plasma industry for either HIV or hepatitis C (HCV).

The source plasma industry collects approximately 14 million of plasma each year. The majority of source plasma is used to produce immune globulins, albumin and other blood products utilized in the United States and in other countries. Donors may donate up to two times per week and are remunerated for each donation. Although the source collection industry plays an important role in the production of blood products, little information regarding HIV or HCV rates within the industry has been published to date.

The objectives of this study of HIV and HCV in plasma donors are to:

1. Analyze the risk behavior characteristics of infected donors to assess distribution and trends of HIV and HCV;

2. Study the motivations and risk factors of HIV and HCV infected deferred donors in order to improve the donor screening and deferral processes;

3. Monitor additional human immunodeficiency and hepatitis viruses, HIV and HCV genetic variation, and other infections relevant to the epidemiology of HIV and HCV among U.S. plasma donors;

4. Evaluate the laboratory characteristics of plasma from infected donors to determine the effectiveness of current and anticipated test modalities; and

5. Evaluate risk factors for transmission of HCV among recently infected individuals.

The above objectives will be attained though a questionnaire designed to evaluate demographic information, knowledge of HIV and HCV, risks for HIV and HCV and motivations for donating plasma. In order to elucidate risks for transmission among this population, a group of HIV and HCV negative persons will also be given the questionnaire. Respondents will be interviewed with the aid of a computer assisted telephone interview (CATI) and respondents will receive a stipend for their time and travel expenses. Participation is voluntary, and all information will be gathered only after written informed consent has been obtained.

The CDC anticipates 430 individuals will be enrolled annually in this study (based upon combined estimates obtained from the plasma companies regarding the number of HIV and HCV positive donors identified per year, plus the number of HIV and HCV negative individuals enrolled as comparisons). It has been estimated that the interview will take approximately 20 minutes to complete; therefore, the response burden will be 143 hours. The approximate hourly wage earned per respondent is $10.00/hour. The total cost to the respondents would be $1430.00.

Form name	Number of respondents	Number of responses/ respondent	Avg. burden per response (in hrs.)	Total Burden (in hrs.)
Questionnaire	430	1	20/60	143

Date: October 14, 1999.

Nancy Cheal,

Acting Associate Director 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–00–02]

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 Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Projects

1. Surveillance and Evaluation of Blood Donors Positive for Human Immunodeficiency Virus (HIV) Antibody or HIV Antigen Surveillance and Evaluation of Blood Donors Positive for Human Immunodeficiency Virus (HIV) Antibody or HIV Antigen (0920–0329)—Extension—National Center for HIV, STD, and TB Prevention (NCHSTP). In 1987, the President directed the Department of Health and Human Services (DHHS) to determine the nationwide incidence of, to predict the future of, and to determine the extent to which human immunodeficiency virus (HIV) is present in various segments of our population. In response, CDC formed an epidemiological team to summarize existing information. An extensive review of published and unpublished data led to the conclusion that even though there is information suggesting a very large number of Americans were infected, there was no substitute for carefully and scientifically obtained incidence and prevalence data. The need to monitor HIV seroprevalence existed on the national and at the state and local levels for public health management: Targeting and evaluating prevention programs, planning future health care needs and determining health policy.

On a national basis, HIV seroprevalence projects in 1987 consisted of monitoring the HIV status of: Civilian applicants for military service; blood donors, including follow-up risk factor evaluation in seropositives; and Job Corps entrants. HIV prevalence was studied in settings of special public health interest including selected colleges and prisons, among health care workers in hospital emergency rooms and among Native Americans and homeless persons. Other national data sources were examined, such as cohort studies of groups at risk, including homosexual and bisexual men and IV drug users, providing information on knowledge of AIDS and

risk behaviors, changes in behavior, and incidence of HIV infection.

In 1987, OMB approved the ''Family of HIV Seroprevalence Surveys'' (0920–0232). These surveys included seven seroprevalence surveys that involved interaction with individuals (non-blinded surveys). One of these surveys was the surveillance and evaluation of blood donors.

The objectives of this study are to: (1) Estimate the prevalence and incidence of HIV infection among blood donors at participating blood centers; (2) evaluate the characteristics of infected donors to strengthen the effectiveness of the donor screening and deferral processes; (3) analyze the risk behavior characteristics of infected donors to assess distribution and trends of HIV; (4) monitor additional human immunodeficiency viruses, HIV genetic variation, and other infections relevant to the epidemiology of HIV among U.S. blood donors and seroconverted recipients; (5) estimate the risk of HIV transmission from screened blood; (6) and evaluate new tests to decrease transmission by window period donors.

In 1993 and 1996, OMB again approved for 3 years each, the surveillance and evaluation of blood donors who test positive for Human Immunodeficiency Virus (HIV) Antibody and their needle-sharing and sexual partners (0920–0329). This request is for an additional 3-year approval. The CDC anticipates 125 positive donors will enroll annually in this study (based upon previous 3 year enrollment rates and epidemiological progress of the disease). The interview takes approximately 1 hour to complete for those who agree to the interview and 10 minutes to complete for those who refuse to enroll. The total cost to the respondent is $8,206.19 over the 3-year period.

Respondents	Number of respondents	Number of responses/Respondent	Avg. burden response (in hours)	Total burden (in hours)
Blood donors (interviewed)	375	1	1.0	375
Blood donors (refuse interview)	275	1	0.16	44
Total				419.00

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Nancy Cheal,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–00–04]

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

Gene-Environment Interactions in Beryllium Sensitization and Disease Among Current and Former Beryllium Industry Workers—NEW—National Institute for Occupational Safety and Health (NIOSH). Beryllium is a light weight metal with wide application in modern technology. The size of the U.S.A. Workforce at risk of beryllium exposure is estimated at approximately 30,000, with exposed workers in primary production, nuclear power and weapons, aerospace, scrap metal reclaiming, specialty ceramics, and electronics industries. Demand for beryllium is growing worldwide, which means that increasing numbers of workers are likely to be exposed. An acute pneumonitis due to occupational exposure to beryllium was common in the 1940s and 1950s, but has virtually disappeared with improvements in work-site control measures. Even with the improved controls, as many as 5% of currently-exposed workers will develop chronic beryllium disease (CBD).

CBD is a chronic granulomatous lung disease mediated through a poorly understood immunologic mechanism in workers who become sensitized. Sensitization can be detected using a blood test, that is used by the industry as a screening tool. The screening test for sensitization was first reported in 1989, but many questions remain about the natural history of sensitization and disease, as well as exposure risk factors. Sensitized workers, identified through workplace screening programs, undergo clinical diagnostic tests to determine whether they have CBD. The proportion of sensitized workers who have beryllium disease at initial clinical evaluation has varied form 41–100% in different workplaces. Sensitized workers often develop CBD with follow-up, but whether all sensitized workers will eventually develop beryllium disease is unknown. Early diagnosis at the subclinical stage and careful follow-up seems prudent in that CBD usually responds to corticosteroid treatment. However, the efficacy of screening in preventing adverse outcomes of the disease has not yet been evaluated. While recent research has suggested that a genetic determinant of the immune response could be a susceptibility factor, this has not been well characterized.

The National Institute of Occupational Safety and Health (NIOSH) wants to determine how beryllium workers and former workers develop beryllium disease and how to prevent it. Through the proposed study, NIOSH has the opportunity to contribute to the scientific understanding of this disease in the context of environmental and genetic etiologic factors. The goals of this investigation are to: (1) determine the incidence of beryllium sensitization or disease over a 6-year period; (2) seek an association with exposure measurements; (3) identify a genetic determinant of susceptibility to CBD; and (4) characterize that genetic determinant to ascertain if it is associated with clinical impairment or progression of disease. Through a greater understanding of the environmental and genetic risk factors associated with the onset and progression of CBD, NIOSH will be able to develop strategies for both primary and secondary prevention applicable to beryllium-exposed workers. The total annual burden hours are 250.