e: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-24-23DV]

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 "Focus groups among adults with or caring for individuals with congenital heart defects (CHD), muscular dystrophy (MD), and spina bifida (SB)" 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 April 7, 2023 to obtain comments from the public and affected agencies. CDC received one public comment related to this 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

Focus Groups Among Adults with or Caring for Individuals with Congenital Heart Defects (CHD), Muscular Dystrophy (MD), and Spina Bifida (SB) – New – National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Congenital heart defects (CHD) are the most common type of structural birth defects in the United States, affecting approximately one in 110 live-born children, and are a leading cause of birth defect-associated infant mortality, morbidity, and healthcare costs. CHD mortality has

decreased over the past few decades due to advances in diagnosis and medical interventions. As a result, more individuals are living into adulthood with CHD, a lifelong condition that can result in an increasing need for specialist care and clinical interventions over time. There is a lack of information on adults that are lost to cardiac care since most data sources only have access to patients that have been hospitalized or that are currently in cardiac care. A better understanding of the factors that contribute to adults not remaining in or seeking cardiac care will fill an important knowledge gap and could help shape future interventions to bring this population back to cardiac care.

Muscular dystrophies (MD) are a group of rare inherited disorders characterized by progressive and irreversible muscle weakness and wasting. The nine major types of MD (Duchenne and Becker [DBMD], myotonic dystrophy [DM], congenital [CMD], limb girdle [LGMD], Emory-Dreifuss [EDMD], facioscapulohumeral [FSHD], distal, and oculopharyngeal [OPMD]) vary by age of onset, muscle groups affected, genes involved, severity, and progression of disease. In 2002, CDC implemented the Muscular Dystrophy Surveillance, Tracking, and Research Network (MD STARnet [DD-19-002]). Now in its fourth funding cycle, MDSTARnet has conducted surveillance and collected epidemiologic and clinical data on people with DBMD, DM, FSHD, LGMD, CMD, OPMD, EDMD, and distal MD and has published numerous articles in scientific journals. However, qualitative data on the experiences of individuals with certain types of MD (DBMD, DM, FSHD, LGMD, and CMD) or their caregivers are limited. The MD portion of this collection will focus on gathering qualitative information to better understand the personal experiences of adults (≥18 years) with DBMD, FSHD, DM, and LGMD as well as adult caregivers of youth (<18 years) with DBMD, congenital or juvenile onset DM, and CMD. Specifically, qualitative data on barriers to accessing and receiving care, the journey to diagnosis, and for those diagnosed early in life the transition into adulthood will help to address a gap in the literature and inform future research and surveillance efforts.

Spina bifida (SB) is among the most common disabling birth defects in the United States. Based on national data from 2010-2014, the estimated birth prevalence for spina bifida is 3.9 per 10,000 live births. SB impacts different organ systems, resulting in the need for various types of clinical specialists. In 2008, CDC implemented the National Spina Bifida Patient Registry (NSBPR; [DD-19-001]) with SB clinics across the United States. In 2014, CDC funded a subset of NSBPR clinics to establish and implement the "Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida" (UMPIRE Protocol; [DD-14-002]). NSBPR and UMPIRE have generated numerous publications on clinical interventions, health outcomes, and lessons learned. However, increases in survival for individuals with SB have prompted the need for greater understanding of the complexities involved in their clinical and psychological care. Qualitative data on individual and caregiver experiences with SB, including barriers to accessing specialty care, managing one's skin health and bowel and bladder function, and the transition from childhood to adulthood (for those with MD diagnosed prior to adulthood) are needed to guide future SB surveillance and research projects as well as the care of those aging into adulthood.

The purpose of this Information Collection Request (ICR) is to recruit individuals for virtual focus groups and gather qualitative data from adults with or caring for individuals with congenital heart defects (CHD), muscular dystrophies (MD), and spina bifida (SB). This data will be collected by KRC Research, a contracted research firm, over the course of the study and will provide firsthand perspectives on the types of care individuals receive with a special focus on receipt of and access to medical care and barriers and facilitators to accessing, receiving, or reengaging care; the journey to diagnosis; and the transition from pediatric to adult care (for persons diagnosed during childhood). This information may be used to address gaps in knowledge, inform future surveillance, research, and data collection, and gather patient and caregiver perspectives that may be shared with clinicians and inform clinical care.

The total estimated annualized burden for all audiences is 603 hours. There are no costs to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Adults with a CHD that have been out of cardiac care	CHD Screening Questionnaire	410	1	10/60
Adults with a CHD that have been out of cardiac care	CHD Focus Group Guide	80	1	105/60
Adults with MD or adult caregivers of individuals with MD	MD Screening Tool	210	1	10/60
Adults with MD or adult caregivers of individuals with MD	MD Focus Group Guide	137	1	105/60
Adults with SB or adult caregivers of individuals with SB	SB Screening Tool	90	1	10/60
Adults with SB or adult caregivers of individuals with SB	SB Focus Group Guide	60	1	105/60

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