

Board of Governors of the Federal Reserve System, September 12, 2003.
Robert deV. Frierson,
Deputy Secretary of the Board.
 [FR Doc. 03-23819 Filed 9-17-03; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-69-03]

Proposed Data Collections Submitted for Public Comment and Recommendations

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) 498-1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project: Health and Safety Outcomes Related to Work Schedules in Nurses—NEW—The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). The mission of the National Institute for Occupational Safety and Health is to promote safety

and health at work for all people through research and prevention.

In the United States, approximately 1.1 million registered nurses work shift schedules to provide essential nursing services that are required around the clock. A recent U.S. government report indicates that the average nurse works more than 40 hours per week. Both shift work and overtime have been independently associated with increased health and safety risks. Little is known about the combined influence of shift work and overtime. In addition, most previous shift work studies of nurses have used young participants. However, the age of the average working U.S. registered nurse is now 43.3 years and has been increasing over the past 20 years. This aging workforce will be more vulnerable to the adverse health and safety risks associated with shift work and overtime. This study will examine the combined influence of shift work and overtime on health and safety in the current registered nurse workforce. The study will provide data for work schedule design recommendations. Potential secondary benefits to society will be improved patient outcomes.

Specific Aim 1. Examine if certain characteristics of shift work schedules, such as shift length (*i.e.* 12-hour, 8-hour shifts), night work, and rotating work schedules are associated with increased health and safety risks.

Specific Aim 2. Examine how shift work and overtime interact to influence health and safety risks.

Specific Aim 3. Examine if disturbances of sleep, family life, and social life mediate effects of work schedules on health and safety.

The study is based on the theoretical model by Barton et al. (1995) who propose that shift work exerts a negative effect on health and safety outcomes by disturbing sleep, family life, and social life. The study will use a cross-sectional design to survey 1,000 registered nurses who will be randomly selected from 10 large hospitals. Participants will be asked to complete a survey, complete a 7-day sleep/activity diary, provide one set of blood pressure readings, and provide a copy of their work schedule from their hospital records for the previous 3-month period.

The survey includes items for personal characteristics such as age and weight; health history; lifestyle factors such as smoking and alcohol use; sleep characteristics and problems; factors at work and other responsibilities such as child care; work schedule factors; musculoskeletal discomfort; gastrointestinal and cardiovascular symptoms; mood; automobile crashes and near misses; needlestick injuries; and job satisfaction. The study will compute a list of work characteristics based on the actual work start and end times. Statistical modeling will be used to examine characteristics of work schedules associated with increased risk while controlling for demographic, health history, lifestyle, and work-related risk factors. A base model will be developed with significant control variables for each outcome. Work schedule variables will then be added to the base model to test for significant relationships while controlling for co-variants. The annualized burden for this data collection is 1,667 hours.

Form name	Number of respondents	Number of responses/respondent	Avg. burden/response (in hours)
3 month overtime diary	1000	6	5/60
7-day sleep/activity diary	1000	7	5/60
Survey	1000	1	35/60

Dated: August 25, 2003.
Nancy Cheal,
Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-70-03]

Proposed Data Collections Submitted for Public Comment and Recommendations

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Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498-1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project: The National Violent Death Reporting System—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Violence is an important public health problem. In the United States, homicide and suicide are the second and third leading causes of death, respectively, in the 1–34 year old age group.

Unfortunately, public health agencies don't know much more about the problem than the numbers and the sex, race, and age of the victims, all information obtainable from the standard death certificate. Death certificates, however, carry no information about key facts necessary for prevention such as the relationship of the victim and suspect and the circumstances of the deaths, thereby making it impossible to discern anything but the gross contours of the problem. Furthermore, death certificates are typically available 20 months after the completion of a single calendar year. Official publications of national violent death rates, e.g. those in *Morbidity and Mortality Weekly Report*, rarely use data that is less than two years old. Public health interventions aimed at a moving target last seen two years ago may well miss the mark.

Local and federal criminal justice agencies such as the Federal Bureau of Investigation (FBI) provide slightly more information about homicides, but they do not routinely collect standardized data about suicides, which are in fact much more common than homicides.

The FBI's Supplemental Homicide Report system (SHRs) does collect basic information about the victim-suspect relationship and circumstances, like death certificates, it does not link violent deaths that are part of one incident such as homicide-suicides. It also is a voluntary system in which some 10–20 percent of police departments nationwide do not participate. The FBI's National Incident Based Reporting System (NIBRS) addresses some of these deficiencies, but it covers less of the country than SHRs, still includes only homicides, and collects only police information. Also, the Bureau of Justice Statistics Reports do not use data that is less than two years old.

CDC therefore proposes to start a state-based surveillance systems for violent deaths that will provide more detailed and timely information. It will tap into the case records held by medical examiners/coroners, police, and crime labs. Data will be collected centrally by each state in the system, stripped of identifiers, and then sent to the CDC. Information will be collected from these records about the characteristics of the victims and suspects, the circumstances of the deaths, and the weapons involved. States will use standardized data elements and software designed by CDC. Ultimately, this information will guide

states in designing programs that reduce multiple forms of violence.

Neither victim families nor suspects are contacted to collect this information. It all comes from existing records and is collected by state health department staff or their subcontractors. Health departments incur an average of 2.5 hours per death in identifying the deaths from death certificates, contacting the police and medical examiners to get copies of or to view the relevant records, abstracting all the records, various data processing tasks, various administrative tasks, data utilization, training, communications, etc.

The number of state health departments to be funded may be as high as 10 once FY03 cooperative agreements are awarded. Six states were funded thru FY02 cooperative agreements, and up to 4 more may be funded in 2003. NCIPC hopes to eventually fund all 50 states. Violent deaths include all homicides, suicides, legal interventions, deaths from undetermined causes, and unintentional firearm deaths. There are 50,000 such deaths annually among U.S. residents, so the average state will experience approximately 1,000 such deaths each year. The total number of burden hours are 25,000, based on 10 states participating.

Respondents	Number of respondents	No. of responses/respondent	Average burden/response (in hours)
State Health Departments (10)—Completion of case abstraction	1,000	1	2
State Health Departments (10)—Retrieving and refiling records	1,000	1	30/60

Dated: September 12, 2003.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, , Centers for Disease Control and Prevention.

[FR Doc. 03–23826 Filed 9–17–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration

(FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Biological Response Modifiers Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 9, 2003, from 8 a.m. to 6 p.m.; and on October 10, 2003, from 8 a.m. to 2 p.m.

Location: Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Gail Dapolito or Rosanna Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the

Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 9 and 10, 2003, the committee will discuss the following topics: (1) Issues related to manufacturing data and clinical evidence to be provided in a biologics license application (BLA) for marketing approval of allogeneic islet transplantation to treat type 1 diabetes mellitus, (2) hear updates of individual research programs in the Office of Cellular, Tissue and Gene Therapies, and (3) reports of internal research programs in the Office of Cellular, Tissue and Gene Therapies.

Procedure: On October 9, 2003, from 8 a.m. to approximately 5:15 p.m.; and on October 10, 2003, from 8 a.m. to approximately 2 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending