



This document is scheduled to be published in the Federal Register on 03/07/2014 and available online at <http://federalregister.gov/a/2014-04974>, and on FDsys.gov

Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

[60Day-14-0904]

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 D-74, 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

SEARCH for Diabetes in Youth Study (OMB No. 0920-0904, exp. 11/30/2014) - Revision - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Diabetes is one of the most common chronic diseases among children in the United States. When diabetes strikes during childhood, it is routinely assumed to be type 1, or juvenile-onset, diabetes. Type 1 diabetes (T1D) develops when the body's immune system destroys pancreatic cells that make the hormone insulin. Type 2 diabetes begins when the body develops a resistance to insulin and no longer uses it properly. As the need for insulin rises, the pancreas gradually loses its ability to produce sufficient amounts of insulin to regulate blood sugar. Reports of increasing frequency of both type 1 and type 2 diabetes in youth have been among the most concerning aspects of the evolving diabetes epidemic. In response to this growing public health concern, the Centers for Disease Control and

Prevention (CDC) and the National Institutes of Health (NIH) funded the SEARCH for Diabetes in Youth Study.

The SEARCH for Diabetes in Youth Study began in 2000 as a multi-center, epidemiological study, conducted in six geographically dispersed clinical study centers that reflected the racial and ethnic diversity of the U.S. Phases 1 (2000-2005) and 2 (2005-2010) produced estimates of the prevalence and incidence of diabetes among youth age < 20 years, according to diabetes type, age, sex, and race/ethnicity, and characterized selected acute and chronic complications of diabetes and their risk factors, as well as the quality of life and quality of health care. In Phases 1 and 2, the clinical centers and a data coordinating center were funded through cooperative agreements. The information collected at that time was not provided directly to CDC.

Phase 3 (2011-present) builds upon previous efforts. Five clinical sites collect patient-level information that is compiled by a data coordinating center. CDC obtained OMB approval to receive the information in 2011 (SEARCH for Diabetes in Youth, OMB No. 0920-0904, exp. 11/30/2014). Phase 3 includes a case registry of youth < 20 years of age who have been diagnosed with diabetes, and a longitudinal cohort research study about SEARCH cases whose diabetes was incident in 2002 or later. To date, SEARCH Phase 3 has identified an average of

1,361 incident cases of diabetes among youth under 20 years each year of the study and has completed an average of 1,088 participant surveys each year (80% participation rate among registry study participants). As of November 2013, SEARCH Phase 3 has completed visits for 1,839 cohort study participants.

CDC plans to continue information collection for two additional years, with minor changes. Participants in the registry study will continue to complete a Medication Inventory and an Initial Participant Survey; however, the in-person study examination will be discontinued. This change will result in a decrease in burden per respondent. CDC estimates that each clinical site will identify and register an average of 255 cases per year, for a total 1,275 cases across all sites.

No data collection changes are planned for the cohort study. CDC estimates that each clinical site will conduct follow-up on an average of 142 cases per year, for a total of 710 cases across all sites. The items collected for each case include a Health Questionnaire (Youth version), an additional Health Questionnaire (Parent version), Center for Epidemiologic Study-Depression, Quality of Care, Pediatric Quality of Life Survey (Peds QL), SEARCH Michigan Neuropathy Screening Instrument, Diabetes Eating Survey, Low Blood Sugar Survey, Supplemental Survey, Tanner Stage, Retinal Photo, Family Conflict Survey, Pediatric Diabetes Quality of Life Scale,

Physical Exam, Specimen Collection, and Food Frequency Questionnaire.

Findings from the registry study will be used to estimate the incidence of diabetes in youth in the U.S. Findings from the cohort study will be used to estimate the prevalence and incidence of risk factors and complications associated with diabetes in youth, including chronic microvascular complications (retinopathy, nephropathy, and autonomic neuropathy) and selected markers of macrovascular complications (hypertension, arterial stiffness) of diabetes.

Participation is voluntary and there are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Burden (in hr)
SEARCH Registry Study Participants	Medication Inventory	1,275	1	5/60	106
	Initial Participant Survey	1,275	1	10/60	213
SEARCH Cohort Study Participants	Health Questionnaire -Youth	710	1	15/60	178
	Health Questionnaire -Parent	710	1	15/60	178
	CES-Depression	710	1	4/60	47
	Quality of	710	1	13/60	154

	Care				
	Peds QL	710	1	5/60	59
	SEARCH MNSI Neuropathy	710	1	10/60	118
	Diabetes Eating Survey	710	1	5/60	59
	Low Blood Sugar Survey	710	1	5/60	59
	Supplemental Survey	710	1	10/60	118
	Tanner Stage	710	1	5/60	59
	Retinal Photo	710	1	15/60	178
	Family Conflict Survey	710	1	5/60	59
	Pediatric Diabetes QOL Scale	710	1	5/60	59
	Physical Exam	710	1	3	2,130
	Specimen Collection	710	1	20/60	237
	Food Frequency Questionnaire	710	1	20/60	237
				Total	4,248

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

[FR Doc. 2014-04974 Filed 03/06/2014 at 8:45 am;
Publication Date: 03/07/2014]