avg. burden/ response (in hrs)	Total burden hours
State, local, and Territory Registration Officials	57	1	.33	19
Training Applicants	100	1	.25	25
Total				44

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY-12-01]

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) 639-7090. Send written comments to CDC, Desk Officer; Human

Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project: Questionnaire Design Research Laboratory (QDRL) 2001-2003, (OMB No. 0920-0222)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). The QDRL conducts pretesting activities related to the development of NCHS and other Federal survey questionnaires, such as the National Health Interview Survey (NHIS). These activities mainly involve use of the cognitive interview, in which volunteer respondents ("laboratory subjects") are administered draft survey questions, and are asked to

react to those questions. The cognitive interviewer notes sources of error in these questions, based on problems that subjects have in comprehending the questions and in attempting to recall the information requested. After several cycles of testing of small numbers of respondents (generally 10–12), and development of the questions between testing “rounds,” the questionnaires are improved to the point to which they are

ready for field testing and household administration. QDRL staff are also engaged in the conduct of general questionnaire design research, in which survey questions are administered to laboratory subjects using different phrases, or under different administration modes (*e.g.*, face-to-face versus telephone), in order to determine the optimal means for presenting the questions. These investigative pretesting

activities are now routinely used by NCHS and by other survey organizations for testing and development purposes, and result in high data quality at a minimal cost, especially in terms of respondent burden. We also support field testing on occasion to assure adequate pretesting of health survey instruments. Total burden hours for this data collection are 550 hours.

Respondents	Number of respondents	Number of responses per respondent	Avg. burden response (in hours)	Response burden (hours)
2001 test volunteers	500	1	1.1	550
2002 test volunteers	500	1	1.1	550
2003 test volunteers	500	1	1.1	550

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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Proposed Project

National Survey of Hospital Coagulation Laboratories—New—Public Health Practice Program Office (PHPPO), Centers for Disease Control and Prevention (CDC). As part of the

continuing effort to support public health objectives of treatment, disease prevention and surveillance programs, the Centers for Disease Control and Prevention (CDC), Public Health Practice Program Office (PHPPO), seeks to collect information on coagulation testing practices among U.S. hospital laboratories. The purpose of this project is to define the state of testing practices in a random sample of 800 U.S. hospital laboratories for selected coagulation analytes by conducting a questionnaire survey of these laboratories. The objectives of this survey are to collect data to assess the variability of selected analytical and non-analytical variables, such as normal ranges, used for selected coagulation tests. There has not been a systematic and nationally based survey of coagulation testing practices among U.S. hospital laboratories. Such a surveillance is needed due to the impact that coagulation testing practices can have on the diagnosis and management of coagulation disorders.

There is ample evidence of variability in coagulation testing practices based on published literature corresponding to experiences of individual institutions that deal with analytical (*e.g.*, impact of instrument and kit reagents on laboratory results) as well as pre-analytical (such as specimen treatment) and post-analytical (such as results presentation) issues. However, there has not been a systematic survey of national hospital laboratories that has documented the nature and extent of such variability for selected coagulation tests. Preliminary observations

document substantial inter-institutional variability in coagulation testing practices, with likely effect on patient outcome.

This study will explore current practices for one or more selected coagulation tests to document the extent and nature of variability in the testing processes. It is anticipated that information from this study will be used for several purposes. First, results from this project may be used in a future study in order to surmise the potential impact of various testing practices on patient outcomes. A second anticipated use of this study's results is to implement targeted laboratory improvement efforts. Finally, this study may form the basis for a future study to assess the extent and nature of problems in diagnosis and treatment of patients caused by inaccurate laboratory results. Because hypo- and hypercoagulability disorders are prevalent in the U.S. and they are defined to a great extent by laboratory tests, a well designed laboratory practice survey is expected to be of great public health significance for the nation.

CDC plans to sample 800 laboratories that perform selected coagulation tests. The time required to complete a survey will be approximately 0.5 hours. We anticipate that, of the respondents, approximately 80 will be Coagulation Laboratory Directors (physicians) and approximately 720 will be Coagulation Laboratory Supervisors. The total estimated annualized burden is 425 hours.

Respondent	Number of respondents	Responses per respondent	Average No. hrs/response
Laboratory Director	80	1	30/60
Laboratory Supervisor	720	1	30/60