DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-23-22IV]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "The Muscular Dystrophy Surveillance, Tracking, and Research Network (MD STARnet) Living with Muscular Dystrophy Questionnaire" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on September 23, 2022 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

The Muscular Dystrophy Surveillance, Tracking, and Research Network (MD STARnet) Living with Muscular Dystrophy Questionnaire — New — National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Since its establishment in 2002, the MD STARnet has been a population-based surveillance system that aims to identify and collect clinical data on individuals with muscular dystrophy (MD) in select surveillance areas. MD STARnet identifies and collects data on individuals with MD at sources including healthcare facilities where patients with MD receive care and administrative datasets such as vital records and hospital discharge data. Although MDs are rare genetic diseases with an estimated prevalence of 16.1/100,000, they have a high impact on affected individuals, their families, and society. MDs can be classified into nine major groups: Duchenne MD (DMD), Becker MD (BMD), myotonic dystrophy (DM), facioscapulohumeral muscular dystrophy (FSHD), limb-girdle MD (LGMD), Congenital MD (CMD), Emery-Dreifuss MD (EDMD), Oculopharyngeal MD (OPMD), and distal MD. A recent MD STARnet study has estimated the combined prevalence for DMD and BMD to be 1.92–2.48/10,000 males age 5–9 years old. MD STARnet aims to improve understanding of MDs and

ultimately the quality of life of individuals and their families living with MD.

Individuals with MD frequently report pain and fatigue, but studies have primarily been conducted in single clinics and limited to the three most common MDs (DMD, DM, and FSHD). Population-based studies are needed to describe the frequency and management of pain and fatigue and their impact on the lives of individuals with various types of MD. The purpose of the proposed study is to describe the epidemiology of COVID-19 and flu and the experience with pain, fatigue, pregnancy, and infertility for adults living with MD who are identified through MD STARnet. Information will be collected at the seven MD STARnet surveillance sites and will occur primarily via a survey of adult men and women with muscular dystrophy. The survey will primarily be web-based, but a paper version and phone interview will be provided to accommodate participant preferences. The estimated burden per response for the MD STARnet Men Living with Muscular Dystrophy Survey is 15 minutes. The MD STARnet Women Living with Muscular Dystrophy Survey includes additional questions about pregnancy and infertility, and the estimated burden per response is 20 minutes.

Results generated from the study will provide a better understanding of: (1) the occurrence, testing, treatment and severity of COVID-19 in relation to MD; (2) vaccination status and reasons for not receiving COVID-19 and flu vaccinations; (3) the frequency, intensity, and management of pain and fatigue;

and (4) the effect of having MD on pregnancy and fertility on adults living with MD. Ultimately, this information can be used to develop interventions that improve the lives of people with MD and their families.

CDC requests OMB approval for two years. The total estimated annualized burden is 292 hours. Participation is voluntary and there are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Adult Males 18 and over	MD STARnet Men Living with Muscular Dystrophy Survey	538	1	15/60
Adult Females 18 and over	MD STARnet Women Living with Muscular Dystrophy Survey	472	1	20/60

_____

Jeffrey M. Zirger,
Lead,
Information Collection Review Office,
Office of Scientific Integrity,
Office of Science,
Centers for Disease Control and Prevention.

[FR Doc. 2023-04492 Filed: 3/3/2023 8:45 am; Publication Date: 3/6/2023]