

The Department is legally required to ensure that the membership of HHS federal advisory committees is fairly balanced in terms of points of view represented and the functions to be performed by the advisory committee. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on HHS federal advisory committees. Therefore, the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the committee. Appointment to this committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

The Standards of Ethical Conduct for Employees of the Executive Branch are applicable to individuals who are appointed as public members of federal advisory committees. Individuals appointed to serve as public members of federal advisory committees are classified as SGEs. SGEs are government employees for purposes of the conflict of interest laws. Therefore, individuals appointed to serve as public members of the ACBTSA are subject to an ethics review. The ethics review is conducted to determine if the individual has any interests and/or activities in the private sector that may conflict with performance of their official duties as a member of the Committee. Individuals appointed to serve as public members of the Committee will be required to disclose information regarding financial holdings, consultancies, and research grants and/or contracts.

Dated: February 6, 2014.

James J. Berger,

Senior Advisor for Blood and Tissue Safety Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-14-13AHB]

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 404-639-7570 or send comments to Leroy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

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. Written comments should be received within 60 days of this notice.

Proposed Project

Risk Factors for Community-Associated *Clostridium difficile* Infection through the Emerging Infections Program (EIP)—New ICR—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The epidemiology of *C. difficile* has changed dramatically during recent years, with increases in incidence and severity of disease being reported across several countries. In addition, populations previously thought to be at low risk, such as young, healthy individuals residing in the community, are now being identified with severe *C. difficile* infection (CDI). Community-associated CDI is estimated to represent 32% of all CDI based on population-based CDI surveillance data, with an incidence of 30–40 per 100,000 population in the United States. Previous reports have shown that approximately 40% of patients acquiring community-associated CDI (CA-CDI) were not exposed to antibiotics, which is a well-recognized risk factor for CDI; suggesting that additional factors may contribute to infections. Other factors such as proton pump inhibitors have been raised as a risk factor for CDI in the community and on February 8, 2012 the U.S. Food and Drug Administration issued a communication advising physicians to consider the diagnosis of CDI among

patients taking proton pump inhibitors. However, the data on the association of CDI with proton pump inhibitors are still controversial and studies to quantify this association are needed. In addition to the understanding of the factors that predispose patients to CDI, further evaluation of potential *C. difficile* exposure sources in the community is necessary to guide prevention efforts.

The sources of *C. difficile* and the risks for developing CDI in previously thought to be low-risk community populations are not well defined. Although initial evaluation of CA-CDI cases identified several potential risk factors (e.g., outpatient healthcare exposures, infants in the home, and proton pump inhibitor use), the magnitude of association of these risks with disease development using a control population has not been evaluated to date. This proposed case-control study will enable investigators to evaluate these associations and focus future investigations and prevention strategies on those factors identified as significantly associated with disease development.

CDC requests OMB approval to collect information from the public using a standardized questionnaire over a three-year period. The study will have a pediatric and an adult component given that *C. difficile* exposure sources in the community may vary by age. For example, *C. difficile* has been isolated from daycare centers' environment which may be a potential source for *C. difficile* acquisition in pediatric population, but less likely to be a source for adults.

For this project, we estimate that 129 persons \geq 18 years of age with *C. difficile* infection (case-patients) will be contacted for the CDI study interview annually. Of those, 71 will agree and be eligible to participate in the study and will proceed to the full telephone interview. A total of 142 persons \geq 18 years of age without *C. difficile* infection (control-patients) will be contacted for the interview annually. Of those, 71 will agree and be eligible to participate in the study and will complete the full interview. Among the pediatric group, we estimate that 141 and 194 parents of children between 1 and 5 years of age with and without *C. difficile* infection will be contacted for the interview, respectively. Among the case- and control-patients, we estimate that 78 in each group will agree and be eligible to participate in the study and will proceed to the full interview. We anticipate the screening questions to take about 5 minutes and the telephone interview 30 minutes per respondent in

both the adult and pediatric groups. There are no costs to respondents. The

total response burden for the study 201 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents (adult and pediatric)	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Case Subjects > 17 years of age	Screening Process	129	1	5/60
	Telephone interview	71	1	30/60
Control Subjects > 17 years of age	Screening Process	142	1	5/60
	Telephone interview	71	1	30/60
Case Subject ≤ 1–5 years of age	Screening Process	141	1	5/60
	Telephone interview	78	1	30/60
Control Subjects ≤ 1–5 years of age	Screening Process	194	1	5/60
	Telephone interview	78	1	30/60
Total

Leroy A. Richardson,
 Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Head Start Family and Child Experiences Survey (FACES)
OMB No.: 0970–0151

Description: The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new round of the Head Start Family and Child Experiences Survey (FACES).

Featuring a new “Core Plus” study design, FACES will provide data on a set of key indicators, including information for performance measures. The design allows for more rapid and frequent data reporting (Core studies) and serves as a vehicle for studying more complex issues and topics in greater detail and with increased efficiency (Plus studies).

In fall 2014 and spring 2015, the FACES Core study will assess the school readiness skills of Head Start children, survey their parents, and ask their Head Start teachers to rate children’s social and emotional skills. In spring 2015 and again in spring 2017, the number of programs in the FACES Core study sample will increase from the 60 that are used to collect data on children’s school readiness outcomes to 180 for the purpose of conducting observations in 720 Head Start classrooms. Program director, center director, and teacher surveys will also be conducted at these time points. FACES Plus studies include additional survey content of policy or programmatic interest, and may involve more programs being sampled. This

notice is specific to the data collection activities needed to recruit Head Start programs and centers into FACES. A future notice will provide information about data collection for the Core and Plus studies.

The method of data collection for recruitment of all programs (180 for the FACES Core and up to 50 additional programs for FACES Plus studies) will include telephone conversations with program directors and on-site coordinators who serve as liaisons between the FACES study team and the Head Start centers. These calls will inform program staff about the purpose of the study and will be used to identify the number of centers in each program in order to compile the center sampling frame.

The purpose of this data collection is to support the 2007 reauthorization of the Head Start program (Pub.L. 110–134), which calls for periodic assessments of Head Start’s quality and effectiveness.

Respondents: Head Start Program Directors and Staff.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Estimated annual burden hours
Telephone script for program directors	230	77	2	1	154
Telephone script for on-site coordinators	230	77	2	.75	116
Total	270

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L’Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports

Clearance Officer. All requests should be identified by the title of the information collection. Email address: OPREinfocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30

and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should