''The Ethics Bulletin Board System'' (TEBBS). For now, OGE notes that even with these electronic initiatives, the SF 278 reports, once completed, will still need to be printed out and signed manually. Electronic filing is not authorized at this time for the SF 278s.

Public comment is invited on each aspect of the SF 278 Public Financial Disclosure Report as set forth in this notice, including specifically views on the need for and practical utility of this collection of information, the accuracy of OGE's burden estimate, the potential for enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology). The Office of Government Ethics, in consultation with OMB, will consider all comments received in response to this notice. The comments will also become a matter of public record.

Approved: August 1, 1996.

Stephen D. Potts,

Director, Office of Government Ethics.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 DAY–18]

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 Office on (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.

The following requests have been submitted for review since the last publication date on August 2, 1996.

Proposed Projects

1. Case-Control Study of the Effect of Total Dietary Folate Intake on the Clinical Manifestation of Vitamin B 12 Deficiency—New—Fortification of grain products with folic acid has been recommended to increase the intake of folate by women of reproductive age in order to decrease the risk of neural tube birth defects. Fortification high enough to increase the passive consumption of folic acid to the recommended level of 400 ug/day for all women would increase the consumption by some segments of the population to well over the presumed safe upper limit of 1000 ug/day. There is concern, based on case reports, that excess folate consumption may delay the diagnosis of vitamin B 12 deficiency, especially in the elderly. Delayed diagnosis of B 12 deficiency may lead to the development of neuropsychiatric signs and symptoms, some of which may be irreversible. There is no population-based estimate of the prevalence of B 12 deficiency among the elderly, nor is there any population-based data on the frequency with which diagnosis of B 12 deficiency is complicated by folate intake. The Food and Drug Administration has postponed folate fortification pending more data on the potential risks of high levels of folate consumption for the general population.

This is a pilot study to determine the size, feasibility, cost and duration of a population-based survey; the population-based survey would estimate the prevalence of vitamin B 12 deficiency in the general population and estimate the impact of folate intake on its diagnosis. This information is needed to assess the risk that may be posed by high levels of fortification of the food supply with folate.

The proposed pilot study will seek to identify new cases of B 12 deficiency from the computerized laboratory records of a health maintenance organization, determine the nature of the clinical presentation of the cases by medical record review, and evaluate the association of folic acid intake with type of clinical presentation by dietary assessment. 70 individuals with B 12 deficiency and 70 normal controls will participate in a telephone interview about their diet and use of nutritional supplements in the year preceding the diagnosis.

Respondents	No. of respondents	Responses/respondent	Average burden/response (in hrs.)
Cases w/ B 12 deficiency	70	1	1
Normal controls	70	1	1

The total annual burden is 140.

2. Supplement to HIV/AIDS Surveillance (SHAS)—Extension—(0920–0262) There continues to be significant interest from public health, community, minority groups, and affected groups in obtaining more information on persons with HIV/AIDS infection. Since 1989, the Centers for Disease Control and Prevention (CDC), in collaboration with 12 state and local health agencies, has collected data through the national Supplemental HIV/AIDS Surveillance (SHAS) project. The objective of this project is to obtain increased descriptive information on persons with newly reported HIV and AIDS infections, including socioeconomic characteristics, risk behaviors, use of health care services, women's reproductive history and children's health, and information on disabilities. This information supplements information that is routinely collected through national HIV/AIDS surveillance. The information gained from SHAS is used to improve our understanding of minority issues related to the epidemic of HIV, target educational efforts to prevent transmission, and improve services for persons with HIV disease.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hrs.)
Georgia	409	1	0.75
California	325	1	.75
Michigan	164	1	.50
New Mexico	83	1	.75
Arizona	283	1	.75
Colorado	168	1	.75
Connecticut	213	1	.75
Delaware	202	1	.50
Florida	261	1	.50
So. Carolina	206	1	.50
New Jersey	224	1	.75
Washington	146	1	.75

The total annual is 1,806.

3. Examination of Barriers to Participant Compliance in a Flexible Sigmoidoscopy Screening Program, Imperial Cancer Research Fund, United Kingdom—New—As part of an existing screening program, there is significant project savings in this initiative. Colorectal cancer accounts for approximately 9% of all newly diagnosed cancer worldwide. Of all cancer mortality in industrialized nations, colorectal cancer is second only to lung cancer, with the U.S. and Great Britain among the highest in this category. Despite increasing evidence that the early diagnosis of colorectal

cancer through screening examination can significantly prevent and/or reduce the burden of mortality, morbidity, and associated costs, rates of participation in screening remain extremely poor. This study, involving investigators at the Imperial Cancer Research Fund (ICRF) of Great Britain, seeks to identify barriers associated with low compliance in a mass, population-based colorectal cancer screening trial utilizing flexible sigmoidoscopy.

The ICRF has a long history of conducting important mass screening trials relative to cancer early detection and their investigators are considered international experts in colorectal cancer screening. Because the ICRF already has an ongoing population-based colorectal screening program, significant project start-up and infrastructure cost savings have been incorporated into this proposal. Subjects will include randomly selected adults age 55–64 with no known history of colorectal cancer in Glasgow.

The study involves assessment of demographic, environmental, and psychosocial factors which may limit screening participation via surveys and interviews. Informed consent will be obtained and a complete explanation of all medical procedures will be given.

Phase I will involve initial identification, survey query, and solicitation for screening. Phase II will involve telephone and personal interviews, and Phase III will involve final data analysis.

Participation in this study is voluntary and subsequent screening, follow-up and treatment, if indicated, will be provided at no cost to participants. Informed consent will be obtained where appropriate and oversight will be provided by federal and local institutional review.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hrs.)
Population-based sample of adults aged 55–64	6,000	1	.016
Phase III	400	1	.0330

The total burden hours is 1133.

4. Cholera and Vibrio Illness Investigation Report Form—(0920–0322)—Extension—The purpose of the Cholera and other Vibrio Illness Investigation Report Form is to collect information on illness occurring as a result of infection with *Vibrio* species. Vibrios are important pathogens in the United States, and primary septicemia, gastroenteritis, and wound infections have been associated with various species. In particular, gastroenteritis and primary septicemia have been associated with the consumption of undercooked shellfish, and particularly with raw Gulf Coast oysters. Associations have also been linked to wound infections with exposure of broken skin to seawater. Most importantly, *Vibrio cholera* 01 is the organism responsible for cholera, a severe, dehydrating diarrheal illness. Although infections with *Vibrio cholera* 01 are notifiable in all states, an official report form for this illness did not previously exist. The Vibrio Illness Investigation Report Form is used to record information on all *Vibrio*-related illness, as well as more detailed information on cholera illness, which is currently a reportable disease in all states. The form has a separate optional Seafood Investigation section to be completed when applicable. The form provides a consolidated, systematic method by which health departments can report such information, which is then used to gain a better understanding of the incidence, etiology, and epidemiology of all *Vibrio*-related illness occurring in the United States.

Data columns have been added to, and comments space reduced on, the form to facilitate data entry and reduce the burden. No change in the frequency of reporting has occurred or is projected.

Most respondents are epidemiologists or nurses in the local health department, but in some instances infection control nurses or physicians might complete the form.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hrs.)
Local health department staff	90	1	0.33
Health care facility staff	45	1	0.33
Physicians	15	1	0.33

The total annual burden is 50.

5. Metropolitan Atlanta Birth Defect and Risk Factor Surveillance Program—(0920–0010)—Reinstatement—Birth defects are the leading cause of infant mortality in the United States, and they cause a great deal of lifelong morbidity. One in 33 infants are born with a major birth defect. Occasionally, medications of environmental agents have been recognized as causes of birth defects, an example being the drug thalidomide in the early 1960s. Unless surveillance of trends and unusual patterns in birth defects is undertaken, new ''thalidomide'' may be introduced and fail to be recognized in a timely fashion. The Metropolitan Atlanta Congenital Defects Program (MACDP) has conducted such surveillance since 1967 using existing hospital and clinic medical records.

The causes of the majority of birth defects, however, are not known. Birth Defects Risk Factor Surveillance (BDRFS) (which began in January 1993) attempts to find the causes of a selected subset of major anomalies, using an ongoing case-control study approach. BDRFS draws its cases from the data collected by MACDP and conducts in-depth interviews with the parents of affected infants and a comparison set of randomly selected parents of unaffected infants.

The objectives of these two activities are: (1) To conduct surveillance for congenital anomalies in metropolitan Atlanta; (2) to gain new information on causes of birth defects; (3) to further evaluate factors already suspected of influencing the occurrence of birth defects; and (4) to develop and test methods (including the use of biologic markers of exposure and susceptibility) in birth defect surveillance that would be exportable to other birth defects surveillance systems.

Respondents	Number of respondents	Number of responses/respondents	Average burden/response (in hrs.)
Special (ad hoc) studies interview	300	1	1
BDRFS case/control interview	500	1	1
Biologic specimen collection w/wo clinical exam	800	1	0.60

The total annual burden is 1280.

Dated: July 31, 1996.

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

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