

Dated: February 11, 2004.

**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**

[60Day-04-28]

**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 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed 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) 498-1210.

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 or other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-E11, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

*Proposed Project:* Active Surveillance of Ciguatera in Culebra, Puerto Rico—New—National Center for Environmental Health (NCEH), Centers for Diseases Control and Prevention (CDC).

Ciguatera fish poisoning (CFP) is a serious health threat to people in Puerto Rico. Many finfish that live in the island's coral reefs carry ciguatoxin. When people consume these finfish, they can get CFP, a condition that causes gastrointestinal and neurological symptoms. To quantify the health burden caused by CFP, the local department of health tallies the number of cases of CFP reported by health care providers on the island. A recent evaluation of this passive surveillance system determined that the majority of CFP cases that occur on the island are missed. To accurately quantify the health threat of CFP to the population in Puerto Rico, the National Center for

Environmental Health, Centers for Disease Control and Prevention, in conjunction with the Puerto Rico Department of Health will conduct active surveillance for CFP for 12 months in Puerto Rico.

Our active surveillance system will quantify the public health burden of CFP by determining the incidence, risk factors, and economic effect of CFP in Culebra, Puerto Rico. Every 4 months for 1 year, we will administer a questionnaire to each of the 600 households in Culebra. The questionnaire elicits information on household fish consumption and identifies individuals who have developed symptoms of CFP. When we identify individuals having symptoms compatible with CFP, we will administer a second questionnaire. This second questionnaire explores personal risk factors, medical management, and costs incurred while the individuals were ill with CFP. To confirm the presence of ciguatoxin in affected areas, we will collect fish from local reefs, fish vendors, and any appropriate leftover fish from people with CFP. The fish will be analyzed by the U.S. Food and Drug Administration.

Ultimately, the information provided by this study will aid the Puerto Rico Department of Health in controlling the health threat of CFP. Quantifying the incidence, risk factors, and economic burden of CFP will guide the development preventive strategies. There are no costs to respondents.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Household survey .....	600	3	20/60	600
Individual survey .....	100	1	30/60	50
Total .....				650

Dated: February 11, 2004.

**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**

[30Day-26-04]

**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:* Epidemiologic Study Of Gastrointestinal Health Effects And Exposure To Disinfection Byproducts Associated With Consumption Of Conventionally Treated Groundwater—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

The primary goal of drinking water treatment is the removal of microorganisms responsible for waterborne disease. The addition of disinfectants such as chlorine is one of the most important steps in pathogen inactivation and may in some cases (such as in many groundwater systems) be the only treatment employed. However, chlorine also reacts with organic compounds in the water to produce halogenated organic byproducts (disinfection by-products [DBPs]). One of the most commonly measured groups of DBPs is the trihalomethanes (THMs). Human exposure to THMs has been associated with bladder and colorectal cancer. Public water providers must constantly balance the acute risks of gastrointestinal (GI) illness associated with exposure to microbial pathogens

against the long-term risks associated with exposure to DBPs.

Each study household will be visited at the beginning and end of the study to enroll the study participants and to collect biological specimens (blood and serum samples will be collected from a subset (50 percent) of adult household members at the beginning and end of the study) and water samples. A questionnaire will be administered in the home at the beginning of the study to collect data about water use habits and possible exposures to microbial pathogens and THMs. All household members will be asked to provide a saliva specimen each month for the duration of the one-year study. Stool specimens will be collected during episodes of GI symptoms.

The specific aims of the study are to: (1) Determine the risk for GI illness

associated with source water quality and treatment efficacy by comparing GI illness rates in people drinking highly treated bottled water with GI illness rates in people drinking bottled plant water; (2) determine the risk for GI illness associated with the distribution system by comparing GI illness rates in people drinking bottled plant water with GI illness rates in people drinking tap water; (3) determine water concentrations and associated blood concentrations of THMs in the study population; and (4) validate and refine existing models of THM exposure using the THM data collected at the participating households and hydraulic and water quality data collected in the distribution system at the time of household recruitment. The estimated annualized burden is 12,934 hours.

Respondents	Number of respondents	Number of responses/re-spondents	Average burden/ respondent (in hrs.)
Telephone contact .....	12,000	1	10/60
Household enrollment interview .....	1,000	1	10/60
Individual enrollment interview .....	4,000	1	15/60
Water exposure interview .....	900	2	15/60
Biweekly health diary .....	4,000	26	2/60
Biweekly telephone interview .....	900	26	15/60

Dated: February 12, 2004.

**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**

**Integrating Prevention Services for Persons with Bleeding and Clotting Disorders**

*Announcement Type:* Competing Continuation-Initial.

*Funding Opportunity Number:* PA 04013.

*Catalog of Federal Domestic Assistance Number:* 93.283.

*Key Dates:*

*Letter of Intent Deadline:* March 8, 2004.

*Application Deadline:* April 5, 2004.

**I. Funding Opportunity Description**

**Authority:** This program is authorized under Section 301(a) and 317(k)(2) and [42 U.S.C. 247b(k)(2)] of the Public Health Service Act, as amended.

*Purpose and Research Objectives:* The purpose of the program is to (1) determine the efficacy of integrated multi-disciplinary care and prevention services for persons with hemophilia, other hereditary bleeding disorders including women with bleeding disorders, and thrombophilia to reduce morbidity and mortality associated with bleeding and clotting diseases; (2) assess unmet needs for service delivery and identify outreach strategies designed to improve access to care; (3) develop effective messages aimed at disease management and prevention; and (4) foster the development of training programs to enhance provider skills for the delivery of hemostasis and thrombosis care.

This program addresses the “Healthy People 2010” focus area(s) of access to quality health services, disability and secondary conditions, educational and community-based programs, and public health infrastructure.

Measurable outcomes of the program will be in alignment with the following performance goal for CDC: To improve the health and quality of life of Americans with disabilities.

Information learned from this program evaluation will have immediate benefit for the program and the patients

with bleeding and clotting disorders receiving prevention services.

*Activities:* Recipient activities for this program are as follows:

1. Using the principles of the multi-disciplinary comprehensive care model utilized in hemophilia treatment center prevention programs, implement the model in a health care setting that features strong clinical, outreach, education, support and provider training programs for persons with hemophilia, other hereditary bleeding disorders including women with bleeding disorders, and thrombophilia.

*Specifically:*

- Identify unmet needs of target populations and establish outreach mechanisms to improve access to care for persons with bleeding and clotting disorders for the purpose of evaluating prevention interventions.

- Determine strategies that will address unmet needs, assess the efficacy of prevention activities and improve access to under-served populations such as women with bleeding disorders and individuals with thrombophilia.

- Conduct outreach efforts to increase prevention intervention awareness and availability of comprehensive care among the affected population and referring providers and establish referral patterns.